NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

September 3-4, 2025

HYATT PLACE
1790 E PLUMB LN
RENO, NV

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

Please do not remove the book from the meeting room.

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

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

Date Posted: August 12, 2025

AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, September 3, 2025, at 9:00 am. The meeting will continue Thursday, September 4, 2025, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hyatt Place
1790 E Plumb Lane
Reno, NV

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

Please Note:

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

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

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

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

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

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

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

◈ CONSENT AGENDA ◈

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

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

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

   A. EBI, LLC – Parsippany, NJ
   B. Mori Medical Equipment, Inc – Vista, CA
   C. Noctrix Health, Inc – Pleasanton, CA

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

   Background Check Not Required by Law.

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

   D. Amneal Pharmaceuticals, LLC – Glasgow, KY
   E. CooperSurgical, Inc – Fort Worth, TX
   F. Hill-Rom Company, Inc – Batesville, IN
   G. Hill-Rom Company, Inc – Las Vegas, NV
   H. Hill-Rom Company, Inc – Sparks, NV
   I. Hill-Rom Manufacturing, Inc – St Paul, MN

J. HSG-Corp – Fort Worth, TX
K. HSG-Corp – Savannah, GA
L. LENZ Therapeutics, Inc – Solana Beach, CA

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

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

M. Arrowhead Pharmaceuticals, Inc – Pasadena, CA
N. Regeneron Pharmaceuticals, Inc – East Greenbush, NY
O. Regeneron Pharmaceutical, Inc – Rensselear, NY
P. Tisalus Life Sciences, Inc – Westminster, CO

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

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

Q. American Pharmaceutical Distributors – Waterford, MI
R. Hilco Vision – Fairfield, OH

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

S. Accelerated Care Plus Leasing, Inc – Reno, NV
T. AirLife – Litchfield Park, AZ
U. Arteriocyte Medical Systems, Inc – Hopkinton, MA
V. Bayer HealthCare, LLC – Berkely, CA
W. Bright Uro, Inc – Irvine, CA
X. Flexicare, Inc – Irvine, CA
Y. Innovative Neurotronics, Inc – Reno, NV
Z. Ivy Technology, LLC – Louisville, KY
AA. Leica Biosystems Imaging, Inc – Vista, CA
BB. Osteal Therapeutics, Inc – Beverly, MA
CC. Radiometer America, Inc – Middleburgh Heights, OH
DD. Rising Pharmaceuticals – East Windsor, NJ
EE. True Marker Pharmaceuticals – Phoenix, AZ
FF. TSC Life US Inc – Greenwood Village, CO
GG. Vitalcare Health Services – Reno, NV

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

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

4.2.9 **Background checks completed in compliance with NRS 639.500.**

HH. Animal Health International, Inc – Ceres, CA
II. Animal Health International, Inc – Ontario, CA
JJ. Animal Health International, Inc – Ranoke, TX
KK. Animal Health International, Inc – Spanish Fork, UT
LL. Animal Health International, Inc – Twin Falls, ID
MM. Animal Health International, Inc – Visalia, CA
NN. API Expeditors, LLC – Miami, FL
OO. Frontier Dental Supply, Inc – Windsor Mill, MD
PP. Medtronic Logistics, LLC – Loisville, CO
QQ. Medtronic Logistics, LLC – Fort Worth, TX
RR. Medtronic Logistics, LLC – Swedesboro, NJ
SS. Packaging Coordinators, Inc – Croydon, PA
TT. Silver State Medical Supply, LLC – Las Vegas, NV
UU. Stat-Med, Inc – North Las Vegas, NV
VV. TENS Pros – St. Louis, MO

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

WW. Alto Pharmacy – Las Vegas, NV
XX. Community Health Alliance Neil Road Pharmacy – Reno, NV
YY. ER at North Valleys, an Extension of Northern Nevada Medical Center – Sparks, NV
ZZ. Meta Pharmacy Services – Las Vegas, NV
AAA. Renown Pharmacy – Reno, NV
BBB. Smith's Pharmacy #303 – Henderson, NV

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

CCC. Coram CVS/Specialty Infusion Services – San Diego, CA
DDD. Hillstone Pharmacy – Knoxville, TN
EEE. Optimal Balance Pharmacy, LLC – Houston, TX
FFF. RLS (IUSA), Inc – Fullerton, CA
GGG. Turbare Manufacturing – Conway, AR
HHH. WP Pharma Labs – Dallas, TX

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

III. Adegen Pharmacy – Grove City, OH
JJJ. Alto Pharmacy – Denver, CO
KKK. Alto Pharmacy – Plano, TX
LLL. Alto Specialty Pharmacy – Austin, TX
MMM. E-Rxhub – Tampa, FL
NNN. Foundation Pharmacy, LLC – Sunrise, FL
OOO. Medico Pharmacy – Los Angeles, CA
PPP. Praxis Specialty Pharmacy, LLC – Tampa, FL
QQQ. Vibrix Pharmacy – Lindon, UT
RRR. Wedgewood Pharmacy, LLC – Chander, AZ

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

SSS. Medical and Dental Center of Nevada, LLC – Las Vegas, NV

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

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

TTT. Platinum Medical Supplies – Las Vegas, NV

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

◈ REGULAR AGENDA ◈

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

A. Karri Lynn Burgner	(22-247-CS-A-N)
B. McGuff Compounding Pharmacy Services, Inc	(23-070-PH-O)
C. McGuff Company, Inc	(23-070-WH-O)
D. CVS Pharmacy #6625	(23-314-PH-N)
E. Victoreea Harris	(23-314-RPH-C-N)
F. Samuel Chacon	(23-348-CS-N)
G. Revive Rx	(23-411-PH-O)
H. Injured Workers Pharmacy, LLC	(23-428-PH-O)
I. Frank Shallenberger	(23-515-CS-N)
J. Debra Renee McCurtainMurry	(24-131-CS-S)
K. Abdollah Assad	(24-470-CS-N)
L. Kristin Hestdalen	(25-020-CS-N)
M. Bernard Brooks	(25-031-RPH-N)

N. Smith's Pharmacy #315 (25-076-PH-S)
O. Octavia Loraine Brooks (25-076-RPH-S)
P. Alyssa Mercedes Garcia (25-076-PT-S)
Q. Ability Prosthetics and Orthotics of Nevada, LLC (23-234-MP-N)
R. PharMerica (24-370-PH-N)
S. Camilla Kim (24-370-RPH-N)
T. Sean Arora (24-509-CS-N)
U. Cassie Gifford (24-509-PR-A-N)
V. Gabrielle McIntyre (24-509-PR-B-N)
W. Allison Jaggard (24-509-PR-C-N)
X. Qui Thai (22-476-CS-S)
Y. CVS Pharmacy #9981 (25-034-PH-N)
Z. Joseph Delallo (25-034-RPH-N)

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

   A. Advanced Prosthetics & Orthotics – Henderson, NV
   B. Advanced Prosthetics & Orthotics – Las Vegas, NV
   C. Advanced Prosthetics & Orthotics – Pahrump, NV
   D. Fix My Oxygen, LLC – Las Vegas, NV

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

   A. National Health Rx – Las Vegas, NV
   B. Prosource Pharmacy – Las Vegas, NV

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

   A. Avrio Pharmacy – Scottsdale, AZ
   B. Vidrine Pharmaceutical Group, LLC – Lake Charles, LA

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

   A. Packaging Coordinators, Inc – Philadelphia, PA – Background Check Not Required by Law
   B. Patterson Logistic Services, Inc – Dinuba, CA – Background Check Not Required by Law
   C. Patterson Logistic Services, Inc – Boone, IA – Background Check Not Required by Law
   D. Patterson Logistic Services, Inc – Blythwood, SC – Background Check not Required by Law

E. Patterson Logistic Services, Inc – Kent, WA – Background Check not Required by Law
F. Patterson Logistic Services, Inc – South Bend, IN – Background Check not Required by Law

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

    A. Patterson Dental Supply, Inc – Las Vegas, NV – Background Check not Required by Law

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

    A. Eric Disbrow
    B. Jeffrey C. Backofen
    C. Jeffrey Kesten
    D. Melissa Case

12. Discussion and possible action on request for advisory opinion from Advanced Molecular Compounding LLC (NAC 639.150) **(FOR POSSIBLE ACTION)**

13. Presentation on 83rd (2025) Session of the Nevada Legislature by Mike Hillerby (INFORMATIONAL ONLY – NO ACTION)

◈ WORKSHOP ◈

Thursday, September 4, 2025 – 9:00 am

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

    A. A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto.

    B. Amendment to Chapter 639 of the Nevada Administrative Code. The proposed amendments establish standards for licensees relating to staffing, supervision, duties of a pharmacy, duties of a pharmacist and requirements related to the timing of dispensing prescription drugs and devices.

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

16. Executive Secretary Report:

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

17. Date and Location of Next Scheduled Board Meeting:

    October 15-16, 2025 – Las Vegas, NV

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

19. Adjournment

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

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

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

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

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NEVADA STATE BOARD OF PHARMACY

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

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

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

BOARD MEETING MINUTES

July 16-17, 2025

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

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

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

Board Members Present:

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

Board Staff Present:

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

Call to Order and Roll Call – Establishment of Quorum

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

Public Comment at July 16, 2025, 9:07 AM

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There was no public comment.

1. Approval of June 4-5, 2025, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board Action:

Motion: Jade Jacobos moved to approve the June 4-5, 2025, Board Meeting Minutes.

Second: Adam Porath

Action: Passed unanimously.

◈ CONSENT AGENDA ◈

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

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

A. Cardio Partners, Inc – Greenwood, IN
B. CoreVerity, LLC – Shelton, CT
C. Diabetes DME – Lincolnshire, IL
D. Integrated Ortho Services, Inc – Indianapolis, IN
E. J.L. Artificial Limbs & Brace – Bullhead City, AZ
F. JQ Medical Supply – Salt Lake City, UT
G. Koya Medical, Inc – Dallas, TX
H. Medline Industries, LP – Southaven, MS
I. Outset Medical, Inc – San Jose, CA
J. Quest Health Solutions, LLC – Coral Springs, FL
K. Quest Health Solutions, LLC – Santa Rosa, CA
L. TenderHeart Health Outcomes – Austin, TX
M. Zida, LLC – Gainesville, VA

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

Background Check Not Required by Law.

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

N. Vantative US Healthcare, LLC – Largo, FL

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

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

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O. Acclarent, Inc – Irvine, CA
P. Axogen Corporation – Vandalia, OH
Q. Celcuity, Inc – Minneapolis, MN
R. Nuvalent, Inc – Cambridge, MA
S. Outset Medical, Inc – San Jose, CA
T. Replimune, Inc – Framingham, MA
U. Unicycive Therapeutics, Inc – Los Altos, CA

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

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

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

V. Boxout – Fort Worth, TX
W. Brookfield Pharmaceuticals, Inc – Bookefield, WI
X. LivaNova USA, Inc – Arvada, CO
Y. LivaNova USA, Inc – Houston, TX
Z. ONY Biotech, Inc – Amherst, NY
AA. Optinose US, Inc – Yardley, PA
BB. Orasis Pharmaceuticals, Inc – Ponte Vedra, FL
CC. Ortho Technology, Inc – Carlsbad, CA
DD. Patterson Dental Supply, Inc – Meza, AZ
EE. Patterson Dental Supply, Inc – Roseville, CA
FF. Patterson Dental Supply, Inc – Salt Lake City, UT
GG. Respironics Novametrix, LLC – Andover, MA
HH. Ritedose Pharmaceuticals, LLC – Columbia, SC
II. Takeda Pharmaceuticals America, Inc – Cambridge, MA
JJ. Vistamerica USA, LLC – Scottsdale, AZ

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

KK. Fisher BioServices, Inc – Frederick, MD
LL. J. Knipper and Company, Inc – Memphis, TN
MM. Paterson Veterinary Supply, Inc – Phoenix, AZ

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

NN. Convatec, Inc – Berkeley, NJ

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

OO. Airlie Pharma – Leeland, NC
PP. Catalent San Diego, Inc – San Diego, CA
QQ. Hashem Echad Corp EchoPharm – Dania Beach, FL
RR. Ixtus Medical Supply, Inc – Union Grove, WI
SS. Kuehne + Nagel, Inc – Cranburry, NJ
TT. Kuehne + Nagel, Inc – Durham, NC
UU. Kuehne + Nagel, Inc – Plainfield, IN
VV. MD Hospital Supplies, Inc – Forest Hill, MD
WW. UPS Supply Chain Solutions, Inc – Louisville, KY

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

XX. Costco Pharmacy #1709 – Las Vegas, NV

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

YY. Pure Pharmacy – Fishers, IN

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

ZZ. C3 Pharmacy – St George, UT
AAA. HealthDyne Pharmacy FL, LLC – Lakeland, FL
BBB. Lumicera Health Services, LLC – Irvine, CA P
CCC. harma Fusion, LLC – Bullhead City, AZ
DDD. Prime Therapeutics Pharmacy, LLC – Orlando, FL
EEE. Prime Therapeutics Pharmacy, LLC – West Valley, UT
FFF. UK Specialty Pharmacy – Lexington, KY

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

GGG. East Russell Surgery Partners – Las Vegas, NV
HHH. St. Mary's Outpatient Center at Galena, LLC – Reno, NV

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

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

4.9 Application for Nevada Manufacturer (NAC 639.609) – Non- Appearance **(FOR POSSIBLE ACTION)**

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Consent Agenda.

Second: Jade Jacobo

Action: Passed unanimously.

◈ REGULAR AGENDA ◈

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

F. CVS Pharmacy #17244 (23-174-PH-S)
G. Kimberly Kersten (23-174-RPH-S)

Brian Convery, Esq. was present on behalf of CVS Pharmacy #17244.

Kimberly Kersten was present.

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

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that CVS Pharmacy #17244 is responsible for the acts of its employees who made an error in a prescription and failed to provide medication counseling to a patient..

Mr. Kandt presented the proposed stipulations for each respondent.

The proposed stipulated penalties for Kimberly Kersten, Certificate of Registration No. 20889, are the following: 1) Respondent fined $1,500 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs. The fine and fee will be due and payable by September 1, 2025.

The proposed stipulated penalties for CVS Pharmacy #17244, Pharmacy License No. PH02188, are the following: 1) Respondent fined $3,000 for the violations; and 2) Respondent assessed $1,000 in attorney's fees and costs. The fine and fee will be due and payable by September 1, 2025.

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Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the proposed Stipulations and Orders for Kimberly Kersten and CVS Pharmacy #17244 as presented by Mr. Kandt.

Second: Chanyis Taylor

Action: Motion passed (Jacobo recused).

J. Hill-Rom (24-500-MP-S)

William Stilling, Esq. (Counsel) and Daniel Mallory (Representative of Baxter International) were present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that respondent engaged in the business of selling, leasing, supply and/or distributing medical devices to hospitals and other licensed care facilities without a license to engage in business as a wholesaler.

Mr. Kandt presented the proposed stipulation for the respondent.

The proposed stipulated penalties for Hill-Rom Company Inc., License No. MP00038, are the following: 1) Respondent fined $2,500 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs.

Mr. Kandt noted that the respondent paid a $5,000 Citation and Fine due to unlicensed practice from the Board and since then has applied for a wholesaling license in Nevada.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the proposed Stipulation and Order for Hill-Rom as presented by Mr. Kandt.

Second: Krystal Freitas

Action: Passed unanimously.

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

Lyn Beggs (Counsel) and Michael McClendon (Owner) were present.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Respondent engaged in business as a medical products provider

DRAFT

and failed to service and communicate with a patient who needed emergency oxygen equipment and supplies.

Mr. Zunino stated that Count Nine of the accusation will be dismissed and presented the proposed stipulation for the respondent.

The proposed stipulated penalties for Pulmonary Solutions, LLC, License No. MP02951, are the following: 1) Respondent acknowledges that License No. MP02951 was forfeited when it was not renewed; 2) Respondent fined $8,000 for the violations; and 3) Respondent assessed $1,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the proposed Stipulation and Order for Pulmonary Solutions, LLC, as presented by Mr. Zunino.

Adam Porath suggested one additional inspection be done at the location.

Board discussion ensued.

Ms. Beggs provided clarification to the Board.

The Board requested that an extra inspection be completed by Board staff, separate from the Stipulation and Order in this case.

Second: Adam Porath

Action: Passed unanimously.

S. Michael Vargas-Lagunas (22-490-CS-S)

Randall Tindall (Counsel) and Michael Vargas-Lagunas were present.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Respondent Vargas-Lagunas allowed a non-practitioner to receive, possess, store and/or administer dangerous drugs outside of respondent's presence.

The proposed stipulated penalties for Michael Vargas-Lagunas, Certificate of Registration No. CS15547, are the following: 1) a public reprimand; 2) Respondent fined $5,000 for the violations; and 3) Respondent assessed $1,000 in attorney's fees and costs.

Board discussion ensued.

DRAFT

Jade Jacobo was excused from the meeting at 9:40 AM.

Jade Jacobo returned to the meeting at 9:45 AM.

Board Action:

Motion: Krystal Freitas moved to approve the proposed Stipulation and Order for Michael Vargas-Lagunas as presented by Mr. Zunino.

Second: Adam Porath

Action: Passed unanimously.

N. Matthew Okeke (19-013-CS-S)
O. Matthew Okeke (25-241-CS-S)

Jade Jacobo was excused from the meeting at 10:08 AM.

Liborius Agwara, Esq. was present on behalf of Matthew Okeke.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Respondent issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances while travelling out of country which is in violation of Nevada Law. In addition, respondent participated in deceitful transactions and billed Medicaid for services that respondent did not provide. Additionally, The Board took reciprocal action based on discipline that the Nevada State Board of Medical Examiners took for numerous findings of professional misconduct.

The proposed stipulated penalties for Matthew Okeke, Certificate of Registration No. CS10935, are the following: 1) Respondent's Certificate of Registration No. CS10935 is revoked, effective immediately, and Respondent shall not petition for reinstatement for a period of one (1) year; 2) Respondent fined $10,000 for the violations, payable if Respondent petitions for reinstatement; and 3) Respondent assessed $3,000 in attorney's fees and costs, payable if Respondent petitions for reinstatement.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the proposed Stipulation and Order for Matthew Okeke, as presented by Mr. Zunino.

Second: Krystal Freitas

Action: Motion passed (Jacobo excused).

E. Wells Pharmacy (23-050-PH-O)

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Jeremy Kilbur (Pro Hac Vice Sponsor), Melissa Stefko (Senior Vice President of Regulatory), and Jason Balogh (Counsel) were present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Respondent compounded essential copies of commercially available drugs without a "statement of significant difference" for each prescription documenting a medical need specific to the patient for the compounded product.

Jade Jacobo returned to the meeting at 10:18 AM.

Mr. Kandt requested to amend paragraph 2 of the accusation to reflect the date of “January 1, 2022” instead of “January 1, 2002”.

Mr. Kandt called Kenneth Scheuber as a witness.

Kenneth Scheuber, Investigator for the Nevada Board of Pharmacy, was sworn in and subject to examination.

Mr. Kandt questioned Mr. Scheuber on the components of Exhibit A, and requested that it be admitted into the record.

Mr. Balogh had no objections.

President Park entered Exhibits A into the record.

Mr. Kandt questioned Mr. Scheuber on the components of Exhibit B, and requested that it be admitted into the record.

Mr. Balogh had no objections.

President Park entered Exhibit B into the record.

Mr. Kandt questioned Mr. Scheuber on the components of Exhibit C, and requested that it be admitted into the record.

Mr. Balogh had no objections.

President Park entered Exhibit C into the record.

Mr. Kandt questioned Mr. Scheuber on the components of Exhibit D, and requested that it be admitted into the record.

Mr. Balogh had no objections.

President Park entered Exhibit D into the record.

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Mr. Kandt questioned Mr. Scheuber on the components of Exhibit E, and requested that it be admitted into the record.

Mr. Balogh had no objections.

President Park entered Exhibit E into the record.

Mr. Balogh cross-examined Mr. Scheuber.

Mr. Kandt called Joe Dodge as a witness.

Joe Dodge, Board Inspector for the Nevada Board of Pharmacy, was sworn in and subject to examination.

The Board heard testimony and received evidence.

Mr. Balogh cross-examined Mr. Dodge.

Mr. Balogh called Melissa Stefko as a witness and President Park reminded Ms. Stefko that she was under oath.

Chanyis Taylor was excused from the meeting at 11:26 AM.

Mr. Kandt cross-examined Ms. Stefko.

Mr. Balogh re-examined Ms. Stefko.

The Board questioned Ms. Stefko and received testimony.

Both parties gave their closing remarks.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to make the Findings of Fact consistent with paragraphs 1-3 of the Accusation, amending paragraph 2 of the Accusation to state “seventeen (17) prescriptions” instead of “twenty-eight (28) prescriptions”.

Second: Adam Porath

Action: Motion passed (Taylor excused).

Board Action:

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Motion: Jade Jacobo moved to make the Conclusions of Law consistent with paragraphs 4-9 of the Accusation.

Second: Adam Porath

Action: Motion passed (Taylor excused).

Board Action:

Motion: Jade Jacobo moved to find Respondent guilty on Count One, consistent with paragraph 10 of the Accusation.

Second: Adam Porath

Action: Motion passed (Taylor excused).

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

Mr. Balogh had no objections.

President Park entered Exhibit F into the record.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve a $2,500 fine for Wells Pharmacy; award the attorney's fees and costs of $3,884.85 on the basis that they were reasonable, necessary, and actually incurred; and for an additional inspection to be completed by Board staff at the owner's expense within the next six (6) months from the date of the Order.

Second: Jade Jacobo

Action: Motion passed (Taylor excused).

R. Mary Southard (22-464-PT-S)

No one was present on behalf of Mary Southard.

Gregory Zunino, Senior General Counsel for Nevada Board of Pharmacy, prosecuted the case alleging that Respondent Southard falsely stated on her renewal application that she had not been convicted of any felony or misdemeanor offenses since her last renewal. However, she was convicted of two felony offenses in July 2022.

Mr. Zunino requested that proof of service of the Notice of Hearing, the certified mail

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tracking numbers of the Notice of Hearing, and the memorandum of fees and costs be admitted into the record as Exhibits 1-3.

President Park admitted Exhibits 1-3 into the record.

Board discussion ensued.

Board Action:

Motion: President Park moved to find that Respondent Southard was properly noticed for the hearing; to make the Findings of Fact consistent with paragraphs 2-6 of the Accusation; to make the Findings of Law consistent with paragraphs 7-10 of the Accusation; and to make the Findings of Guilt consistent with paragraphs 11-19 of the Accusation. Regarding Discipline, Respondent Southard's Certificate of Registration No. PT17066 is retroactively revoked to October 31, 2024; a $500 fine for the violations to be collected if and when the Respondent petitions for reinstatement; and to award $757.41 in attorney's fees and costs to be collected if and when the Respondent petitions for reinstatement, on the basis that they were reasonable, necessary, and actually incurred.

Second: Jade Jacobo

Action: Motion passed (Taylor excused).

A. Ajumobi Charles Agu (22-535-CS-S)

No one was present on behalf of Ajumobi Charles Agu.

Brett Kandt, General Counsel for Nevada Board of Pharmacy, prosecuted the Order to Show Cause hearing due to Respondent Agu failed to pay the $5,000 fine and $4,065.51 in attorney's fees and costs in Case No. 22-535-CS-S.

Mr. Kandt requested the proofs of service of the Notice of Hearing as presented in Exhibits 1-3 be admitted into the record.

President Park admitted Exhibits 1-3 into the record.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to find Respondent Agu in violation of the disciplinary order for failure to pay the fine and attorney's fees and costs; and to find that Respondent Agu was properly served with notice of the hearing.

Second: Krystal Freitas

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Action: Motion passed (Taylor excused).

Board Action:

Motion: Jade Jacobo moved to refer Respondent Agu's nonpayment of the fine and attorney's fees and costs to the State Controller's Office for collections.

Second: Krystal Freitas

Action: Motion passed (Taylor excused).

U. Kwasha Felton (22-204-PT-S)

No one was present on behalf of Kwasha Felton.

Gregory Zunino, Senior General Counsel for Nevada Board of Pharmacy, prosecuted the case alleging that Respondent Felton stole $320 from her place of employment at Walgreen's Pharmacy #5862.

Mr. Zunino requested that the proof of service of the Notice of Hearing, the certified mail tracking numbers of the Notice of Hearing, and the Declaration by Board staff be admitted into record as Exhibits 1-3.

President Park admitted Exhibits 1-3 into the record.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to find that the Respondent Southard was properly noticed for the hearing; to make the Findings of Fact consistent with paragraphs 2-6 of the Accusation; to make the Findings of Law consistent with paragraph 7 of the Accusation; and to make the Findings of Guilt consistent with paragraphs 8-9 of the Accusation. Regarding Discipline, Respondent Felton's Certificate of Registration No. PT26333 is retroactively revoked to October 31, 2024, and cannot petition for reinstatement for a period of one (1) year; a $500 fine for the violations to be collected if and when the Respondent petitions for reinstatement; and to award $482.27 in attorney's fees and costs of, to be collected if and when the Respondent petitions for reinstatement, on the basis that they were reasonable, necessary, and actually incurred.

Second: Adam Porath

Action: Motion passed (Taylor excused).

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X. Robert Ingham (23-489-CS-S)

No one was present on behalf of Robert Ingham.

Gregory Zunino, Senior General Counsel for Nevada Board of Pharmacy, prosecuted the case alleging that Respondent Ingham allowed his medical assistants to use his credentials to issue prescriptions for controlled substances and failed to query the PMP as required by Nevada Law.

Mr. Zunino requested that the proof of service of the Notice of Hearing, the certified mail tracking numbers of the Notice of Hearing, and the certified mail tracking information from USPS be admitted into record as Exhibits 1-3.

President Park admitted Exhibits 1-3 into the record.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to find that the Respondent Ingham was properly noticed for the hearing; to make the Findings of Fact consistent with paragraphs 2-8 of the Accusation; to make the Findings of Law consistent with paragraphs 9-18 of the Accusation; and to make the Findings of Guilt consistent with paragraphs 19-27 of the Accusation. Regarding Discipline, Respondent is publicly reprimanded; shall pay a $5,000 fine for the violations, due and payable within thirty (30) days of the date of the Order; and shall reimburse the Board for $691.46 in attorney's fees and costs, due and payable within thirty (30) days from the date of the Order on the basis that they were reasonable, necessary, and actually incurred.

Second: Jade Jacobo

Action: Motion passed (Taylor excused).

B. Evergreen Pharmacy (23-007-PH-S)

This matter was continued.

C. Paula Lynne Santos (23-007-RPH-A-S)

This matter was continued.

D. Nazokat Nigmatova (23-007-RPH-B-S)

This matter was continued.

K. Smith's Pharmacy #315 (25-076-PH-S)

This matter was continued.

L. Octavia Loraine Brooks (25-076-RPH-S)

This matter was continued.

M. Alyssa Mercedes Garcia (25-076-PT-S)

This matter was continued.

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

This matter was continued.

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

This matter was continued.

V. Qui Thai (22-476-CS-S)

This matter was continued.

W. Kaveh Kashani (23-104-CS-S)

This matter was continued.

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

This matter was continued.

Chanyis Taylor returned to the meeting at 1:00 PM.

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

A. OptumCare Cancer Pharmacy in Henderson – Henderson, NV

Colby Meier (Pharmacist in Charge), Brandy DePoorter (Vice President of Pharmacy Operations), and Ita Bernardo (IV Technician and Infusion Manager) were present.

President Park disclosed that she was familiar with Mr. Meier but could participate in this matter fairly and without bias.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

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Motion: Adam Porath moved to approve the Compounding Pharmacy License for OptumCare Cancer Pharmacy in Henderson pending a favorable inspection and completion of two extra hours of continuing education (CE) on USP 800 for the pharmacist in charge.

Second: Krystal Freitas

Action: Passed unanimously.

6. Application for Nevada Manufacturer (NAC 639.609) – Appearance (**FOR POSSIBLE ACTION)**

A. Bespoke Pharmaceutical, LLC – Las Vegas, NV

Eric Sparks, Facility Manager, was present.

President Park disclosed that she was familiar with Mr. Sparks but could participate in this matter fairly and without bias.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Manufacturer License for Bespoke Pharmaceutical, LLC.

Second: Adam Porath

Action: Passed unanimously.

16. Application for Pharmaceutical Technician in Training Registration (NAC 639.240) –

Appearance. (**FOR POSSIBLE ACTION)**

A. Larrissa Smith

Larrissa Smith was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

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Motion: Jade Jacobo moved to approve the Pharmaceutical Technician in Training Registration for Larrissa Smith pending a favorable PRN-PRN evaluation or equivalent and drug screening.

Second: Richard Tomasso

Action: Passed unanimously.

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

A. Trina Colby

Trina Colby was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to approve the Pharmaceutical Technician Registration for Trina Colby.

Second: Adam Porath

Action: Passed unanimously.

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

H. Melissa Gauda (24-141-RPH-S)

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, stated that Respondent Gauda had paid the citation and fine due in this case; therefore, the Accusation was dismissed.

20. Executive Secretary Report

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

19. General Counsel Report

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

Public comment at July 16, 2025, at 2:48 PM

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There was no public comment.

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

Board Members Present:

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

Board Members Not Present:

Richard Tomasso

Board Staff Present:

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

Call to Order and Roll Call – Establishment of Quorum

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

Public comment at July 17, 2025, at 9:03 AM

There was no public comment.

◈ WORKSHOP ◈

Thursday, July 17, 2025 – 9:00 AM

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

    A. **Amendment to Nevada Administrative Code (NAC) 639.** The proposed amendment specifies the requirements for pharmacies and practitioners to be authorized to engage in the sterile or nonsterile compounding of drug products.

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, provided the Board with background on the proposed amendment.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, provided clarification.

Board discussion ensued.

President Park opened the floor for public comment.

The following person(s) offered public comment:

Liz McMenamin, Retail Association of Nevada.

Mr. Wuest provided confirmation and clarification to comments made.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt the proposed regulations by Board staff.

Second: Krystal Freitas

Action: Passed unanimously.

17. Review and approval of the Policy Manual **(FOR POSSIBLE ACTION)**

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, provided the Board with background and proposed changes made to the policy manual.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Policy Manual as presented by Board staff.

Second: Adam Porath

Action: Passed unanimously.

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

A. Smart Choice Medical, LLC – Knoxville, TX

Justin Ferreira (Managing member) and Laura Hawks (Compliance Officer) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Medical, Devices, Equipment and Gases License for Smart Choice Medical, LLC.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. Advantixx Pharmacy, LLC – Las Vegas, NV

Osmel Villarreal (Administrator) and Soyoung Eom (Pharmacist in Charge) were present.

President Park disclosed that she was familiar with Soyoung Eom, but she can participate fairly and without bias.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada Pharmacy License for Advantixx Pharmacy, LLC.

Second: Adam Porath

Action: Passed unanimously.

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

B. Melissa Pickert

No appearance was required.

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

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B. AZ Care Pharmacy – Las Vegas, NV

Kardam Panjabi (Owner) and Brian Ford (Pharmacist in Charge) were present.

The Board heard testimony and asked questions of the applicants.

Mr. Panjabi stated that their pharmacy location had changed, and an updated application would be sent to the Board.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Pharmacy License for AZ Care Pharmacy.

Second: Jade Jacobo

Action: Passed unanimously.

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

A. Precision Fulfillment Pharmacy – Boca Raton, FL

Connor Longo, Officer of the Parent Company, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Out-of-State Pharmacy License for Precision Fulfillment Pharmacy.

Second: Krystal Freitas

Action: Passed unanimously.

B. Walgreens HUB Solutions #21609 – Pittsburgh, PA

This application was continued.

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

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A. MedRevival, LLC – Henderson, NV – Background Check completed in compliance with NRS 639.500

Chad Cole (Owner), Michael Lyle (Owner), and Courtney Cole (Designated representative and Administrator) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Nevada Wholesaler License for MedRevival, LLC.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. Vogue Recovery Center – Las Vegas, NV

Araneth Ellison-Smith (Director of Nursing), Leon Knox (Executive Director), and Brian Bulfur (Pharmacy Management Consultant), and Murray Robinson (Pharmacist in Charge) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Ambulatory Surgery Center License for Vogue Recovery Center.

Second: Jade Jacobo

Action: Passed unanimously.

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

A. Mark Cuban Cost Plus Manufacturing and Compounding, LLC – Dallas,

TX

Alexander Oshmyansky (Chief Executive Officer), Faiez Usman (Chief Manufacturing Officer), and Matthew Callesen (Vice President of Quality) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Compounding Pharmacy License for Mark Cuban Cost Plus Manufacturing and Compounding, LLC.

Second: Krystal Freitas

Action: Passed unanimously.

B. New Solutions Functional Wellness Pharmacy – Amarillo, TX

Christy Sims (Corporate Pharmacist), Taylor Fyfe (Co-Owner), and Mikala Conatser (Pharmacist in Charge) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the Compounding Pharmacy License for New Solutions Functional Wellness Pharmacy.

Second: Jade Jacobo

Action: Passed unanimously.

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

A. Milla Pharmaceuticals, Inc – White Bear Lake, MN – Background Check Not Required by Law

Erik Lazarich, Designated Representative, was present.

The Board heard testimony and asked questions of the applicant.

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Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Out-of-State Wholesaler License for Milla Pharmaceuticals, Inc.

Second: Jade Jacobo

Action: Passed unanimously.

22. Public Comment

Yenh Long, Deputy Secretary for the Nevada Board of Pharmacy, advised that the Nevada law continuing education (CE) course is available on the Board's website.

21. Date and Location of Next Scheduled Board Meeting:

September 3-4, 2025 – Reno, NV

23. Adjournment

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4A

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☐ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*	M P00365	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: EBI, LLC

MDEG Physical Address: 1 Gatehall Drive Suite 303

City: Parsippany State: NJ Zip: 07054

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-526-2579 Website: ebibonestimulator.com

Email: payer.relations@highridgemedical.com

Name of MDEG Administrator (NAC 639.694): Vincent Binetti

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:30AM-5:00PM	■ Tue: 8:30AM-5:00PM	■ Wed: 8:30AM-5:00PM	■ Thurs: 8:30AM-5:00PM	■ Fri: 8:30AM-5:00PM
☐ Sat:	☐ Sun:	☐ Holidays:		

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

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

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): AHP EOS Intermediate, Inc.

Corporation/Organization Name: AHP EOS Buyer, Inc.

Mailing Address: 1 Gatehall Drive Suite 303

City: Parisppany State: NJ Zip: 07054

Telephone: 201-213-7436 Email: vincent.binetti@highridgemedical.com

Contact Person Name: Vincent Binetti

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Vincent Binetti

Print Name of Authorized Person Submitting Application

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

6-4-2025

Date

Board Use Only	Date Received: 6/9/25	Amount: $500 - cc

State	Medicaid Provider Number
Arizona APEP	Provider ID: 034067
Alabama	
Arkansas Medicaid	166333716
Arkansas Medicaid	166333716
Arkansas Medicaid	138816741
Colorado Medicaid	9000151718
Florida Medicaid	121434300
Georgia Medicaid	Provider ID 000238059X
	Payee ID 300010943C
Illinois Medicaid IMPACT	3116510000000
Kansas Medicaid	30003900000000
Louisiana Medicaid	1992046
Montana Medicaid	PID0000679507
Montana Medicaid	PID0000679507
New Mexico Medicaid	PID000T1278

Nevada Medicaid	LID3389426
Oklahoma Medicaid	100793280 A
Puerto Rico	PID & Service Location:039784500
South Carolina Medicaid	Legacy PID 414314
Tenncare	4581280
Texas Medicaid	PID074183701
Texas Medicaid	PID074183701
Wyoming Medicaid	114348400
Medicare Number NJ:	0504210001
Medicare Number AL:	0504210002

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 06/04/2025

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

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

PRODUCER Willis Towers Watson Northeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: WTW Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@wtwco.com

INSURER(S) AFFORDING COVERAGE	NAIC#
INSURER A: Berkley National Insurance Company	38911
INSURER B: Gemini Insurance Company	10833
INSURER C: AXIS Insurance Company	37273
INSURER D:	
INSURER E:	
INSURER F:	

INSURED
AHP EOS Holdings, Inc.
1 Gatehall Drive
Ste 303
Parsippany, NJ 07054

COVERAGES **CERTIFICATE NUMBER:** W39278427 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			LNP 5077530-10	05/29/2025	05/29/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG EBL AGGREGATE	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ $ 2,000,000
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY X HIRED AUTOS ONLY SCHEDULED AUTOS X NON-OWNED AUTOS ONLY			LCA 5077529-10	05/29/2025	05/29/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			LNP 5077530-10	05/29/2025	05/29/2026	EACH OCCURRENCE AGGREGATE	$ 10,000,000 $ 10,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		LWC 5077532-10	05/29/2025	05/29/2026	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000
B	Products Liability / Errors and Omissions			GL_18654-1	05/29/2025	05/29/2026	Each Claim Aggregate	$10,000,000 $10,000,000

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

This Voids and Replaces Previously Issued Certificate Dated 06/03/2025 WITH ID: W39266774.

This certificate is issued for the insureds normal business operations.
SEE ATTACHED

CERTIFICATE HOLDER

EBI, LLC
1 Gatehall Drive
Ste 303
Parsippany, NJ 07054

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Patricia A Fong

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SR ID: 27877758 BATCH: 3990806

AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Northeast, Inc.		AHP EOS Holdings, Inc. 1 Gatehall Drive Ste 303 Parsippany, NJ 07054
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

INSURER AFFORDING COVERAGE: AXIS Insurance Company NAIC#: 37273

POLICY NUMBER: P-001-001630902-01 EFF DATE: 05/29/2025 EXP DATE: 05/29/2026

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Transit	Any One Vessel	$1,000,000
Domestic Transit	Any One Conveyance	$1,000,000

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SR ID: 27877758 BATCH: 3990806 CERT: W39278427

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "EBI, LLC" IS DULY REGISTERED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIFTH DAY OF JUNE, A.D. 2025.

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

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5474320 8300

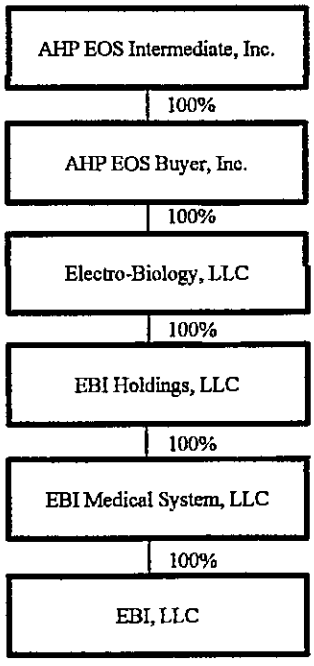
SR# 20253180266

Authentication: 204038722

Date: 06-25-25

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

Medical Products Provider – Medical Devices, Equipment and Gases (MDEG) Application
Section 9: List of all Officers and Directors
License No. MP00365



Entity	Directors	Officers
AHP EOS Intermediate, Inc.	Donald Casey; Garrett Lustig; Eddie Zhao; David Burgstahler; Kevin Kenny	Kevin Kenny (CEO); Vincent Binetti (COO, Secretary, Treasurer)
AHP EOS Buyer, Inc.	Donald Casey; Garrett Lustig; Eddie Zhao; David Burgstahler; Kevin Kenny	Kevin Kenny (CEO); Vincent Binetti (COO, Secretary, Treasurer)
Electro-Biology, LLC	N/A	Kevin Kenny (CEO); Vincent Binetti (COO, Secretary, Treasurer)
EBI Holdings LLC	N/A	Kevin Kenny (CEO); Vincent Binetti (COO, Secretary, Treasurer)
EBI Medical Systems LLC	N/A	Kevin Kenny (CEO); Vincent Binetti (COO, Secretary, Treasurer)
EBI LLC	N/A	Kevin Kenny (CEO); Vincent Binetti (COO, Secretary, Treasurer)

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 6/4/2025

Registration Number: 5002755 **Registered as:** Wholesale

Name: EBI, LLC

DBA:

Address: 1 GATEHALL DR, STE 303 , PARSIPPANY, NJ 07054

Original Issue Date: 01/14/2000 **Expiration Date:** 01/31/2026

Current Issue Date: 12/05/2024

Disciplines: No

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0752338

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

1 GATEHALL DR, STE 303 PARSIPPANY, NJ 07054-

Reg. No.
5002755

EBI, LLC
1 GATEHALL DR, STE 303
PARSIPPANY, NJ 07054-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2026

Establishment Copy

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG EBI, LLC MDEG License # (if applicable) MP00365

Physical Address 1 Gatehall Drive, Suite 303

City Parsippany State NJ Zip 07054

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-526-2579 Website ebibonestimulator.com

Licensing Company Email payer.relations@highridgemedical.com

Section 2: Personal Information

First Vincent Middle _____ Last Binetti

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

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

Mailing Address [redacted]

City [redacted] State [redacted] Zip 07676-5238

Telephone [redacted] Email vincent.binetti@highridgemedical.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Saint Peter's University		1990-1996	
Address	City	State	Zip
2641 John F. Kennedy Blvd	Jersey City	NJ	07306
Diploma/Degree obtained, if any			
Bachelors of Science (BS) in Accounting			

School Name		From - To (MM/YY – MM/YY)	
Ridgefield Park High School		1981-1985	
Address	City	State	Zip
1 Ozzie Nelson DR	Ridgefield Park	NJ	07660
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/2002 – Present	[redacted]	[redacted]	[redacted]	07676
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
EBI, LLC				
Business Address		**City**	**State**	**Zip**
1 Gatehall Drive, Suite 303		Parsippany	NJ	07054
Phone	**Title**		**Number of Employed Hours**	
1800-526-2579	COO		18,458	
Description of Duties				
Includes, but is not limited to, managing all sales, marketing, R&D, manufacturing, finance, and all supporting functions of the bone healing business				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

I, Vincent Binetti, **certify that as the MDEG Administrator for**

EBI, LLC,

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

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

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

Vincent Binetti

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-4-2025

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site EBI, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) MP00365

Physical Address 1 Gatehall Drive, Suite 303

City Parsippany State NJ Zip 07054

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-526-2579 Website ebibonestimulator.com

Licensing Company Email payer.relations@highridgemedical.com

Section 2: Personal Information

First Vincent Middle _____ Last Binetti

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

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

Mailing Address [redacted]

City [redacted] State [redacted] Zip 07676-5238

Telephone [redacted] Email vincent.binetti@highridgemedical.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Saint Peters University		1990-1996	
Address	**City**	**State**	**Zip**
2641 John F Kennedy BLVD	Jersey City	NJ	07306
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Ridgefield Park High School		1981-1985	
Address	**City**	**State**	**Zip**
1 Ozzie Nelson Dr	Ridgefield	NJ	07660
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/2002- Present	[redacted]	[redacted]	[redacted]	07676
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
EBI, LLC			4/2016-Present
Business Address	**City**	**State**	**Zip**
1 Gatehall Drive, Suite 303	Parsippany	NJ	07054
Phone	**Title**		
1800-526-2579	COO		
Description of Duties			
Includes, but is not limited to, managing all sales, marketing, R&D, manufacturing, finance, and all supporting functions of the bone healing business			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

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

Vincent Binetti

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/04/2025

Date

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

State of New Jersey, ss. County of Union

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

Carol Salazar

Original Signature

6/4/2025

Date

Subscribed and Sworn to before me this 4 day of June.

Carol Salazar

Notary Public Signature

CAROL A. SALAZAR
Notary Public, State of New Jersey
My Commission Expires
February 02, 2027

(Seal)

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

EBI, LLC

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on May 24, 1999, and was in existence or authorized to transact business in the State of Indiana on June 04, 2025.

I further certify this Domestic Limited Liability Company has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, June 04, 2025

Diego Morales

DIEGO MORALES
SECRETARY OF STATE

LP99050044 / 20254446066

All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate

Expires on July 04, 2025.

4B

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Mori Medical Equipment, inc

MDEG Physical Address: 2320 La Mirada Dr

City: Vista State: CA Zip: 92081

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 760-659-4200 Website: www.MoriMedicalEquipment.com

Email: gmori@morimedicalequipment.com

Name of MDEG Administrator (NAC 639.694): Gordon Mori

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9am to 4pm	■ Tue: 9am to 4pm	■ Wed: 9am to 4pm	■ Thurs: 9am to 4pm	■ Fri: 9am to 4pm
☐ Sat:	☐ Sun:	☐ Holidays:		

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

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

PTAN - 6679440001
Medi-Cal (Medicaid CA) 4751042, NM - 53364795, AZ - 187067, ID 023792,
WA - 2054539, MI - V50350054, NE - 100295510D.

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

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): _____

Corporation/Organization Name: Mori Medical Equipment, inc

Mailing Address: 2320 La Mirada Dr

City: Vista State: CA Zip: 92081

Telephone: 760-659-4200 Email: headoffice@MoriMedicalEquipment.com

Contact Person Name: Gordon Mori

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Gordon Muri

Print Name of Authorized Person Submitting Application

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

May 20, 2025

Date

Board Use Only	Date Received: 5/27/25	Amount: $500 ck 1968

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 07/25/2025

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

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

PRODUCER	HARDING INSURANCE AGENCY, INC. PO BOX 131360 Carlsbad, CA 92013-1360 License #: 0F09658	CONTACT NAME: Josh Causing PHONE (A/C, No, Ext): (760)603-1100 FAX (A/C, No): (760)603-1102 E-MAIL ADDRESS: joshc@hardinginsuranceonline.com	
		INSURER(S) AFFORDING COVERAGE	NAIC #
INSURED	MORI MEDICAL EQUIPMENT 2320 La Mirada Dr Vista, CA 92081	INSURER A: Benchmark Insurance Company	41394
		INSURER B: Infinity Select Insurance Company	20260
		INSURER C: Technology Insurance Company	42376
		INSURER D: Security National Insurance Company	19879
		INSURER E:	
		INSURER F:	

COVERAGES CERTIFICATE NUMBER: 00001836-2729116 REVISION NUMBER: 6

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			D1024 G7193-2	08/01/2025	08/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000 $
B	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [X] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY [X] COMP DED $1,000 COLL DED $1,000			50025258501	06/30/2025	06/30/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) UIM	$ 1,000,000 $ $ $ $ 1000000
A	[X] UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE [X] DED [ ] RETENTION $ 0			UM1024 7194-2	08/01/2025	08/01/2026	EACH OCCURRENCE AGGREGATE [ ]	$ 1,000,000 $ 1,000,000 $
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			TWC4536546	01/20/2025	01/20/2026	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
D	Business Property			SPP1824569 01	08/01/2025	08/01/2026	Limit	250,000
D	Business			SPP1824569 01	08/01/2025	08/01/2026	Income	50,000

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

Evidence of General Liability, Business Property, Business Income, Worker's Compensation, Excess Liability, Inland Marine, Commercial Auto, and Professional Errors & Omissions.

Additional Insured:
Professional E&O Each Claim $1,000,000
Professional E&O Aggregate $3,000,000
(continued on ACORD 101 Additional Remarks Schedule)

CERTIFICATE HOLDER

General Certificate of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

(JCC)

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AGENCY CUSTOMER ID: 00001836

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
HARDING INSURANCE AGENCY, INC.	MORI MEDICAL EQUIPMENT
POLICY NUMBER: N/A	
CARRIER: Multiple Carriers / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

(continued from Description of Operations)
Inland Marine Limit $250,000

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STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Mori Medical Equipment
2320 La Mirada Drive
Vista, CA 92081

LICENSE NUMBER: 99878
EXPIRATION DATE: 8/2/2026

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

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

Printed: 7/3/2025

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	MORI MEDICAL EQUIPMENT, INC.
Entity No.:	3383696
Registration Date:	06/06/2011
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of May 20, 2025. •

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 329669741

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

Officers & Directors of Mori Medical Equipment, Inc

as of May 22, 2025

President & CEO - Gordon Mori 100%

COO - Andrew Mori

Company Secretary - Aya Mori

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Mori Medical Equipment, inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): 99878

Physical Address: 2320 La Mirada Dr

City: Vista State: CA Zip: 92081

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 760-659-4200 Website: www.MoriMedicalEquipment.com

Licensing Company Email: headoffice@morimedicalequipment.com

Section 2: Personal Information

First: Gordon Middle: Last: Mori

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

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

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: 92081

Telephone: [redacted] Email: gmori@morimedicalequipment.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Columbia University		09/1983 - 12/1984	
Address	**City**	**State**	**Zip**
665 West 130th Street	New York City	CA	10027
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Brigham Young University		09/1978 - 07/1980	
Address	**City**	**State**	**Zip**
	Provo	UT	84602
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
Jordan High School		09/1974 - 09/1977	
Address	**City**	**State**	**Zip**
95 E Beetdigger Blvd	Sandy	UT	84070
Diploma/Degree obtained, if any			
High School			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2022-Present	[redacted]	[redacted]	[redacted]	92084
02/21 - 07/22				92078
01/17 - 01/21				92067
04/10 - 12/16				92009
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Mori Medical Equipment			06/11 to present	
Business Address		**City**	**State**	**Zip**
2320 La Mirada Dr		Vista	CA	92081
Phone	**Title**			
760-659-4200	CEO			
Description of Duties				
Managed the entire business				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

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

Gordon Mori

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

May 20, 2025

Date

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

State of California, ss. County of San Diego

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

Original Signature

May 22, 2025

Date

Subscribed and Sworn to before me this 22nd day of May.

Notary Public Signature

JACOB STEPHEN GOAD
Notary Public - California
San Diego County
Commission # 2444790
My Comm. Expires Apr 20, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Mori Medical Equipment MDEG License # (if applicable) 99878

Physical Address 2320 La Mirada Dr

City Vista State CA Zip 92081

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 760-659-4200 Website www.MoriMedicalEquipment.com

Licensing Company Email _____

Section 2: Personal Information

First Gordon Middle _____ Last Mori

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

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

Mailing Address [redacted]

City [redacted] State [redacted] Zip 92081

Telephone [redacted] Email gmori@MoriMedicalEquipment.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Columbia University		09/1983-12/1984	
Address	**City**	**State**	**Zip**
665 West 130th Street	New York City	NY	10027
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Brigham Young University		09/1978-07/1980	
Address	**City**	**State**	**Zip**
	Provo	UT	84602
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
Jordan High School		09/1974-09/1977	
Address	**City**	**State**	**Zip**
95 E Beetdigger Blvd	Sandy	UT	84070
Diploma/Degree obtained, if any			
High School			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2022-present	[redacted]	[redacted]	[redacted]	92084
02/2021-07/2022				92078
01/2017-01/2021				92067
04/2010-12/2016				92009
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Mori Medical Equipment			06/2011-present	
Business Address		**City**	**State**	**Zip**
2320 La Mirada Dr		Vista	CA	92081
Phone	**Title**		**Number of Employed Hours**	
760-659-4200	CEO		42000	
Description of Duties				
CEO of Durable Medical Equipment				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Gordon Mori, **certify that as the MDEG Administrator for**

Mori Medical Equipment,

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

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

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

Gordon Mori
Print Name (First, Last)

Gordon Mori
Original Signature (electronic, copies or stamps not accepted)

May 20, 2025
Date

Board Use Only	Date Received: 5/27/25

Kristy Langston

From: Gordon Mori <gmori@morimedicalequipment.com>
Sent: Thursday, July 10, 2025 10:22 AM
To: Kristy Langston
Subject: Re: Mori Medical Equipment, Inc MDEG Application
Attachments: Nevada Pharmacy application 20250709.pdf

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

I have been working in DME since 2011. I have a detailed knowledge of all the products we provide. For Nevada we will be providing NarrowBand UVB Lights. I am very familiar with this equipment and the clinical studies support the use of this equipment for common skin ailments as well at T-Cell Lymphoma. I have trained our staff of CSR and well as Office Manager and COO. We have all had multiple inservice sessions from the manufacturer of the equipment, Phothera. We deal with patients using this equipment every day and are well versed and available to answer questions from the patients/members.

Please find attached the response to sections three and four. If you need anything else please let me know. I have added your email to my list so future emails won't go to spam.

Regards
Gordon Mori [redacted]
CEO Mori Medical Equipment
T:760-659-4200 F:760-856-5500
2320 La Mirada Dr., Vista, CA 92081

From: Kristy Langston <klangston@pharmacy.nv.gov>
Sent: Thursday, July 10, 2025 10:04 AM
To: Gordon Mori <gmori@morimedicalequipment.com>
Subject: Mori Medical Equipment, Inc MDEG Application

Hi Gordon,
Thank you for taking time to discuss the Mori Medical Equipment, Inc MDEG application deficiencies with me. Please complete sections three and four of the attached document. If there is no information to report for either question you may put NA. Additionally, please provide a statement regarding your work experience/knowledge pertaining to the medical products provided by Mori Medical Equipment.

Thank you,

Kristy Langston
Licensing Supervisor
Nevada State Board of Pharmacy
(775) 850-1440 xt 131
klangston@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

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NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Noctrix Health, Inc.

MDEG Physical Address: 6700 Koll Center Pkwy, Suite 205

City: Pleasanton State: CA Zip: 94566

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 866-327-3757 Website: www.noctrixhealth.com

Email: bonnie.chan@noctrixhealth.com

Name of MDEG Administrator (NAC 639.694): Bonnie Chan

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☒ Others: Neurostimulators & Supplies (DMEPOS PD04)
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9am-4pm	■ Tue: 9am-4pm	■ Wed: 9am-4pm	■ Thurs: 9am-4pm	■ Fri: 9am-4pm
☐ Sat:	☐ Sun:	☐ Holidays:		

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
PTAN # 8319350001

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

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

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

   a) A practicing health professional; or

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): N/A

Corporation/Organization Name: Noctrix Health, Inc.

Mailing Address: 6700 Koll Center Pkwy, Suite 310

City: Pleasanton State: CA Zip: 94566

Telephone: 866-327-3757 Email: bonnie.chan@noctrixhealth.com

Contact Person Name: Bonnie Chan

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Bonnie Chan

Print Name of Authorized Person Submitting Application

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

6/17/2025

Date

Board Use Only	Date Received: 6/24/25	Amount: $500-ck 1273

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/4/2024

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

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

PRODUCER
Arthur J. Gallagher Risk Management Services, LLC
160 West Santa Clara Street
Suite 300
San Jose CA 95113

License#: 0D69293

CONTACT NAME:
PHONE (A/C, No, Ext): 408-973-9500 **FAX (A/C, No):** 408-257-2985
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Hartford Accident and Indemnity Company	22357
INSURER B : Hartford Underwriters Insurance Company	30104
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Noctrix Health, Inc
6700 Koll Center Parkway, Suite 310
Pleasanton CA 94566

NOCTHEA-01

COVERAGES **CERTIFICATE NUMBER:** 398853290 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY ☐ CLAIMS-MADE ☒ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY ☐ PRO-JECT ☐ LOC ☐ OTHER:	Y	Y	57SBAAX3BN5	10/29/2024	10/29/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ Excluded $
B	AUTOMOBILE LIABILITY ☐ ANY AUTO ☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY			57SBAAX3BN5	10/29/2024	10/29/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ $ $ $
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB ☐ CLAIMS-MADE ☐ DED ☐ RETENTION $			57SBAAX3BN5	10/29/2024	10/29/2025	EACH OCCURRENCE AGGREGATE $	$ 3,000,000 $ 3,000,000 $
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N ☐ If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	Y	57WECAC2KUT	10/29/2024	10/29/2025	X PER STATUTE ☐ OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000

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

CERTIFICATE HOLDER

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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Delaware

The First State

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

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

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

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

6118478 8300

SR# 20250944769

Authentication: 203094955

Date: 03-06-25

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

Re: List of Shareholders

List of all shareholders owning 5% or more of Noctrix Health, Inc.

Name	Address	Ownership
Shriram Raghunathan (Director/Officer)	[redacted]	12.39%
OrbiMed Private Investments VIII, LP	601 Lexington Ave, 54th fl. New York, NY 10022	25.05%
Treo Ventures I, L.P.	5470 Kietzke Lane Suite 300 PMB 209 Reno, Nevada 89511	16.25%
LivaNova USA, Inc.	100 Cyberonics Blvd. Houston, TX77058	5.52%
New Emerging Medical Opportunities Fund V SCSp. (Sectoral)	8, Rue Lou Hemmer L-1748, Senningerberg Luxembourg	8.57%
All other shareholders own < 5%		32.22%
TOTAL		**100%**

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Noctrix Health Inc
6700 Koll Center Pkwy Suite # 205
Pleasanton, CA 94566

LICENSE NUMBER: 119342
EXPIRATION DATE: 7/5/2026

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

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

Printed: 5/29/2025

OSP 07 102308

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Noctrix Health, Inc.

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

Physical Address: 6700 Koll Center Pkwy, Suite 205

City: Pleasanton State: CA Zip: 94566

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 837-327-3757 Website: www.noctrixhealth.com

Licensing Company Email: bonnie.chan@noctrixhealth.com

Section 2: Personal Information

First: Shriram Middle: Last: Raghunathan

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

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

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: 94552

Telephone: [redacted] Email: shri@noctrixhealth.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
STANFORD UNIVERSITY		05/15 – 06/16	
Address	**City**	**State**	**Zip**
450 JANE STANFORD WAY	STANFORD	CA	94305
Diploma/Degree obtained, if any: POST-DOCTORAL FELLOWSHIP			

School Name		From - To (MM/YY – MM/YY)	
PURDUE UNIVERSITY		08/06 – 12/10	
Address	**City**	**State**	**Zip**
610 PURDUE MALL	WEST LAFAYETTE	IN	47907
Diploma/Degree obtained, if any: Ph.D.			

School Name		From - To (MM/YY – MM/YY)	
ANNA UNIVERSITY			
Address	**City**	**State**	**Zip**
SARDAR PATEL RD	CHENNAI	TN	600025
Diploma/Degree obtained, if any: B.E (Electronics Engineering)		INDIA	

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/19 – PRESENT	[redacted]	[redacted]	[redacted]	94552
06/18 – 11/19				94538
06/16 – 06/18				95134
05/15 – 06/16				94025
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name: NOCTRIX HEALTH			From - To (MM/YY – MM/YY): 06/16 - PRESENT
Business Address: 6700 KOLL CENTER PKWY STE 310	City: PLEASANTON	State: CA	Zip: 94566
Phone: 628 222 1626	Title: CEO		
Description of Duties: CEO, FOUNDER			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/19/2023	12/2024	CA	OAKLAND	ALAMEDA

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
23CV056892	SUPERIOR COURT OF THE STATE OF CALIFORNIA

Reason/Charge	
COMPLAINT RE: WRONGFUL DISCHARGE OF EMPLOYEE	

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
NOCTRIX HEALTH, RICHARD MARTIN	

Name of Business/Industry/Entity
NOCTRIX HEALTH

Provide explanation below:

FORMER EMPLOYEE ALLEGED COMPLAINT AGAINST NOCTRIX HEALTH (RICHARD MARTIN) RELATING TO WRONGFUL DISCHARGE, RETALIATION AND DISRIMINATION/ HARRASSMENT.

SETTLED IN ~~ARBITRATION~~ 12/2024

Original Signature (electronic, copies or stamps not accepted)

06/18/23
Date

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

SHRIRAM RAGHUNATHAN

Print Name (First, Last)

See Attached Certificate

S.R

Original Signature (electronic, copies or stamps not accepted)

06/18/2025

Date

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

State of California, ss. County of Alameda

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

See Attached Certificate

Original Signature

06/18/2025

Date

Subscribed and Sworn to before me this 18th day of June, 2025

Notary Public Signature

See Attached Certificate

(Seal)

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

State of California
County of Alameda

Subscribed and sworn to (or affirmed) before me on this 18th day of June, 2025, by Shriram Raghunathan, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

RAHUL SINGH
Notary Public - California
Alameda County
Commission # 2434487
My Comm. Expires Jan 16, 2027

(Seal) Signature

Docusign Envelope ID: 02CE611F-7240-4FD4-AACD-E890B7FC2CF2

CONFIDENTIAL SETTLEMENT AGREEMENT AND FULL AND FINAL RELEASE

[redacted]

RECITALS

A. THE ACTION

[redacted]

B. DENIAL OF LIABILITY

[redacted]

C. SETTLEMENT

[redacted]

TERMS AND CONDITIONS OF AGREEMENT

In consideration of the terms and conditions of this Agreement as set forth below, the adequacy of which is hereby acknowledged, and in light of the circumstances outlined in the Recitals, which are incorporated fully herein by this reference, and in order to fully settle all claims between the Parties, it is agreed as follows:

1.0 SETTLEMENT PAYMENT AND CONSIDERATION

[redacted]

[redacted]

[redacted]

[redacted]

2.0 MUTUAL RELEASE OF ALL CLAIMS

[redacted]

Docusign Envelope ID: 02CE611F-7240-4FD4-AACD-E890B7FC2CF2

[redacted]

Docusign Envelope ID: 02CE611F-7240-4FD4-AACD-E890B7FC2CF2

[redacted]

[redacted]

[redacted]

[redacted]

3.0 CONFIDENTIALITY AND NON-DISCLOSURE

[redacted]

[redacted]

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4.0 NON-DEFAMATION

[redacted]

5.0 ATTORNEYS' FEES

[redacted]

6.0 VOLUNTARY AND INFORMED EXECUTION

[redacted]

7.0 WARRANTY OF CAPACITY TO EXECUTE AGREEMENT

[redacted]

8.0 ENTIRE AGREEMENT

[redacted]

[redacted]

9.0 NO ADMISSIONS

[redacted]

10.0 SCOPE OF AGREEMENT

[redacted]

11.0 INTERPRETATION OF THE AGREEMENT

[redacted]

12.0 PAYMENT OF ALL WAGES

[redacted]

13.0 COUNTERPARTS

[redacted]

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[redacted]

14.0 MEDI-CAL/MEDICARE

[redacted]

15.0 APPLICABLE LAW AND REMEDIES

[redacted]

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[redacted]

16.0 ENTIRE AGREEMENT

[redacted]

PLEASE READ CAREFULLY. THIS SETTLEMENT AGREEMENT AND GENERAL RELEASE INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

DATED: December 13, 2024

Alexandra Ryan

DATED: December 14, 2024

Noctrix Health, Inc.

Signed by:

By: _____

Title: Chief Financial Officer

DATED: December 14, 2024

Signed by:

Richard Martin

Richard Martin

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Noctrix Health, Inc. MDEG License # (if applicable): application pending

Physical Address: 6700 Koll Center Pkwy, Suite 205

City: Pleasanton State: CA Zip: 94566

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 837-327-3757 Website: www.noctrixhealth.com

Licensing Company Email: bonnie.chan@noctrixhealth.com

Section 2: Personal Information

First: Bonnie Chan Middle: Last: Chan

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

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

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: 94566

Telephone: [redacted] Email: bonnie.chan@noctrixhealth.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
Harvard University			07/2008 - 06/2009	
Address		**City**	**State**	**Zip**
79 John F. Kennedy St.		Cambridge	MA	02138
Diploma/Degree obtained, if any				
Master in Public Administration				

School Name			From - To (MM/YY – MM/YY)	
University of New Hampshire			09/1997 - 05/2001	
Address		**City**	**State**	**Zip**
105 Main St.		Durham	NH	03824
Diploma/Degree obtained, if any				
Bachelors of Science, Business Administration				

School Name			From - To (MM/YY – MM/YY)	
Memorial High School			09/1994 - 06/1997	
Address		**City**	**State**	**Zip**
1 Crusader Way		Manchester	NH	03103
Diploma/Degree obtained, if any				
High School Diploma				

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2020 - Present	[redacted]	[redacted]	[redacted]	94577
From - To (MM/YY – MM/YY)				Zip
10/2014 - 07/2020				77007
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Noctrix Health, Inc.			01/2024 - Present	
Business Address		**City**	**State**	**Zip**
6700 Koll Center Pkwy, Suite 205		Pleasanton	CA	94566
Phone	**Title**		**Number of Employed Hours**	
866-327-3757	General Manager		2720	
Description of Duties				
Primary adminstrator and responsible for Noctrix Health, Inc. DME facility's daily operations.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/17/2025

Date

I, Bonnie Chan, **certify that as the MDEG Administrator for**

Noctrix Health, Inc.,

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

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

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

Bonnie Chan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/17/2025

Date

Board Use Only	Date Received: 6/24/25

Board of Certification/Accreditation

Owings Mills, Maryland

Accredited Facility

Practice limited to DMEPOS supplier categories:
PD04

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

Noctrix Health Inc

6700 Koll Center Pkwy Ste 205
PLEASANTON, California 94566

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

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

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

S70366
Facility Number

August 31, 2026
Accredited Through

Accredited Since: August 15, 2023

BOC is a CMS deemed accrediting organization.

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

4D

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: Amneal Pharmaceuticals LLC

Physical Address: 100 Commerce Dr.

City: Glasgow State: KY Zip: 42141

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 270.576.5851 Website: www.amneal.com

Name of Designated Representative (DR): Marty Ross

Licensing Company Email: licensing@amneal.com DR Email: mross@amneal.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Over the Counter medications	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7-14-25

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Philips
Address: 428 Technology Drive City: Menomonie State: WI Zip: 54751

Name: Jerome Stevens Pharmaceuticals Inc.
Address: 60 DaVinci Drive City: Bohemia State: NY Zip: 11716

Name: Bora Pharmaceuticals
Address: No. 1, Kedong 3rd Road, Jhunan Science City: Jhunan, Miao-Li County State: Taiwa Zip:

Name: CMO-Mabxience
Address: S/N 24009 City: Leon State: Spain Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Amneal Pharmaceuticals, Inc.
Corporation Name: Amneal Pharmaceuticals LLC
Mailing Address: 400 Crossing Blvd., Third Floor
City: Bridgewater State: NJ Zip: 08807
Telephone: 908.947.3120 Email: licensing@amneal.com
Contact Person Name: Kansas Walbert

Date of SEC Registration: 11.7.2023 | SEC Registration Number: 001-38485 | Stock Exchange Symbol: AMRX

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

N/A

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Amneal Pharmaceuticals LLC

Facility Name

Marty Ross

Print Name of Authorized Person Submitting Application

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

7-14-25

Date

Board Use Only	Date Received: 7/15/25	Amount: $1000.00

Officer	Title	Birthdate	Phone	Last 4 of SS#	Business address	Shareholders
Andrew "Andy" Boyer	EVP, Chief Commercial Operations- Generics & Biosciences	[redacted]	[redacted]	[redacted]	400 Crossings Boulevard. Third Floor Bridgewater, NJ 08807	Chintu Patel 8.19% Chirag Patel 7.08%
Anastasios Konidaris	EVP & Chief Financial Officer- Finance				400 Crossings Boulevard. Third Floor Bridgewater, NJ 08807	
Nikita D. Shah	EVP, Chief Human Resources Officer and Strategic Planning Officer				400 Crossings Boulevard. Third Floor Bridgewater, NJ 08807	
Chirag Patel	President & CEO				400 Crossings Boulevard. Third Floor Bridgewater, NJ 08807	
Chintu Patel	Co- CEO				400 Crossings Boulevard. Third Floor Bridgewater, NJ 08807	

Top Shareholders

Set forth below is a table demonstrating the ownership of the Amneal Group[6] as of March 14, 2025:

Name[1]	Shares of Class A Common Stock[2]	% of Class
Akram Mahesh[7]	26,856,413	8.57%
Tushar Patel[8]	48,578,209	15.50%
Dipan Patel[9]	23,828,992	7.60%
Chintu Patel[4]	25,670,306	8.19%
Chirag Patel[5]	22,180,421	7.08%
Other Members of the Amneal Group	10,015,765	3.20%
TOTAL AMNEAL GROUP[9]	**157,130,106**	**50.14%**

* *Less than 1%*

(1) *Unless otherwise noted, the address for each beneficial owner listed on the table is Amneal Pharmaceuticals, Inc., 400 Crossing Boulevard, Bridgewater, NJ 08807.*

(2) *Column includes shares underlying exercisable stock options and stock options and restricted stock unit awards that will vest within 60 days of March 14, 2024.*

(3) *J. Kevin Buchi may be deemed to beneficially own 262,072 shares of Class A common stock held of record by a family trust.*

(4) *Chintu Patel may be deemed to beneficially own 24,753,252 shares of Class A common stock held of record by The Chintu Patel Revocable Trust and The Falguni Patel Revocable Trust.*

(5) *Chirag Patel may be deemed to beneficially own 21,269,420 shares of Class A common stock held of record by The Chirag Patel Revocable Trust and The Priti Patel Revocable Trust. Mr. Patel has pledged to Credit Suisse AG 21,269,420 shares of Class A common stock to secure the obligations of those certain borrowers to the Promissory Note and Collateral Agreement dated December 10, 2021 (as modified from time to time).*

(6) *See "Corporate Governance – Corporate Structure" above for a discussion of the relationship between the Amneal Group and the Company. Messrs. Chintu Patel, Chirag Patel and Gautam Patel are members of the Amneal Group and also members of our Board, and their shares are reported in the "Executive Officers and Directors" table above. Shares of Class A common stock held by members of the Amneal Group other than Messrs. Akram Mahesh, Chintu Patel, Chirag Patel, Dipan Patel and Tushar Patel are not reported in this table.*

(7) *Akram Mahesh, c/o Tattva Fiduciary Company, 100 West Liberty Street, 10th Floor, Reno, NV 89501. As reported in the Schedule 13G/A filed by Akram Mahesh on November 14, 2024, Akram Mahesh has the sole power to (a) vote or direct the vote of and (b) dispose or direct the disposition of 26,856,413 shares.*

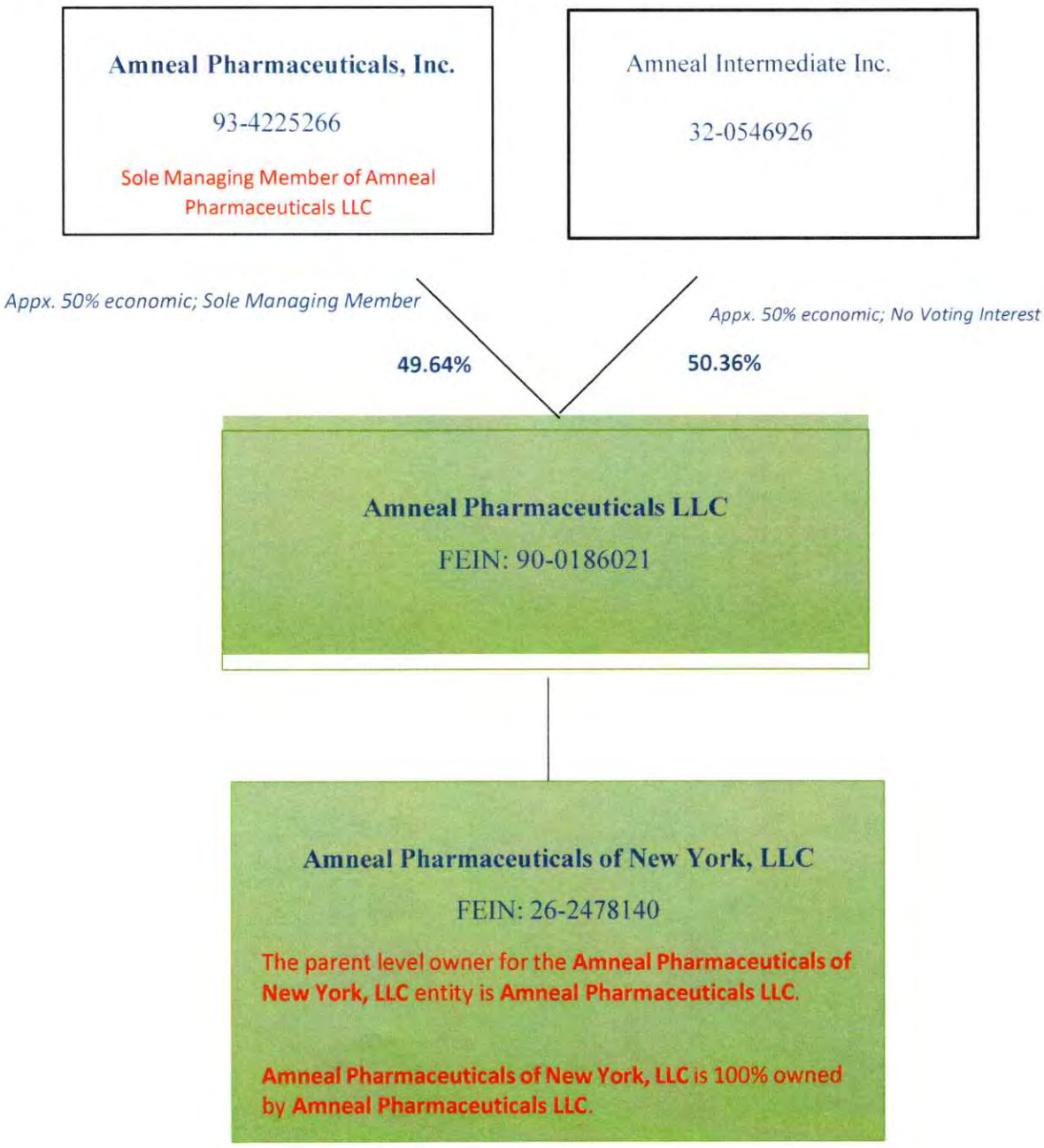
(8) *c/o Tarsadia Investments, LLC, 520 Newport Center Drive, Twenty-First Floor, Newport Beach, CA 92660. Tushar Patel may be deemed to beneficially own 53,578,209 shares of Class A common stock held of record by Tushar Patel Family Trust.*

(9) *c/o Buckhead America Hospitality, 2855 Springhill Parkway, Smyrna, GA 30080. Dipan Patel may be deemed to beneficially own 23,828,992 shares of Class A common stock held of record by Dipan Patel Living Trust, AP-1 Trust, AP-2 Trust, AP-3 Trust, AP-5 Trust, AP-7 Trust, and AP-9 Trust.*

To our knowledge, except as noted above, no person or entity is the beneficial owner of more than five percent of the voting power of the Company's stock.

Amneal Pharmaceuticals LLC

Corporate Structure and Ownership



Amneal Pharmaceuticals of New York, LLC

The parent level owner for the Amneal Pharmaceuticals of New York, LLC entity (FEIN: 26-2478140) is Amneal Pharmaceuticals LLC (FEIN: 90-0186021).

Amneal Pharmaceuticals LLC

400 Crossing Boulevard, Third Floor, Bridgewater, NJ 08807
FEIN: 90-0186021
Incorporated in the State of Delaware on 6/15/2004

Amneal Pharmaceuticals, Inc. (is the sole Managing Member of Amneal Pharmaceuticals LLC)

400 Crossing Boulevard, Third Floor,
Bridgewater, New Jersey 08807-2863
Ownership: 49%
Incorporated in the State of Delaware

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AMNEAL PHARMACEUTICALS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF JUNE, A.D. 2025.

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

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

3809030 8300

SR# 20253001415

Authentication: 203891335

Date: 06-09-25

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

Commonwealth of Kentucky
Michael G. Adams, Secretary of State

Michael G. Adams
Secretary of State
P. O. Box 718
Frankfort, KY 40602-0718
(502) 564-3490
http://www.sos.ky.gov

Certificate of Authorization

Authentication number: 332992
Visit https://web.sos.ky.gov/ftshow/certvalidate.aspx to authenticate this certificate.

I, Michael G. Adams, Secretary of State of the Commonwealth of Kentucky, do hereby certify that according to the records in the Office of the Secretary of State,

AMNEAL PHARMACEUTICALS LLC

, a limited liability company authorized under the laws of the state of Delaware, is authorized to transact business in the Commonwealth of Kentucky, and received the authority to transact business in Kentucky on December 10, 2008.

I further certify that all fees and penalties owed to the Secretary of State have been paid; that an application for certificate of withdrawal has not been filed; and that the most recent annual report required by KRS 14A.6-010 has been delivered to the Secretary of State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my Official Seal at Frankfort, Kentucky, this 22nd day of April, 2025, in the 233rd year of the Commonwealth.

Michael G. Adams
Secretary of State
Commonwealth of Kentucky
332992/0719192

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Wholesaler

NUMBER: W07619

PIC: Marty Ross

Issued to:
Amneal Pharmaceuticals LLC

EFFECTIVE DATE: 02/27/2025

EXPIRATION DATE: 09/30/2025

100 Commerce Drive
Glasgow, KY 42141

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address, and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBJG3168

Application/License No. _____

Amneal Pharmaceuticals, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 100 Commerce Drive Glasgow, KY 42141 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza, Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 8, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16 day of April, 20 25.

APPLICANT/PRINCIPAL
Amneal Pharmaceuticals, LLC

Authorized Representative

SURETY COMPANY
Hartford Fire Insurance Company

Surety Company's Representative

Bonnie Rice, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Michelle Lute-Heatherly

Witness Loretta Jones

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT: **Agency Name:** MARSH USA LLC

- [X] **Hartford Fire Insurance Company,** a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company,** a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois,** a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :

Bonnie Rice

of

Knoxville, TN

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of April 16, 2025.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____
Commission file number 001-38485

Amneal Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**93-4225266**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Crossing Boulevard, Bridgewater, NJ	**08807**
(Address of principal executive offices)	**(Zip Code)**

(908) 947-3120
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, par value $0.01 per share	AMRX	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's outstanding shares of common stock, other than shares held by persons who may be deemed affiliates of the registrant, computed by reference to the price at which the registrant's common stock was last sold on The Nasdaq Stock Market LLC as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2024), was approximately $1.6 billion.

As of February 14, 2025, there were 309,966,341 shares of the registrant's Class A common stock outstanding, with a par value of $0.01.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be furnished pursuant to Part III of this Form 10-K will be set forth in, and is hereby incorporated by reference herein from, the registrant's definitive proxy statement for its 2025 Annual Meeting of Stockholders, to be filed by the registrant with the Securities and Exchange Commission pursuant to Regulation 14A no later than 120 days after December 31, 2024 (the "2025 Proxy Statement").

Amneal Pharmaceuticals, Inc.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K and other publicly available documents of Amneal Pharmaceuticals, Inc. contain "forward-looking statements" within the meaning of the safe harbor provisions of the United States ("U.S.") Private Securities Litigation Reform Act of 1995. Management and representatives of Amneal Pharmaceuticals, Inc. and its subsidiaries ("the Company", "we", "us" or "our") also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "targets," "estimates," and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; our strategy for growth; product development; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of our control. Investors should realize that if underlying assumptions prove inaccurate, known or unknown risks or uncertainties materialize, or other factors or circumstances change, our actual results and financial condition could vary materially from expectations and projections expressed or implied in our forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements.

Summary of Material Risks

Risks and uncertainties that make an investment in the Company speculative or risky or that could cause our actual results to differ materially from the forward-looking statements contained in this Annual Report on Form 10-K, include, but are not limited to:

- our ability to successfully develop, license, acquire and commercialize new products on a timely basis;
- the competition we face in the pharmaceutical industry from brand and generic drug product companies, and the impact of that competition on our ability to set prices;
- our ability to obtain exclusive marketing rights for our products;
- the impact of illegal distribution and sale by third parties of counterfeit versions of our products or stolen products;
- the impact of negative market perceptions of us and the safety and quality of our products;
- our revenues are derived from the sales of a limited number of products, a substantial portion of which are through a limited number of customers;
- the continuing trend of consolidation of certain customer groups;
- our dependence on third-party suppliers and distributors for raw materials for our products and certain finished goods;
- the imposition of tariffs may adversely affect our business, results of operations and financial condition
- legal, regulatory and legislative efforts by our brand competitors to deter competition from our generic alternatives;
- our dependence on information technology systems and infrastructure and the potential for cybersecurity incidents, and risks associated with artificial intelligence;
- the impact of a prolonged business interruption within our supply chain;
- our ability to attract, hire and retain highly skilled personnel;
- risks related to federal regulation of arrangements between manufacturers of branded and generic products;
- our reliance on certain licenses to proprietary technologies from time to time;
- the significant amount of resources we expend on research and development ("R&D");
- the risk of claims brought against us by third parties such as those described in *Note 20. Commitments and Contingencies - Other Litigation Related to the Company's Business*;
- risks related to changes in the regulatory environment, including U.S. federal and state laws related to government contracting, healthcare fraud abuse and health information privacy and security and changes in such laws;
- changes to Food and Drug Administration ("FDA") product approval requirements;
- the impact of healthcare reform and changes in coverage and reimbursement levels by governmental authorities and other third-party payers;
- our dependence on third-party agreements for a portion of our product offerings;
- our substantial amount of indebtedness and our ability to generate sufficient cash to service our indebtedness in the future, and the impact of interest rate fluctuations on such indebtedness;
- our potential expansion into additional international markets subjecting us to increased regulatory, economic, social and political uncertainties;
- our ability to identify, make and integrate acquisitions or investments in complementary businesses and products on advantageous terms;

- the impact of global economic, political or other catastrophic events;
- our obligations under a tax receivable agreement may be significant;
- the high concentration of ownership of our Class A common stock and the fact that we are controlled by the Amneal Group (as defined below in *Item 1. Business*); and
- such other factors as may be set forth elsewhere in this Annual Report on Form 10-K, particularly in the section entitled *1A. Risk Factors* and our public filings with the SEC.

Investors also should carefully read the Risk Factors described in *Item 1A. Risk Factors* for a description of certain risks that could, among other things, cause our actual results to differ materially from those expressed in our forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in *Item 1A. Risk Factors* to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

PART I.

Item 1. Business

Overview

Amneal Pharmaceuticals, Inc. (the "Company", "we," "us," or "our") is a global biopharmaceutical company that develops, manufactures, markets, and distributes a diverse portfolio of essential medicines. Our Affordable Medicines segment includes retail generics, injectables, and biosimilars. In our Specialty segment, we offer a portfolio of branded pharmaceuticals focused primarily on central nervous system and endocrine disorders. Through our AvKARE segment, we are a distributor of pharmaceuticals and other products for the U.S. federal government, retail, and institutional markets. We operate principally in the United States ("U.S."), India, and Ireland. Refer to the section "Segments of the Business" below for an overview of our segments, including the change in name of the Affordable Medicines segment.

Corporate Structure

We are a holding company, whose principal assets are common units (the "Amneal Common Units") of Amneal Pharmaceuticals, LLC ("Amneal"). Immediately prior to the Reorganization (as defined herein), we held 50.4% of the Amneal Common Units and the group, together with their affiliates and certain assignees, who owned Amneal when it was a private company (the "Members" or the "Amneal Group") held the remaining 49.6%. On November 7, 2023, we implemented a plan pursuant to which the Company and Amneal reorganized and simplified our corporate structure by eliminating our umbrella partnership-C-corporation structure and converting to a more traditional C-corporation structure whereby all stockholders hold their voting and economic interests directly through the public company (the "Reorganization"). Effective with the Reorganization, we hold 100% of the Amneal Common Units and continue to consolidate the financial statements of Amneal and its subsidiaries. Refer to *Note 1. Nature of Operations* in our consolidated financial statements for additional information about the Reorganization.

Although we had a minority economic interest in Amneal prior to March 2023, we were Amneal's sole managing member (and we continue to be the sole managing member), having the sole voting power to make all of Amneal's business decisions and control its management. Therefore, we consolidated the financial statements of Amneal and its subsidiaries for all periods prior to the Reorganization. We recorded non-controlling interests for the portion of Amneal's economic interests that we did not hold prior to the Reorganization.

Alliance and Collaboration

Collaboration to Develop and Supply Medicines for Obesity and Metabolic Diseases

On September 30, 2024, we entered into a collaboration agreement to develop and supply a new portfolio of weight loss medicines globally with Metsera, Inc. ("Metsera"), a clinical stage biopharmaceutical company (the "Metsera Agreement"). We will serve as Metsera's preferred supply partner for developed markets, including the United States and Europe. In addition, we have been granted an exclusive license to commercialize Metsera products covered under the agreement in selected emerging markets, including India and certain countries in Southeast Asia, Africa and the Middle East.

Under the terms of the Metsera Agreement, we will be responsible for performing certain development activities on behalf of Metsera. Upon Metsera obtaining regulatory approval for any or all the weight loss medicines referred to above, we will manufacture commercial products on behalf of Metsera.

We plan to construct two new greenfield manufacturing facilities in India; one for peptide synthesis and one for sterile fill-finish manufacturing. Metsera will contribute an agreed percentage of the construction costs, up to $100 million, subject to annual maximums, as defined in the Metsera agreement.

The initial term of the Metsera Agreement is seven years from the first commercial sale. Metsera has the sole right to renew the agreement for an additional five-year period. Following this initial renewal, the agreement may be extended by mutual written consent.

License Agreement with Zambon Biotech

On February 23, 2024, we entered into a license, distribution and supply agreement with Zambon Biotech S.A. ("Zambon") granting Zambon the exclusive rights to seek regulatory approval and commercialize IPX203 in Europe (the "Zambon License Agreement"). The term for the Zambon License Agreement is 15 years commencing from the commercial launch of the product, which can automatically renew for successive two-year periods unless either party provides notice declining such

renewal at least one year in advance. Zambon will be responsible for the performance of all R&D activities, regulatory approval, commercialization, and marketing activities for the territories in the agreement to be conducted to obtain regulatory approval for each product. Upon achieving regulatory approval for products, we will be responsible for manufacturing and supplying products to Zambon.

As of December 31, 2024, IPX203 had not been approved for sale outside of the United States, where it is marketed as CREXONT®. CREXONT® (combination of carbidopa and levodopa extended release capsules) is indicated in the United States for the treatment of Parkinson's disease.

Knight Therapeutics International S.A. License Agreement

On January 24, 2024, we entered into a 15-year license, distribution and supply agreement with Knight Therapeutics International S.A. ("Knight") granting Knight the exclusive rights to seek regulatory approval and commercialize IPX203 in Canada and Latin America (the "Knight License Agreement"). The Knight License Agreement will automatically renew for successive two-year periods unless either party provides notice declining such renewal at least one year in advance.

Knight will be responsible for the performance of all R&D activities, regulatory approval, commercialization, and marketing activities for the territories in the agreement to be conducted to obtain regulatory approval for each product. Upon achieving regulatory approval for products, Amneal will be responsible for manufacturing and supplying products to Knight.

As of December 31, 2024, IPX203 had not been approved for sale outside of the United States, where it is marketed as CREXONT®.

ONGENTYS® License and Supply Agreement

On December 5, 2023, we entered into a license agreement with BIAL-Portela & Ca., S.A. ("BIAL") for the exclusive rights to market and distribute ONGENTYS® (opicapone) in the U.S. starting on December 18, 2023 and ending at such time when generic opicapone sales reach certain predetermined thresholds (the "BIAL Agreement"). ONGENTYS® is BIAL's proprietary, once-daily, peripherally-acting, highly-selective catechol-O-methyltransferase inhibitor approved by the U.S. Food and Drug Administration (the "FDA") in 2020 as an add-on treatment to carbidopa/levodopa in patients with Parkinson's disease experiencing "off" episodes. Under the BIAL Agreement, we are responsible for commercialization and marketing of ONGENTYS® in the U.S. and BIAL is responsible for manufacturing and supply. We commenced distribution of ONGENTYS® in early 2024.

Orion Corporation License Agreement

On December 28, 2022, we signed a long-term license agreement with Orion Corporation ("Orion"), a globally operating Finnish pharmaceutical company, to commercialize a number of our complex generic products in most parts of Europe, Australia and New Zealand (the "Orion Agreement"). The initial term of the Orion Agreement commences upon commercial launch of the products and will continue for eight years. The Orion Agreement will automatically renew for successive two-year terms unless either party declines such renewal in writing at least one year in advance. As of December 31, 2024, the initial term has not commenced.

Licensing and Supply Agreement with mAbxience S.L.

On May 7, 2018, we entered into a licensing and supply agreement with mAbxience S.L. ("mAbxience"), for its biosimilar candidate for Avastin® (bevacizumab). We are the exclusive partner in the U.S. market. On April 13, 2022, the FDA approved our biologics license application for bevacizumab-maly, a biosimilar referencing Avastin®.

License and Supply Agreement with Kashiv Biosciences LLC

In December 2022, we entered into a development and supply agreement specific to four generic product candidates with Kashiv Biosciences LLC ("Kashiv"). Pursuant to the development supply agreement, we maintained a right of first offer and negotiation to the licensing of each generic product candidate. In March 2024, we entered into a license and supply agreement with Kashiv for the development and commercialization of a long-acting injectable (the "Injectable License and Supply Agreement"). The existing development supply agreement remains effective for the remaining three generic product candidates.

Subject to the terms of the Injectable License and Supply Agreement, we are responsible for development, regulatory approval, and commercialization of the product candidate in the U.S., whereas Kashiv is responsible for development and regulatory approval of the product candidate for all other territories outside the U.S. Contingent upon Kashiv obtaining regulatory approval outside the U.S., we shall manufacture the commercial supply for Kashiv at a stated price. The term of the agreement is 10 years from the respective product's launch date in the U.S. As of December 31, 2024, the term has not commenced.

For additional information about our alliance and collaboration agreements, refer to *Note 5. Alliance and Collaboration* and *Note 23. Related Party Transactions* in our consolidated financial statements.

Acquisition

Baclofen Franchise

On December 30, 2021, we entered into an asset purchase agreement with certain entities affiliated with Saol International Limited (collectively, "Saol"), a private specialty pharmaceutical company, pursuant to which we agreed to acquire Saol's baclofen franchise, including Lioresal®, LYVISPAH™, and a pipeline product under development (the "Saol Acquisition"). The Saol Acquisition expanded our commercial institutional and specialty portfolio in neurology and added commercial infrastructure in advance of our entry into the biosimilar institutional market during October 2022. Consideration for the Saol Acquisition included approximately $84.7 million, paid at closing with cash on hand, and contingent royalty payments based on annual net sales for certain acquired assets, beginning in 2023. The transaction closed on February 9, 2022.

For additional information about our acquisition, refer to *Note 3. Acquisition* in our consolidated financial statements.

Segments of the Business

We have three reportable segments: Affordable Medicines (formerly known as Generics), Specialty, and AvKARE.

During the fourth quarter of 2024, we changed the name of our Generics segment to "Affordable Medicines" to reflect the full product offering of the segment. The segment name change did not result in any change to the composition of our reportable segments and, therefore, did not result in any changes to our historical segment results.

Affordable Medicines

Prescription pharmaceutical products are sold either as branded or generic products. Generic pharmaceutical products have the same active product ingredient ("API"), dosage form, strength, route of administration, and conditions of use as patented branded pharmaceutical products, are bioequivalent to the brand it copies, and are usually marketed under their chemical (generic) names rather than brand names. Generic pharmaceutical products are intended to provide a cost-effective alternative for consumers while maintaining the safety, efficacy, quality and stability of the branded product, and as such are generally sold at prices below their branded equivalents. Typically, a generic pharmaceutical may not be marketed until the expiration of applicable patent(s) on the corresponding branded product, unless the resolution of patent litigation results in an earlier opportunity to enter the market. Generic manufacturers are required to file and receive approval for an Abbreviated New Drug Application ("ANDA") to market a generic pharmaceutical product. Manufacturers of biosimilars are required to file a Biologics License Application ("BLA") to introduce, or deliver for introduction, a biologic product into interstate commerce and market the product for one or more indications. Refer to *Item 1. Business - Pharmaceutical Approval Process in the United States - New Drug Application and Biologics License Application* for additional information.

Our Affordable Medicines segment includes approximately 270 product families covering an extensive range of dosage forms and delivery systems, including both immediate and extended-release oral solids, powders, liquids, sterile injectables, nasal sprays, inhalation and respiratory products, biosimilar products, ophthalmics, films, transdermal patches and topicals. We focus on developing products that have substantial barriers-to-entry due to complex drug formulations or manufacturing, or legal or regulatory challenges. Focusing on these products allows us the opportunity to offer first-to-file ("FTF"), first-to-market ("FTM") and other high-value products to customers. A generic pharmaceutical product is considered an FTF product if the ANDA filed with respect to such product is the first to be filed for such product. Pursuant to the Hatch-Waxman Amendments, FTF products may receive a statutory 180-day exclusivity period, subject to certain conditions. A generic product that does not qualify as an FTF may still be an FTM product. A generic product is considered an FTM product if it is the first marketed generic version of a branded pharmaceutical. FTF, FTM and high-value products tend to be more profitable and often have longer life cycles than other generic pharmaceuticals. As such, the timing of new product introductions can have a significant impact on our financial results. Market entry by additional competitors generally has a negative impact on the volume and pricing of the affected products. Additionally, pricing is often affected by factors outside of our control. Refer to "Pharmaceutical Approval Process in the United States," below, for more information.

As of December 31, 2024, our Affordable Medicines segment had 76 products with a pending ANDA and another 56 products in various stages of development in our pipeline, 74% of which are non-oral solid products. We have an integrated, team-based approach to product development that combines our formulation, regulatory, legal, manufacturing and commercial capabilities.

Our Affordable Medicines segment has a growing portfolio of institutional injectable products primarily for the U.S. hospital market. Our R&D pipeline has prioritized new product innovations in injectables, such as drug/device combinations, peptides, long-acting injectables and large volume parenteral bags. We have expanded our manufacturing capabilities and infrastructure to support the needs of this expanding business with a focus on development, commercialization and scaling a differentiated injectables portfolio. During 2023, we launched 39 new products, of which 14 were injectables. In May 2023, the FDA approved for manufacturing our fourth and largest injectable site. During 2024, we launched 22 new products, of which 12 were injectables.

In 2022 we began to commercialize an initial portfolio of oncology biosimilars in the U.S. Alymsys®, a biosimilar referencing Avastin®, launched in October 2022, followed by Releuko®, a biosimilar referencing Neupogen®, in November 2022 and Flynetra™, a biosimilar referencing Neulasta®, in May 2023. On October 12, 2023, we announced the addition of two denosumab biosimilars referencing both Prolia® and XGEVA® to our biosimilar pipeline. The two denosumab products are being developed by mAbxience S.L., a global biotech company with over a decade of experience in the development, manufacture, and commercialization of biopharmaceuticals. To further grow our oncology biosimilars sales, we are focused on serving oncology clinics, integrated health systems and specialty pharmacies. We are focused on expanding our oncology and biosimilar portfolio with additional molecules, and we seek to vertically integrate by expanding our biosimilar capabilities.

In March 2024, we amended the Kashiv Biosimilar Agreement (as defined in *Note 23. Related Party Transactions*) to include two additional in-development products, a pre-filled auto-injector delivery system for peg-filgrastim and a pre-filled on-body injector (OBI) delivery system for peg-filgrastim. In July 2024, we entered into an exclusive license and commercialization agreement with Kashiv Biosciences LLC to distribute and sell Omalizumab, a biosimilar to XOLAIR®, in the U.S. and India (refer to *Note 23. Related Party Transactions.*)

Our Affordable Medicines segment had net revenue of $1.69 billion, $1.47 billion and $1.43 billion and operating income of $270.1 million, $276.2 million and $224.2 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Specialty

Our Specialty segment is engaged in the development, promotion, sale and distribution of proprietary branded pharmaceutical products, with a focus on products addressing central nervous system ("CNS") disorders, including Parkinson's disease, and endocrine disorders. Our portfolio of products includes CREXONT® (combination of carbidopa and levodopa extended release capsules), RYTARY® (extended release oral capsule formulation of carbidopa-levodopa), UNITHROID® (levothyroxine sodium), and ONGENTYS® (opicapone). On August 7, 2024, the FDA approved our new drug application ("NDA") for CREXONT®, previously referred to as IPX203. In September 2024, we began selling CREXONT®, which is indicated for the treatment of Parkinson's disease, Parkinson's disease caused by infection or inflammation of the brain, or Parkinson's disease-like symptoms that may result from carbon monoxide or manganese poisoning in adults. RYTARY® is indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication. ONGENTYS® is an add-on treatment to carbidopa/levodopa in patients with Parkinson's disease experiencing "off" episodes, which we commenced selling in early 2024 under a license agreement with BIAL-Portela & Ca., S.A. UNITHROID®, indicated for the treatment of hypothyroidism, is sold under a license and distribution agreement with Jerome Stevens Pharmaceuticals, Inc.

Our Specialty products are marketed through skilled specialty sales and marketing teams, who call on neurologists, movement disorder specialists, endocrinologists and primary care physicians throughout the U.S. Our Specialty segment also has other product candidates that are in varying stages of development.

For Specialty products, the majority of such products' commercial value is usually realized during the period in which the product has market exclusivity. In the U.S., when market exclusivity expires and generic versions of a product are approved and marketed, there can often be substantial and rapid declines in the branded product's sales. In 2025, we expect to lose exclusivity for RYTARY®, an extended-release oral capsule formulation of carbidopa-levodopa for the treatment of Parkinson's disease.

Our Specialty segment had net revenue of $445.7 million, $390.5 million and $374.1 million and operating income of $113.6 million, $65.3 million and $72.6 million, for the years ended December 31, 2024, 2023 and 2022, respectively.

AvKARE

Our AvKARE segment provides pharmaceuticals, medical and surgical products, and services primarily to governmental agencies, predominantly focused on serving the U.S. Department of Defense and the U.S. Department of Veterans Affairs. AvKARE is also a re-packager of bottle and unit dose pharmaceuticals and vitamins under the registered names of AvKARE and AvPAK. AvKARE is also a wholesale distributor of pharmaceuticals, over the counter drugs and medical supplies to its retail and institutional customers that are located throughout the U.S. focused primarily on entities that provide care to low-income and uninsured patients. Operating results for the sale of Amneal products by AvKARE are included in our Affordable Medicines reportable segment.

Our AvKARE segment had net revenue of $662.9 million, $531.7 million and $406.1 million and operating income of $42.9 million, $31.5 million and $3.3 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Geographic Areas

We operate in the U.S., India, and Ireland. Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, more restrictive economic policies and higher political and legal system uncertainties. See further discussion of this risk in *Item 1A. Risk Factors*.

Sales & Marketing and Customers

In the U.S. and the Commonwealth of Puerto Rico, we market our Affordable Medicines and Specialty products primarily through major wholesalers and distributors, retail pharmacies, mail-order pharmacies and directly into hospitals and institutions. The majority of our Affordable Medicines pharmaceutical products are marketed to large group purchasing organizations ("GPOs") and sold through wholesalers, directly to large chain retailers or to mail order customers. Our sterile injectable products and biosimilars utilize a dedicated field-based sales force and are generally marketed to GPOs and specialty distributors, and sold through wholesalers, and occasionally directly to large hospitals and institutions. All of our wholesalers purchase products and warehouse them for retail drug stores, independent pharmacies and managed care organizations, such as hospitals, nursing homes, health maintenance organizations ("HMOs"), clinics, pharmacy benefit management companies and mail-order customers. Our Specialty segment, which promotes branded pharmaceutical products, employs a team of dedicated field-based sales representatives to engage in the direct marketing and promotion of our branded products to physicians and healthcare providers.

Refer to "AvKARE" in the section "Segments of the Business" above for a description of our AvKARE segment's customers.

For the year ended December 31, 2024, on a consolidated basis, our four largest customers, Cencora, Inc., McKesson Drug Co., Cardinal Health, Inc., and CVS Health Corporation, accounted for approximately 70% of our net revenue. In total, we currently have approximately 1,300 customers (including over 1,100 customers specific to our AvKARE segment), some of which are part of large purchasing groups.

We have no long-term agreements that guarantee future business with any of our major customers and the loss of or substantial reduction in orders from any one or more of these customers could have a material adverse effect on our operating results, prospects and financial condition.

Competition

The pharmaceutical industry is highly competitive and is affected by new technologies, new developments, government regulations, health care legislation, availability of financing, and other factors. Many of our competitors have longer operating histories and substantially greater financial, R&D, marketing, and other resources than we do. Competing manufacturers of generic pharmaceutical products create value for our customers by offering substitutes for branded pharmaceutical products at significantly lower prices, and at times we may not be able to differentiate our product offerings from those of our competitors, successfully formulate and bring to market new products that are less expensive than those of our competitors or offer commercial terms as favorable as those of our competitors. We compete with numerous other companies that currently operate, or intend to operate, in the pharmaceutical industry, including companies that are engaged in the development of controlled-release drug delivery technologies and products, and other manufacturers that may decide to undertake development of such products. Our principal competitors in the generic/biosimilar pharmaceutical products market include Teva Pharmaceutical Industries Ltd., Viatris Inc., Sandoz Group, Pfizer Inc., Fresenius Kabi KGaA, Hikma Pharmaceuticals PLC, Dr. Reddy's Laboratories Ltd., Amphastar Pharmaceuticals, Inc., Sun Pharmaceutical Industries Ltd., Lupin Pharmaceuticals, Inc., Zydus

Pharmaceuticals USA Inc., and Aurobindo Pharma Limited. Our principal competitors in the specialty pharmaceutical products market include Supernus Pharmaceuticals, Inc., Jazz Pharmaceuticals PLC, AbbVie Inc., and Alkermes PLC.

Our AvKARE segment is also highly competitive, with new smaller competitors entering the space regularly. Our competitors are other wholesalers, including Cardinal Health, Inc., Cencora, Inc., McKesson Drug Co., and manufacturers / re-packagers such as Golden State Medical Supply.

By focusing on our high-value products with complex dosage forms and high barriers-to-entry, as well as taking advantage of our vertically integrated supply chain and selective use of internal API, we aim to manufacture more profitable products relative to our competition.

The Hatch-Waxman Amendments amended the Federal Food, Drug and Cosmetic Act ("FDCA") and provided for a period of 180 days of generic marketing exclusivity for each applicant that is FTF an ANDA with a Paragraph IV certification, which signifies a challenge to at least one brand patent. The holder of an approved FTF ANDA that successfully challenges the relevant innovator drug patent(s) usually enjoys higher market share and sales during the 180-day period of exclusivity. When the exclusivity period concludes, other generic competitors may launch their versions of the product, which may cause significant price erosion and loss of market share. In cases where we are the holder of an ANDA for a FTF product, upon the expiration of the 180-day exclusivity period, we may adjust the price of such product and provide price adjustments to our customers for the difference between the lower price and the price at which we previously sold the product then held in inventory by our customers. These adjustments are commonly known as shelf stock adjustments. In certain circumstances, we may decide not to provide price adjustments to certain customers and, as a result, we may receive returns of unsold product from these customers and forego future sales volume as opposed to reducing pricing.

Authorized generic pharmaceutical products, which are generic labeled versions of pharmaceutical products introduced by brand companies (directly or through a third-party) under the brand's NDA, have also increased competition in the generic pharmaceutical industry. Authorized generic pharmaceutical products may be sold prior to, during and subsequent to the 180-day exclusivity period and are a significant source of competition, because brand companies do not face any regulatory barriers to rapidly introducing generic versions of their pharmaceutical products.

Additionally, consolidation among wholesalers and retailers and the formation of GPOs has caused increased price competition in the generic pharmaceutical market. The downward price adjustments demanded by distributors of generic pharmaceutical products have reduced revenue and average product gross margin across the industry. Should these price reductions continue or even increase, it could have a material adverse effect on our revenue and gross margin. Further, even if we reduce the prices we charge our customers, that does not ensure that the prices consumers pay for those drugs will be similarly reduced.

The main competitive factors in the generic pharmaceutical market include:

- a generic pharmaceutical products manufacturer's ability to rapidly develop and obtain regulatory approval for and supply commercial quantities of generic pharmaceutical products;
- the introduction of other generic pharmaceutical manufacturers' products in direct competition with our products;
- the introduction of authorized generic pharmaceutical products in direct competition with our products;
- consolidation among our customers and the formation of buyer consortia;
- pricing pressures by competitors and customers, even if similar price savings are not passed on to consumers;
- product quality of our generic pharmaceutical competitors;
- our and our competitors' breadth of product offerings across its portfolio;
- our ability and the ability of our generic pharmaceutical competitors to quickly enter the market after the expiration of patents or statutory exclusivity periods, limiting the extent and duration of profitability for our products;
- the willingness of our customers to switch their source of supply of products among various generic pharmaceutical competitors;
- the ability of our generic pharmaceutical competitors to identify and market niche products;
- our and our competitors' level of service (including maintenance of inventories for timely delivery) and reputation as a reliable developer and manufacturer of generic pharmaceutical products; and
- product appearance and labeling for our products and those of our competitors.

In the brand-name pharmaceutical market, our principal competitors are pharmaceutical companies that are focused on Parkinson's disease and other CNS disorders. In addition, with respect to products that we are developing internally and/or any additional products we may in-license from third parties, we expect that we will face increased competition from large

pharmaceutical companies, drug delivery companies and other specialty pharmaceutical companies that have focused on the same disorders as our branded products.

Research and Development

R&D activities represent a significant part of our business. R&D expenditures relate to the processes of discovering, testing and developing new products, upfront payments and milestones, improving existing products, as well as demonstrating product efficacy, if applicable, and regulatory compliance prior to launch. We are committed to investing in R&D with the aim of delivering high quality and innovative products. For the years ended December 31, 2024, 2023 and 2022, our R&D expense was $190.7 million, $164.0 million and $195.7 million, respectively.

Raw Materials

Raw materials, including APIs, essential to our business are generally readily available from various suppliers/sources. We purchase raw materials from manufacturers/distributors of bulk pharmaceutical chemicals and we also manufacture certain APIs at our facilities in India. In some cases, however, the raw materials used to manufacture our products are available only from a single supplier. Further, even if more than one supplier exists, we may choose, and have done so in the case of our API suppliers for a majority of our products, to list only one supplier in our product applications submitted to the FDA. Generally, we would need as long as 18 months to find and qualify a new sole-source supplier. If we receive less than one year's termination notice from a sole-source supplier that it intends to cease supplying raw materials, it could result in disruption of our ability to produce the drug involved. Although to date we have only experienced occasional interruptions in supplies, no assurance can be given that we will continue to receive uninterrupted or adequate supplies of such raw materials. Any inability to obtain raw materials on a timely basis, or any significant price increases not passed on to customers, could have a material adverse effect on our business.

Because legal and regulatory requirements mandate that our product marketing authorizations specify API and raw material suppliers, if a specified supplier were for any reason unable to continue to supply us, we would need to seek FDA approval of a new supplier. The resulting delay in the manufacture and marketing of the impacted pharmaceutical product during the FDA process to qualify and approve the new supplier could, depending on the product, have a material adverse effect on our results of operations and financial condition. We protect against the risk of such an event by generally providing for, where feasible, two or more suppliers of raw materials for the pharmaceutical products we manufacture, including those for which we manufacture API in-house. Additionally, we may enter into a contract with a raw material distributor in order to secure adequate supply for specific products.

For a discussion of the risks relating to tariffs on APIs, refer to the risk factor "*Changes in trade policy, including the imposition of tariffs may adversely affect our business, results of operations and financial condition*" in Part 1. Item 1A. Risk Factors.

Manufacturing and Distribution

We have a network of manufacturing sites and co-located R&D centers within the U.S., India and Ireland, with broad dosage capabilities. We also have a distribution center for our Affordable Medicines and Specialty products in Glasgow, Kentucky. We manufacture the majority of our Affordable Medicines products internally; of these products, for the year ended December 31, 2024, those manufactured in our U.S. facilities contributed 44% of Affordable Medicines product net revenue compared to 28% for those manufactured in India. We rely on third-party manufacturers to supply products in our Affordable Medicines portfolio representing approximately 28% of our Affordable Medicines net revenue for the year ended December 31, 2024. Most of our Specialty products are manufactured by third-party manufacturers. In addition, we selectively manufacture API for a subset of our products, which helps to reduce the cost of manufacturing for our products and gives us greater control over our supply chain.

Our AvKARE segment's distribution centers are located in Fountain Run, Kentucky and Philadelphia, Pennsylvania.

Government Regulation

The business of developing, manufacturing, selling, distributing, and marketing generic, biosimilar, and branded products is subject to significant health, safety, and environmental laws and regulations, including those governing the approval and pricing of products, clinical trials, laboratory procedures, privacy and security of health and other sensitive information and the handling, use, storage, treatment and disposal of hazardous materials and wastes. These regulatory regimes are overseen by

governmental bodies, principally the FDA and, as applicable, the Drug Enforcement Administration (the "DEA"), the Department of Health and Human Services, the Federal Trade Commission (the "FTC") and several state and local government or other agencies, including individual data protection authorities, in the U.S. and abroad. Failure to comply with the laws and regulations of these governmental agencies may result in legal or other enforcement actions, including suspension of regulatory approval, delays in regulatory approval, clinical holds, orders to cease non-compliant activities and potential civil and criminal actions against us. The regulatory environment, particularly enforcement positions, statutes and legal interpretations applicable to the pharmaceutical industry are constantly in flux and not always clear. Significant changes in this environment could have a material adverse effect on our financial condition and results of operations.

The FDCA, the Public Health Service Act (the "PHSA"), the Controlled Substances Act, the regulations that implement these laws and other statutes and regulations govern the development, testing, manufacture, packaging, use, distribution, safety, effectiveness, labeling, storage, record keeping, approval, marketing, sale, and promotion of our products, as well as post-marketing requirements for safety surveillance and reporting. Failure to comply with these laws and regulations can result in judicial and/or administrative sanctions, such as warning letters, recalls, product seizures, injunctions, fines, total or partial suspension of distribution or production, exclusion or debarment from government programs and contracts, restitution, disgorgement and criminal prosecutions. The FDA has the authority to withdraw its approval of pharmaceuticals at any time, in accordance with its regulatory due process procedures, and can enforce the recall of products.

Pharmaceutical Approval Process in the United States

In the U.S., the FDA regulates pharmaceuticals and biologics under the FDCA and the PHSA, and their implementing regulations. To market a new drug or biologic, considerable data must be submitted to the FDA for review and approval. In addition to approval, the FDA also regulates research, development, preclinical and clinical testing, manufacturing, packaging, storage, distribution, recordkeeping, labeling, advertising, promotion, marketing, post-approval monitoring and reporting, and import and export of drugs and biologics. If we fail to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval, we may be subject to a variety of administrative or judicial sanctions, which could include, among other actions, the FDA's refusal to approve pending applications, delays in approval, suspension or withdrawal of an approval, imposition of a clinical hold, orders to cease non-compliant activities, criminal charges, issuance of warning letters and other types of enforcement-related letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, exclusion from participation in government programs and contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA, the U.S. Department of Justice ("DOJ") or other governmental entities.

Generally, the following types of applications are used to obtain FDA approval.

New Drug Application and Biologics License Application

For a drug product containing an active ingredient not previously approved by the FDA, a prospective manufacturer must submit a complete NDA containing the results of clinical studies supporting the drug product's safety and efficacy in addition to data and information related to drug product quality and manufacturing. An NDA is also required for a drug with a previously approved active ingredient if the drug will be used to treat an indication for which the drug was not previously approved or if the dosage form, strength or method of delivery is changed and requires clinical studies to support the change. A BLA is required to introduce, or deliver for introduction, a biologic product into interstate commerce and market the product for one or more indications. The process required by the FDA before a new pharmaceutical or biological product may be approved for marketing in the U.S. generally involves the steps listed below.

- Laboratory and clinical tests;
- Submission to the FDA of an Investigational New Drug ("IND") application;
- Adequate and well-controlled human clinical studies conducted according to the FDA's requirements for good clinical practice ("GCP") and additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product for its proposed conditions of use;
- For pharmaceutical products, submission of an NDA containing the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its proposed conditions of use, proposed labeling, extensive data addressing such matters such as drug product quality and manufacturing, and certain information with regards to patents related to the proposed drug product;
- For biological products, submission of a BLA that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical studies, as well as information on the chemistry, manufacturing and controls to ensure product identity and quality, and proposed labeling;
- For certain products, development and implementation of a Risk Evaluation and Mitigation Strategy ("REMS");

- Scale-up to commercial manufacturing;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess compliance with current good manufacturing practices ("cGMP"), and, if applicable, the FDA's current good tissue practice;
- Potential FDA inspection of the nonclinical and clinical study sites and the clinical study sponsor that generated the data in support of the NDA or BLA; and
- FDA review and approval or licensure of an NDA or of the BLA.

Prior to beginning the first clinical trial with a product candidate, the sponsor must submit an IND to the FDA and the IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises safety concerns or questions about the proposed clinical trial and places the IND on clinical hold within that 30-day time period. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds. Similarly, an independent institutional review board ("IRB") can suspend or terminate approval of a clinical trial at its site if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined. Phase 1 studies are designed to assess safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. If favorable, Phase 2 studies are initiated to evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage and dosing schedule, as well as identify any adverse effects that could limit the product's usefulness. If data from the Phase 2 trials are favorable, large-scale Phase 3 trials are undertaken to confirm the product's efficacy and safety.

During all phases of clinical development, FDA and others require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators, and certain progress and safety reports must be submitted to the FDA. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all.

Assuming successful completion of all required testing in accordance with regulatory requirements, the submission of an NDA or BLA requesting approval to market the product is subject to a substantial application user fee, which may be reduced or waived if the FDA finds that certain criteria are met, and there are certain exemptions for products designated for rare diseases or conditions. The submission of an NDA or BLA is not a guarantee that the FDA will find it complete and accept it for filing. After the application is deemed filed by the FDA, FDA staff will review an NDA or BLA to determine, among other things, whether a product is safe and efficacious for its proposed conditions of use. There can be no assurance that a product will obtain the regulatory approvals necessary for it to be marketed.

If, after reviewing the NDA or BLA, the FDA determines that the application cannot be approved in its current form, the FDA sends the applicant a complete response letter ("CRL") identifying all outstanding deficiencies that preclude final approval. The FDA then halts its review until the applicant resubmits the NDA or BLA with new information designed to address the deficiencies. An applicant receiving a CRL may resubmit the application with data and information addressing all of the FDA's concerns or requirements set forth in the CRL, withdraw the application without prejudice to a subsequent submission of a related application or request a hearing on whether there are grounds for denying approval of the application. If a product receives regulatory approval, the approval is limited to specific diseases and dosages or the indications for use for which approval had been sought. In addition, the FDA may require an applicant to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market. The agency may also impose requirements that the NDA or BLA holder conduct new studies, make labeling changes, implement a REMS, and take other corrective measures.

The FDA has a number of programs, including fast track, breakthrough therapy, priority review and accelerated approval, intended to expedite the development or review of products that meet certain criteria, and applicants may explore some of these opportunities for their product candidates, if appropriate. These programs do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may

later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Additionally, in the context of public health emergencies, applicants may seek an Emergency Use Authorization ("EUA") from the FDA, which if granted, allows for the distribution and use of unapproved products during the declared public health emergency or to allow a medical countermeasure to be used in an emergency caused by a chemical, biological, radiological and nuclear agent, in accordance with the conditions set forth in the EUA, unless the EUA is otherwise terminated.

NDA User Fee Program

On September 30, 2022, President Biden signed into law the FDA User Fee Reauthorization Act of 2022, which includes the reauthorization of the Prescription Drug User Fee Act ("PDUFA VII") from fiscal year 2023 through 2027. The program provides for the continued timely review of new NDAs and BLAs. PDUFA VII enhancements include modernizing the user fee structure, a focus on human resource and financial management improvement including a significant increase in staff capacity and capabilities to support the review of cell and gene therapy products; the creation of capacity planning capability; enhancing use of regulatory tools via benefit-risk, patient-focused drug development, complex innovative trial designs, and model informed drug development; enhancing staffing for breakthrough therapy reviews; focusing on communication with industry; and exploring real world evidence in regulatory decision-making.

Biosimilar and Interchangeable Biologics License Application

A biosimilar product is a biologic product that is highly similar to an existing FDA-approved biological product (which is referred to as the "reference product") and has no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. The FDA approves biosimilars through an abbreviated review process, with the goal of demonstrating biosimilarity between the proposed biosimilar and its reference product. Ultimately, the process entails less expensive and fewer clinical trials than a "full" BLA.

Biosimilar license application submissions typically included analytical studies that provide comparative analytical data to demonstrate the structural and functional similarity of the proposed biosimilar product to the reference product and evaluate the impact of any differences identified. The application must also include an assessment of toxicity and a clinical study or studies sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and for which licensure is sought for the proposed biological product. Pharmacology studies may demonstrate that the proposed biosimilar is processed by the human body in the same way and with the same effects as the reference product. The application may also include an immunogenicity assessment, which evaluates a patient's immune response to the proposed biosimilar. An applicant may need to conduct additional comparative clinical studies to demonstrate whether there are any clinically meaningful differences between the proposed biosimilar and the reference product.

An interchangeable biosimilar is a biosimilar that may be substituted for the reference product without the intervention of the prescribing health care provider that prescribed the reference product, depending on state pharmacy laws. In addition to establishing biosimilarity to the reference product per the process described above, a manufacturer of an interchangeable biosimilar must also submit information to the FDA to show that the proposed interchangeable product can be expected to produce the same clinical result as the reference product in any given patient. If the biological product is to be administered more than once to an individual, then the manufacturer in certain circumstances also submits information in the application that demonstrates the risk in terms of safety or diminished efficacy of alternating between the biological product and the reference product is not greater than the risk of using the reference product without switching. All biosimilars are approved only after they meet the FDA's rigorous approval standards.

Biosimilar User Fee Program

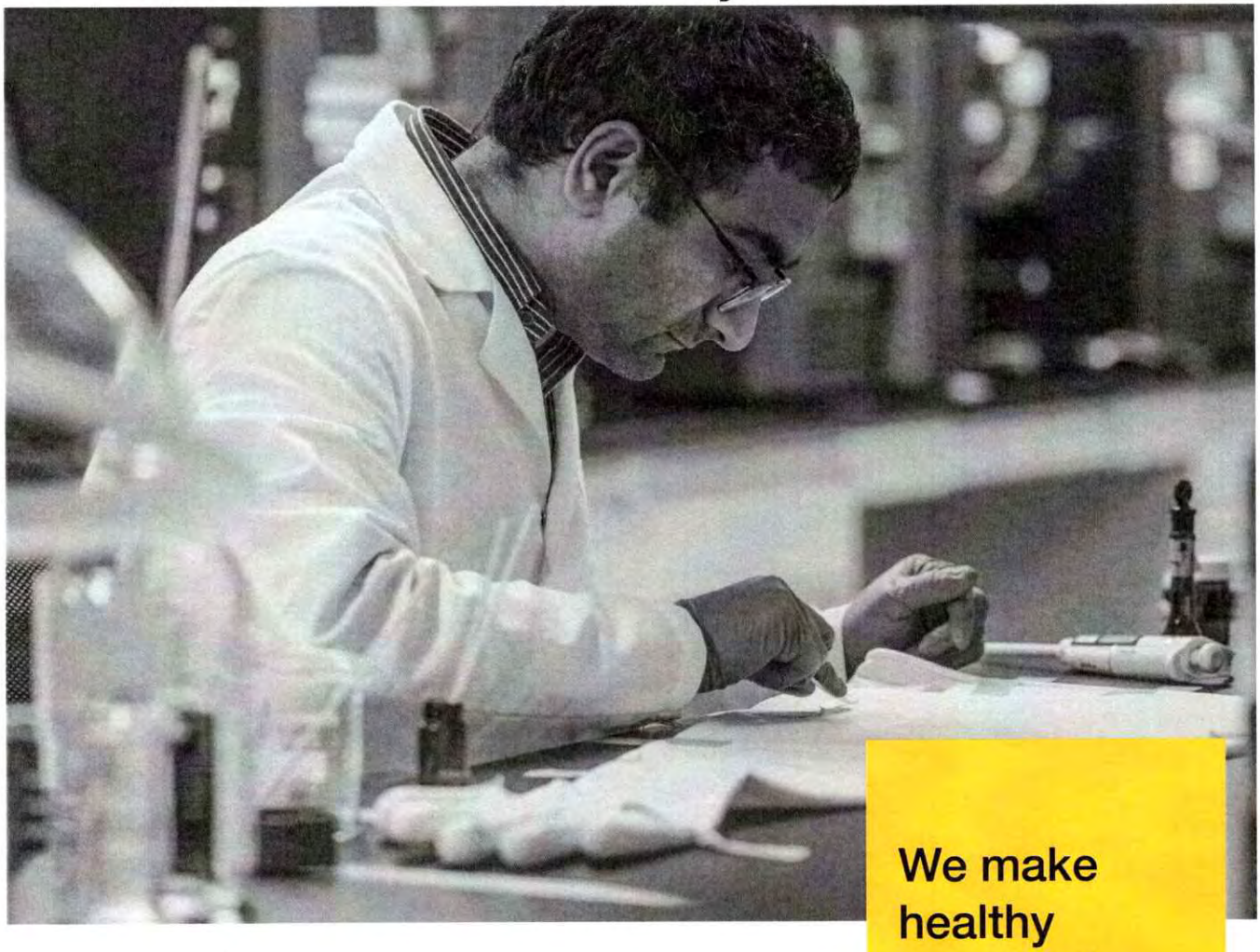
The Biosimilar User Fee Act was reauthorized for the second time on September 30, 2022 ("BsUFA III"). In the reauthorization of BsUFA III, enhancements include new supplement types and expedited review timelines; enhancing communication and feedback during the biosimilar biological development process; enhancing pre-licensure inspection communication; introducing a new pilot program to enhance regulatory decision-making and facilitate science-based recommendation; and enhancing financial management, transparency, and strategic hiring.

Abbreviated New Drug Application

For a generic version of an approved drug product approved under an NDA, an ANDA relies on the FDA's previous finding of safety and effectiveness for a reference listed drug ("RLD") and, as a result, may be approved without submission of the same

Amneal Pharmaceuticals, Inc.

Notice of 2025 Annual Meeting of Stockholders and Proxy Statement



amneal

Amneal.com

amneal

We make healthy possible.

Notice of 2025 Annual Meeting of Stockholders and Proxy Statement

You are cordially invited to attend the Amneal Pharmaceuticals, Inc. 2025 Annual Meeting of Stockholders.

TUESDAY, MAY 6, 2025

9:00 a.m., Eastern Daylight Time

Virtual Meeting at www.virtualshareholdermeeting.com/AMRX2025

Items to be Voted On

1. Elect as directors the 11 nominees named in the accompanying proxy statement;
2. Approve the compensation of our named executive officers on an advisory basis;
3. Conduct an advisory vote on the frequency of future "say on pay" votes;
4. Ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for fiscal year 2025; and
5. Transact such other business as may properly come before the annual meeting or any adjournment or postponement of the meeting.

Record Date

You are eligible to vote if you were a stockholder of record at the close of business on March 14, 2025. A list of stockholders of record will be made available to stockholders during the meeting at www.virtualshareholdermeeting.com/AMRX2025 when you enter your 16-Digit Control Number.

Voting

Your vote is important, and you are invited to attend the annual meeting. Whether or not you expect to attend the annual meeting, we encourage you to vote as soon as possible. To ensure your shares are voted, you may vote your shares in advance of the meeting over the internet, by telephone or, if you requested to receive printed proxy materials, by mailing a proxy or voting instruction card. Voting over the internet, by telephone or by mail will ensure your representation at the annual meeting regardless of whether you attend the meeting.

Virtual Annual Meeting

We are once again hosting a virtual meeting this year. The live audio webcast will be available at www.virtualshareholdermeeting.com/AMRX2025.

This proxy statement and the related materials are first being distributed or made available to stockholders on or about March 25, 2025.

By Order of the Board of Directors,

Jason B. Daly

Executive Vice President, Chief Legal Officer & Corporate Secretary

Bridgewater, New Jersey
March 25, 2025

Review your proxy statement and vote in advance of the meeting in one of three ways:



INTERNET
Visit the website on your proxy card



BY TELEPHONE
Call the telephone number on your proxy card



BY MAIL
Sign, date and return your proxy card in the enclosed envelope

Please refer to the enclosed proxy materials or the information forwarded by your bank, broker or other holder of record to see which voting methods are available to you.

Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting of Stockholders to be held on May 6, 2025:

The notice of annual meeting, this proxy statement and our annual report on Form 10-K for the fiscal year ended December 31, 2024 are available at www.proxyvote.com.

amneal

We make healthy possible.

To Our Fellow Stockholders, Stakeholders and Colleagues,



Chintu Patel
Co-Founder, Co-Chief Executive Officer, and Director



Chirag Patel
Co-Founder, Co-Chief Executive Officer, President and Director

2024 was an excellent year of strong performance and growth across our business with impactful new launches. Amneal is a diversified and growing biopharmaceutical company across each of our three business segments: Specialty, Affordable Medicines (including Biosimilars, Retail, Injectables, and International) and AvKARE's distribution business. Since our founding in 2002, our mission has centered on improving access to affordable, high-quality, and innovative medicines. We are proud of the impact we had in 2024 as we continue to expand in the most impactful and innovative areas of pharmaceuticals. Looking forward, we are focused on continuing to deliver value for all of our stakeholders.

2024 Highlights

Across Amneal, notable accomplishments in 2024 included:

- U.S. Federal Drug Administration approval and launch of CREXONT® for Parkinson's disease to advance the standard of care for treating patients;
- Signed collaboration with Metsera to develop, manufacture and commercialize new weight loss and obesity medicines globally;
- Continued uptake of our first three biosimilars (ALYMSYS®, RELEUKO® and FYLNETRA®) and added three more programs (2 denosumab and omalizumab) to our biosimilar pipeline;
- Launched over ten new injectable products, including our first three ready-to-use 505(b)(2) injectables, which eliminate medication preparation steps for hospitals and institutions;
- Drove double-digit revenue growth in our Affordable Medicines segment, driven by complex products and new launches;
- Delivered double-digit revenue growth in our Specialty segment, driven by RYTARY®, UNITHROID®, ONGENTYS® and CREXONT®, while advancing our pipeline, including a DHE autoinjector; and
- Drove continued, strong double-digit revenue growth in our durable AvKARE segment driven by impactful new launches in the U.S.

These achievements contributed to strong 2024 financial performance, highlighted by 17% revenue growth. Since 2019, the Company has driven top-line growth each year, which reflects the diversity of the portfolio and durability of the business. Driven by consistent revenue growth and cash generation, the Company's balance sheet as of fiscal year-end is strong. During 2024, we paid down $182 million in debt and reduced net leverage to our lowest levels yet.

Making Healthy Possible and Accessible for All

At Amneal, we believe that our Company's mission of providing access to high-quality and innovative medicines is about building healthy communities and a healthy planet. We have a deep commitment to safeguarding the environment and serving humanity to ensure that we are building a resilient business well into the future.

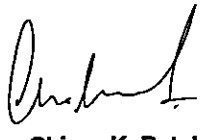
We bring this vision to life in part through our belonging and inclusion programming that nurtures the best and brightest in global talent. We are deepening our portfolio of innovative products to help address unmet therapeutic needs. We are directing our R&D expertise to create new complex products that help improve patient access. We continuously optimize our manufacturing operations to reduce our emissions. We contribute to stronger health outcomes across our local communities through our partnerships, corporate philanthropy and volunteerism.

We invite you to read Amneal Pharmaceuticals' "*At a Glance*," which describes what we do and how we improve access to medications for patients around the world. We encourage you to read the pages of this proxy statement and we welcome your continued support as "We make healthy possible" together.

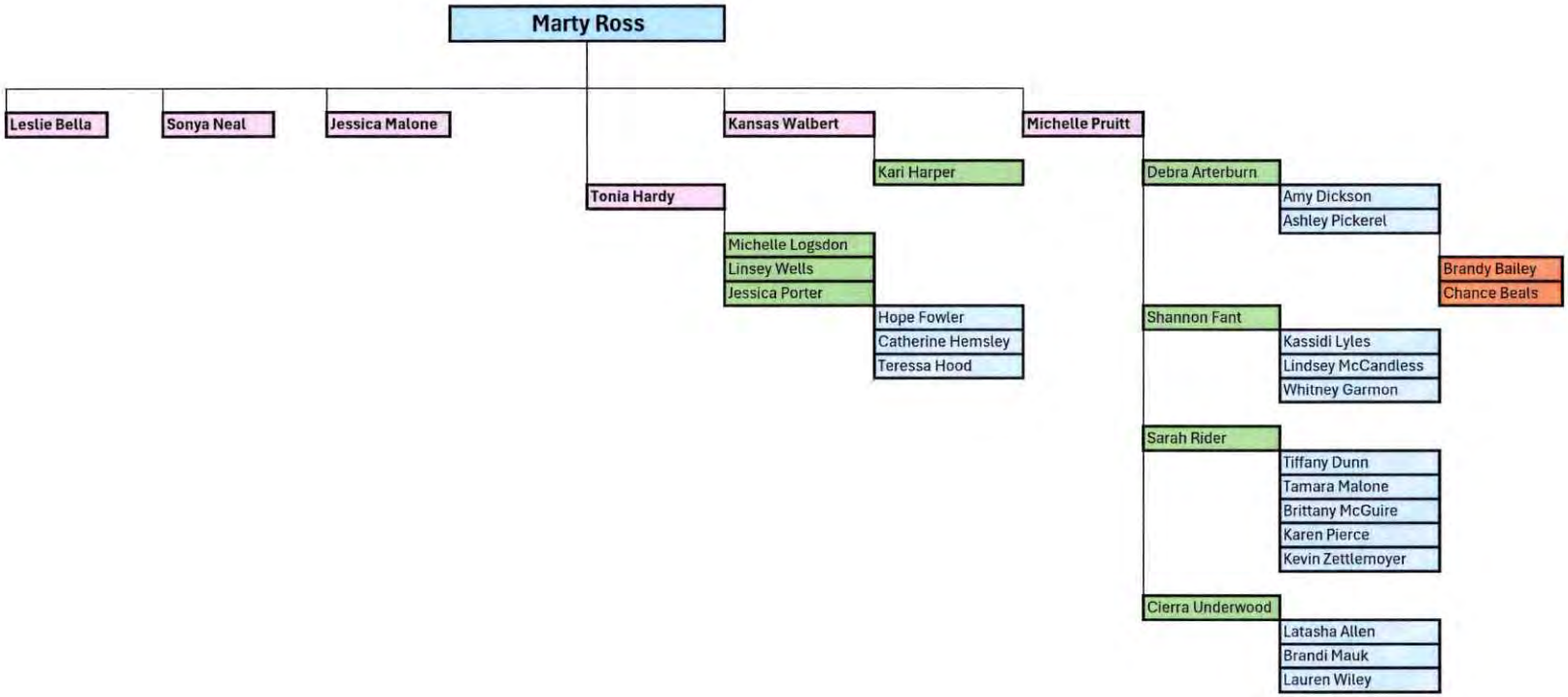
Sincerely,



Chintu Patel
Co-Founder, Co-CEO and Director



Chirag K. Patel
Co-Founder, Co-CEO, President and Director
March 25, 2025


Marty Ross
Leslie Bella
Sonya Neal
Jessica Malone
Kansas Walbert
Kari Harper
Tonia Hardy
Michelle Logsdon
Linsey Wells
Jessica Porter
Hope Fowler
Catherine Hemsley
Teressa Hood
Michelle Pruitt
Debra Arterburn
Amy Dickson
Ashley Pickerel
Brandy Bailey
Chance Beals
Shannon Fant
Kassidi Lyles
Lindsey McCandless
Whitney Garmon
Sarah Rider
Tiffany Dunn
Tamara Malone
Brittany McGuire
Karen Pierce
Kevin Zettlemoyer
Cierra Underwood
Latasha Allen
Brandi Mauk
Lauren Wiley

4E

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: CooperSurgical, Inc. (a wholly owned subsidiary of the Cooper Companies, Inc., a publicly traded company)

Physical Address: 15100 Heritage Parkway

City: Fort Worth State: TX Zip: 76177

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (337) 212-5695 Website: _____

Name of Designated Representative (DR): Andre Lamont Anderson, Sr

Licensing Company Email: _____ DR Email: andre.anderson@coopersurgical.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Distributors		■ Others: Medical Device Distribution Center

CooperSurgical, Inc. is a wholly owned subsidiary of Cooper Companies, Inc. [Nasdaq: COO] and Cooper Companies, Inc. has no individual shareholders with at least 10% interest. The only entity with more than a 10% stake in Cooper Companies is Vanguard Group, Inc., with a reported ownership interest of 11.92%

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: The applicant facility does not sell, dispense, or distribute pharmaceutical products of any kind.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation The date of SEC registration, SEC registration number, and stock exchange symbol provided is for the publicly traded parent company, Cooper Companies, Inc. [Nasdaq: COO].

State of Incorporation: Delaware

Parent Company (if any): The Cooper Companies, Inc.

Corporation Name: CooperSurgical, Inc. (A wholly owned subsidiary of The Cooper Companies, Inc., a publicly traded corporation)

Mailing Address: 95 Corporate Dr.

City: Trumbull State: CT Zip: 06611

Telephone: (716) 930-3662 Email: Thomas.mehs@coopersurgical.com

Contact Person Name: Thomas Mehs

Date of SEC Registration: 11/20/1990 | SEC Registration Number: 001-08597 | Stock Exchange Symbol: COO

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

CooperSurgical, Inc.

Facility Name

Thomas Mehs

Print Name of Authorized Person Submitting Application

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

7/6/2025

Date

Board Use Only	Date Received: 7/10/25	Amount: $1000.00

Establishment Registration & Device Listing

Establishment:
COOPERSURGICAL, INC.
Business Trade Names:
(1) Ackrad Laboratories, Prism Healthcare, Milex, (2) Origio (3) SAGE In-Vitro Fertilization, Medscand (4) Wallach Surgical Devices, And Lone Star Medical Products

95 CORPORATE DRIVE
Trumbull, CT 06611
Registration Number: 1216677
FEI Number*: 1216677
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
COOPERSURGICAL, INC.
95 CORPORATE DR.
Trumbull, CT US 06611
Owner/Operator Number: 9002384

Official Correspondent:
Mauro Castro
95 CORPORATE DR.
Trumbull, CT 06611
Phone: 203-6120854

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 05/12/2025
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Corporate Directors and Officers List

Board Positions

Name	Position	Appointed
Andrews, Brian George	Director	05/01/2018
Ricupati, Agostino	Director	09/30/2017
Sheffield, Holly	Director	10/01/2020

Officers

Name	Position	Appointed
Andrews, Brian George	Executive Vice President	12/09/2022
	Treasurer	07/31/2018
Avery, Aloma	Secretary	02/23/2024
Avva, Ravikant	Vice President, Global Commercial Operations	12/09/2022
Bacher, Peter	Vice President, Key Accounts & Strategic Alliances	12/09/2022
Blair, Kerry Lee	Chief Operating Officer	07/31/2018
Coward, Mark	Vice President, Equipment Service & Installation	12/09/2022
Desai, Vrunda	Vice President, Medical Affairs	12/09/2022
Donnelly, Matthew	Senior Vice President, Global Sales & Marketing, Medical Device Business	12/09/2022
Fawcett, Lisa	Executive Vice President, Strategy & Market Insights	12/09/2022
Gates, Jennifer	Vice President, Sales & Marketing CBU	12/09/2022
Gelnett, Marc	EVP, Operations / Senior Vice President, Medical Device Operations & Innovation	12/09/2022
Grant, Willie	Vice President, Global Human Resources (CooperSurgical)	12/09/2022
Hemstad, Jonathan	Vice President, R&D Product Engineering	12/09/2022
Ivosevic, Milan	Vice President, R&D	12/09/2022
Jow, Aza Mikko	Assistant Treasurer	05/31/2020
Karlsson, Kristofer	Executive Vice President, Global Fertility Solutions	05/16/2024
Kennedy, Charles	Vice President, Global Professional Education, Training & Development	12/09/2022
Khadder, Nicholas S.	General Counsel	12/09/2022
	Vice President	12/09/2022
Kim, James	Vice President, Tax	12/09/2022
Large, Michael	Vice President, Donor Gamete Services	12/09/2022
Ricupati, Agostino	Senior Vice President	12/09/2022
Schopp, Marc	Vice President, Distribution & Logistics	12/09/2022
Shaffer, Kim	Assistant General Counsel	12/09/2022
	Vice President	12/09/2022
Sheffield, Holly	President	10/01/2020
Shih, Regina	Vice President, Global Regulatory Affairs	12/09/2022
Sliva, Jennifer	Vice President, Global FP&A	12/09/2022
Smith, Charles	Senior Vice President, RA/QA and Life Sciences	12/09/2022
Stark, Wendy L	Assistant Secretary	03/25/1997
Steklenski, Colin	Vice President, Supply Chain	12/09/2022
Stewart, Richard	Vice President, IT Infrastructure, Operations & Security	12/09/2022
Topliff, Matthew	Divisional Chief Financial Officer (CooperSurgical)	04/18/2024
Towne, Mark	Vice President, Business Applications	12/09/2022
Valentine, Mark	Chief Commercial Officer	12/09/2022

Top Four Corporation Shareholders and Their Percent Ownership:

CooperSurgical, Inc., is a wholly owned subsidiary of the Cooper Companies, Inc. The Cooper Companies, Inc., is a publicly traded corporation. The top four corporation shareholders of the Cooper Companies, Inc., are institutional holders:

- Vanguard Group, Inc.
  Ownership Interest: 11.92%

- Blackrock, Inc.
  Ownership Interest: 7.65%

- State Street Corporation
  Ownership Interest: 4.34%

- Kanye Anderson Rudnick Investment Management LLC
  Ownership Interest: 4.04%

Delaware

The First State

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

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "THE COOPER COMPANIES, INC." WAS INCORPORATED ON THE FOURTH DAY OF MARCH, A.D. 1980.

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

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

888132 8300

SR# 20251099265

Authentication: 203192399

Date: 03-17-25

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

TEXAS
Health and Human Services

Texas Department of State Health Services

Jennifer A. Shuford, M.D., M.P.H.
Commissioner

May 2, 2025

Thomas Mehs
Cooper Surgical
Thomas.Mehs@coopersurgical.com

CFN: 2124203
Lic.: 1003649
Type: 2503
File: 9136

Re: License Verification

Dear Thomas Mehs:

This letter shall serve as a verification of licensure for the following firm:
COOPERSURGICAL
15100 HERITAGE PKWY
FORT WORTH, TX 76177

License No.	1003649
Type of license:	Device Distributor
Status of license:	Current
Date license issued:	03/28/2025
Date license expires:	02/16/2027
Disciplinary action:	None

The firm is in good standing as of the date of this letter.

If you have questions or need additional information, please contact me at 512-834-4503, via fax at (512) 834-6759, or email me at Justin.Arnold@dshs.texas.gov.

Sincerely,

Justin Arnold, MBA, RS
Medical Research Specialist
Drugs and Medical Devices Unit
Consumer Protection Division

Mailing address:
Justin Arnold
Drugs and Medical Devices Unit, MC 1987
PO Box 149347
Austin, TX 78714-9347

License Number: 1003649 *Current Date: 04/15/2025 03:17 PM*

Name:	**COOPER SURGICAL INC**
License Type:	**Dev Distributor**
License Status:	**Current**
Expiry Date:	**02/16/2027**
Effective Rank Date:	**03/28/2025**
Modifier(s):	**Distributor**
	Initial Distributor (Importer)
	Own Label Distributor
	Class 1
	Class 2
	Class 3
	Implantable
	In-Vitro Diagnostic
	Sterile-Packaged

Addresses

Physical Loc	Address	COOPERSURGICAL 15100 HERITAGE PKWY FORT WORTH , TX TARRANT 76177 US
Mailing Address	Address	COOPERSURGICAL FORT WORTH , TX TARRANT 76177 US

Food & Drug Owner

Licensee's Role:	**Food & Drug License**
Related Party Role:	**Food & Drug Owner**

Related Party Name	**License**	**Address**
COOPER SURGICAL INC	**Owner #** Status: Current Expiration Date:	TRUMBULL , CT OUT OF STATE/UNKNOWN 06611 US

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/21/2024

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

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

PRODUCER Woodruff-Sawyer & Co. 50 California Street, Floor 12 San Francisco, CA 94111 License#: 0329598	CONTACT NAME: WS Certificates PHONE (A/C, No, Ext): 844-972-6326 FAX (A/C, No): E-MAIL ADDRESS: certificates@woodruffsawyer.com
INSURED Cooper Companies CooperVision Inc. and CooperSurgical Inc. 6101 Bollinger Canyon Road Suite 500 San Ramon, CA 94583	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Chubb Custom Insurance Company — 38989 INSURER B : Illinois Union Insurance Company — 27960 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 342259765 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			99510892	8/1/2024	8/1/2025	EACH OCCURRENCE	$ 5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 5,000,000
							MED EXP (Any one person)	$ 25,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 5,000,000
	☐ POLICY ☒ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ Excluded
	☐ OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						☐ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
B	Products/Completed Operations			G47480899001	8/1/2024	8/1/2025	Each Occ / Agg	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
General Liability Retro-Active Date: 01/01/1986
Products/Completed Operations Retro-Active Date: 01/01/1986.
Re: Coverage is worldwide including Serbia.

CERTIFICATE HOLDER

To Whom It May Concern
CooperVision Inc. and CooperSurgical Inc.
6101 Bollinger Canyon Road, Suite 500
San Ramon, CA 94583

CANCELLATION

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

AUTHORIZED REPRESENTATIVE
Zoe Overbeay

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CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/21/2024

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

PRODUCER Woodruff-Sawyer & Co. 50 California Street, Floor 12 San Francisco, CA 94111 License#: 0329598	**CONTACT NAME:** WS Certificates **PHONE (A/C, No, Ext):** 844-972-6326 **FAX (A/C, No):** **E-MAIL ADDRESS:** certificates@woodruffsawyer.com
INSURED Cooper Companies CooperVision Inc. and CooperSurgical Inc. 6101 Bollinger Canyon Road Suite 500 San Ramon, CA 94583	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Chubb Custom Insurance Company — 38989 **INSURER B :** Illinois Union Insurance Company — 27960 **INSURER C :** **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** 342259765 **REVISION NUMBER:**

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INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			99510892	8/1/2024	8/1/2025	EACH OCCURRENCE	$ 5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 5,000,000
							MED EXP (Any one person)	$ 25,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 5,000,000
	☐ POLICY ☒ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ Excluded
	☐ OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						☐ PER STATUTE ☐ OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ N / A						E.L. EACH ACCIDENT	$
	(Mandatory in NH)						E.L. DISEASE - EA EMPLOYEE	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - POLICY LIMIT	$
B	Products/Completed Operations			G47480899001	8/1/2024	8/1/2025	Each Occ / Agg	$5,000,000

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

General Liability Retro-Active Date: 01/01/1986
Products/Completed Operations Retro-Active Date: 01/01/1986.
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CERTIFICATE HOLDER

To Whom It May Concern
CooperVision Inc. and CooperSurgical Inc.
6101 Bollinger Canyon Road, Suite 500
San Ramon, CA 94583

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Zoe Overbay

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DESIGNATED REPRESENTATIVE

NOTE: In addition to completing this section, you must submit two completed fingerprint cards for the DR; see the information below and the checklist at the end of this application for additional information.

Full Legal Name: Andre Lamont Anderson, Sr
First *Middle* *Last*

SSN: [redacted] **Date of Birth:** [redacted] **Gender:** ■ Male ☐ Female

List at least three years of experience in the manufacture or distribution of prescription drugs/devices

Employer Name: _____ **Dates Employed:** _____

Employer Name: _____ **Dates Employed:** _____

Employer Name: _____ **Dates Employed:** _____

By signing below, I authorize all persons, organizations, governmental agencies, or any others not specifically listed, which are set forth directly or by reference in this application, to release to the Division of Occupational and Professional Licensing, State of Utah, any files, records, or information of any type reasonably required for the Division to properly evaluate my qualifications for licensure/certification/registration by the State of Utah.

Criminal History Disclosure

Fingerprints submitted with this application are used to complete a search through the files of the Utah Bureau of Criminal Identification (BCI) and the Federal Bureau of Investigations (FBI). Prior to submitting fingerprints, you must read and acknowledge, by signing the affidavit below, the Privacy Act Statement found at: https://www.fbi.gov/services/cjis/compact-council/privacy-act-statement. Physical copies of this statement may also be obtained upon request from the Division.

The criminal record information obtained by this search will be used by Division staff to evaluate your ability to obtain licensure in Utah. You may challenge or review your criminal record. For additional information regarding the challenge or review process, please see below.

By signing below, you acknowledge receipt of this information and consent to the background check process described above.

Signature of DR: _____

Printed Name: Andre Lamont Anderson, Sr Date: 16 April 2025

Pharmacy Name: _____

Pharmacy Address: _____
Street/PO Box *City* *State/Zip*

Please see our website, www.dopl.utah.gov/fingerprints.html, for required information and approved locations to obtain fingerprints.

REVIEW OF YOUR CRIMINAL RECORD: If you wish to review or challenge the accuracy of the information in your FBI record, you should contact the agency that contributed the information in question. You may also direct the challenge to the FBI. Please see their website at: https://www.fbi.gov/services/cjis/identity-history-summary-checks. You may also contact them via mail at: FBI: CJIS Division, Attn. Criminal History Analysis Team 1, 1000 Custer Hollow Road, Clarksburg, WV 26306. The FBI will forward the challenge to the respective agency.

If you wish to review or challenge the accuracy of the information in your BCI record, you must complete the required "Record Challenge Form", available at: https://bci.utah.gov/criminal-records/criminal-records-forms/, and submit it directly to BCI.

Agency review of a licensing decision based on your criminal record may be obtained by filing a written request for agency review with the Executive Director of the Department of Commerce within thirty (30) days after notification of the decision. Any such request must comply with the requirements of Utah Code § 63G-4-301 and Utah Admin. Code R151-4-902.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG CooperSurgical, Inc. MDEG License # (if applicable) _____

Physical Address 15100 Heritage Parkway

City Fort Worth State TX Zip 76177

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (716) 930-3662 Website _____

Licensing Company Email Thomas.mehs@coopersurgical.com

Section 2: Personal Information

First Andre Middle Lamont Last Anderson

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

Date of Birth [redacted] SS# or ITIN 466-75-8938 Sex ☑ M ☐ F ☐ ..

Mailing Address [redacted]

City Hickory Creek State TX Zip [redacted]

Telephone [redacted] Email andre.anderson@coopersurgical.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Baker University		[01/09 - 03/09	
Address	City	State	Zip
618 8th St.	Baldwin City	KS	66006
Diploma/Degree obtained, if any			
Associates of Applied Science Degree: Computer Technology			

School Name		From - To (MM/YY – MM/YY)	
Houston Community College System		[08/02 - 04/03	
Address	City	State	Zip
8001 Fulton St.	Houston	TX	77022
Diploma/Degree obtained, if any			
Associates of Applied Science Degree: Fire Fighting Technology			

School Name		From - To (MM/YY – MM/YY)	
Dillard University		[07/95 - 06/99	
Address	City	State	Zip
2601 Gentilly Blvd.	New Orleans	LA	70122
Diploma/Degree obtained, if any			
Bachelor of Arts Degree: Radio, and TV Communications			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/23-PRESENT	[redacted]	[redacted]	TX	[redacted]
04/21- 06/23			AZ	
02/20 -04/21			TX	
08/18-02/20			TX	
07/15 - 08/18			LA	
02/12 - 07/15			TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
CooperSurgical, Inc.			10/24 - Present	
Business Address		**City**	**State**	**Zip**
15100 Heritage Parkway		Fort Worth	TX	76177
Phone	**Title**		**Number of Employed Hours**	
(337) 212-5695	Senior Manager - Finished Goods Distribution		40 (4056)	

Description of Duties

Responsible for the day to day operations of the Distribution Center

Business Name			From - To (MM/YY – MM/YY)	
Quest Diagnostics			09/18 - 4/21	
Business Address		**City**	**State**	**Zip**
4770 REGENT BLVD		IRVING	TX	75063
Phone	**Title**		**Number of Employed Hours**	
972-916-3200	LOGISTICS DISTRIBUTION SUPERVISOR		40 (22,704)	

Description of Duties

Overseeing the day to day departmental operations, including distribution and recovery of medical instruments

Business Name			From - To (MM/YY – MM/YY)	
Clinical Pathology			02/17 - 9/18	
Business Address		**City**	**State**	**Zip**
4555 EXCEL PARKWAY		ADDISON	TX	75001
Phone	**Title**		**Number of Employed Hours**	
469-374-2300	Logistics, Warehouse, and Fleet Manager		40 (13824)	

Description of Duties

Responsible for the day to day operations of the logistics, warehouse distribution and fleet of SW region

Business Name			From - To (MM/YY – MM/YY)	
US Army				
Business Address		**City**	**State**	**Zip**
Ellington Field		Houston	TX	77034
Phone	**Title**		**Number of Employed Hours**	
512-782-8000	NCOIC - Flight medic (68W)		1990 - 2019	

Description of Duties

Senior Non-Commission Officer over a Army Medical unit, that was tasked to oversee the health of Texas Soldiers.

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

Provide explanation below:

N / A

Original Signature (electronic, copies or stamps not accepted)

2 July 2025
Date

I, Andre Lamont Anderson, Sr, **certify that as the MDEG Administrator for**

CooperSurgical, Inc.,

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

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

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

Andre Lamont Anderson, Sr
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2 July 2025
Date

Board Use Only	Date Received: _____

Employee or Req

Adolfo Esquivel

Adriana Hunt

Andre Anderson

Annick Butoke

Arthur Williams

Benjamin Williams

Britney Harden

Calvin Truman

Cameron Johnson

Cameron Oakes

Carla Dickerson

Chunyan Lisa Piao

Clarence Guyton

Clif Roy

Dakari Brinkley

Daniel Alaniz

David Hart

David McDonald

Dayquan Ellzy

Denise Sutherland

Deshawn Brothers

Diabri Hollis

Don Nguyen

Frank Castillo

Hena'Jhia Jackson

JaLicya Bacy

Jim Stephèns

Jose Fernandez

Justyce Gray

Karlo Cordova

Kenneth Neal

Lila Landis

Lonnie Yates

Luis Rodriguez

Margaret Aguilar

Mari Holmes

Marnisha Partridge

Matthew Willey

Mauricio Mora Lopera

Mervin Forbes

Naya Mitchell

Paige Malson

Patrick West

Brenden Doby

Jahier High

Quannezz Sandlin

Ricardo Nava

Rudy (Anthony) Alvarado

Saif Farooqi

Samuel Adams

Sandeep Paudel

Serena Tate

Shatwanna (Shaye) Warren

Stephen Moore

Tammy Romandia

Teimyuis Brown

Thierry Mulunda Mutambayi

Tiffani Wilson

Tommy Garcia

Veronica Benton

Viviana Cedillo

VonToya Knight

Whitney Atkinson

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED OCTOBER 31, 2024

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NO. 001-08597

THE COOPER COMPANIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	94-2657368
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

6101 Bollinger Canyon Road,
Suite 500
San Ramon, California, 94583
(Address of principal executive offices) (Zip Code)

(925) 460-3600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.10 par value	COO	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☒ No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.
Yes ☐ No ☒
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
Emerging growth company ☐
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.
Yes ☒ No ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 30, 2024, the last business day of registrant's most recently completed second fiscal quarter, the aggregate market value of shares of the registrant's common stock held by non-affiliates was $17.6 billion.

Number of shares outstanding of the registrant's common stock, as of November 29, 2024: 199,582,626. The number of shares outstanding as of November 29, 2024, reflects the four-for-one stock split of the registrant's common stock that was effected on February 16, 2024.

Documents Incorporated by Reference:

Document	Part of Form 10-K
Portions of the Proxy Statement for the Annual Meeting of Stockholders scheduled to be held in April 2025	Part III

Our independent registered public accounting firm is KPMG LLP, San Francisco, CA, Auditor ID: 185.

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

Annual Report on Form 10-K
for the Fiscal Year Ended October 31, 2024

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These include statements relating to plans, prospects, goals, strategies, future actions, events or performance and other statements which are other than statements of historical fact, including: statements regarding the expected impact of global macroeconomic conditions, and statements regarding acquisitions (including the acquired companies' financial position, market position, product development and business strategy, expected cost synergies, expected timing and benefits of the transaction, difficulties in integrating entities or operations, as well as estimates of our and the acquired entities' future expenses, sales and earnings per share) that are forward-looking. In addition, all statements regarding anticipated growth in our net sales, anticipated effects of any product recalls, anticipated market conditions, planned product launches, restructuring or business transition expectations, regulatory plans, and expected results of operations and integration of any acquisition are forward-looking. To identify these statements, look for words like "believes," "outlook," "probable," "expects," "may," "will," "should," "could," "seeks," "intends," "plans," "estimates" or "anticipates" and similar words or phrases. Forward-looking statements necessarily depend on assumptions, data or methods that may be incorrect or imprecise and are subject to risks and uncertainties. Among the factors that could cause our actual results and future actions to differ materially from those described in forward-looking statements are those described in our Securities and Exchange Commission filings, including the "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections in this Annual Report on Form 10-K for the fiscal year ended October 31, 2024, as such Risk Factors may be updated in quarterly filings.

We caution investors that forward-looking statements reflect our analysis only on their stated date. We disclaim any intent to update them except as required by law.

Summary Risk Factors

Our business faces significant risks. In addition to the summary below, you should carefully review the "Risk Factors" section of this Annual Report on Form 10-K. We may be subject to additional risks and uncertainties not presently known to us or that we currently deem immaterial. Our business, financial condition and results of operations could be materially adversely affected by any of these risks, and the trading prices of our common stock could decline by virtue of these risks. These risks should be read in conjunction with the other information in this report. Some of the more significant risks relating to our business include:

- Adverse changes in the global or regional general business, political and economic conditions, including the impact of continuing uncertainty and instability of certain countries, man-made or natural disasters and pandemic conditions, that could adversely affect our global markets, and the potential adverse economic impact and related uncertainty caused by these items.
- The impact of international conflicts and the global response to international conflicts on the global and local economy, financial markets, energy markets, currency rates and our ability to supply product to, or through, affected countries.
- Our substantial and expanding international operations and the challenges of managing an organization spread throughout multiple countries and complying with a variety of legal, compliance and regulatory requirements.
- Foreign currency exchange rate and interest rate fluctuations including the risk of fluctuations in the value of foreign currencies or interest rates that would decrease our net sales and earnings.
- Our existing and future variable rate indebtedness and associated interest expense is impacted by rate increases, which could adversely affect our financial health or limit our ability to borrow additional funds.
- Changes in tax laws, examinations by tax authorities, and changes in our geographic composition of income.
- Acquisition-related adverse effects including the failure to successfully achieve the anticipated net sales, margins and earnings benefits of acquisitions, integration delays or costs and the requirement to record significant adjustments to the preliminary fair value of assets acquired and liabilities assumed within the measurement period, required regulatory approvals for an acquisition not being obtained or being delayed or subject to conditions that are not anticipated, adverse impacts of changes to accounting controls and reporting procedures, contingent liabilities or indemnification obligations, increased leverage and lack of access to available financing (including financing for the acquisition or refinancing of debt owed by us on a timely basis and on reasonable terms).
- Compliance costs and potential liability in connection with U.S. and foreign laws and health care regulations pertaining to privacy and security of personal information, such as Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the California Consumer Privacy Act (CCPA) in the U.S. and the General Data Protection Regulation (GDPR) requirements in Europe, including but not limited to those resulting from data security breaches.
- A major disruption in the operations of our manufacturing, accounting and financial reporting, research and development, distribution facilities or raw material supply chain due to challenges associated with integration of acquisitions, man-made or natural disasters, pandemic conditions, cybersecurity incidents or other causes.
- A major disruption in the operations of our manufacturing, accounting and financial reporting, research and development or distribution facilities due to the failure to perform by third-party vendors, including cloud computing providers or other technological problems, including any related to our information systems maintenance, enhancements or new system deployments, integrations or upgrades.
- A successful cybersecurity attack which could interrupt or disrupt our information technology systems, or those of our third-party service providers, or cause the loss of confidential or protected data.
- Market consolidation of large customers globally through mergers or acquisitions resulting in a larger proportion or concentration of our business being derived from fewer customers.
- Disruptions in supplies of raw materials, particularly components used to manufacture our silicone hydrogel lenses.
- New U.S. and foreign government laws and regulations, and changes in existing laws, regulations and enforcement guidance, which affect areas of our operations including, but not limited to, those affecting the health care industry, including the contact lens industry specifically and the medical device or pharmaceutical industries generally, including but not limited to the EU Medical Devices Regulation (MDR) and the EU In Vitro Diagnostic Medical Devices Regulation (IVDR).
- Legal costs, insurance expenses, settlement costs and the risk of an adverse decision, prohibitive injunction or settlement related to product liability, patent infringement, contractual disputes, or other litigation.
- Limitations on sales following product introductions due to poor market acceptance.
- New competitors, product innovations or technologies, including but not limited to, technological advances by competitors, new products and patents attained by competitors, and competitors' expansion through acquisitions.
- Reduced sales, loss of customers, reputational harm and costs and expenses, including from claims and litigation related to product recalls and warning letters.
- Failure to receive, or delays in receiving, regulatory approvals or certifications for products.

- Failure of our customers and end users to obtain adequate coverage and reimbursement from third-party payers for our products and services.
- The requirement to provide for a significant liability or to write off, or accelerate depreciation on, a significant asset, including goodwill, other intangible assets and idle manufacturing facilities and equipment.
- The success of our research and development activities and other start-up projects.
- Dilution to earnings per share from acquisitions or issuing stock.
- Impact and costs incurred from changes in accounting standards and policies.
- Risks related to environmental laws and requirements applicable to our facilities, products or manufacturing processes, including evolving regulations regarding the use of hazardous substances or chemicals in our products.
- Risks related to environmental, social and corporate governance (ESG) issues, including those related to regulatory and disclosure requirements, climate change and sustainability.

Item 1. *Business.*

OVERVIEW

The Cooper Companies, Inc. (Cooper, we or the Company), is a global medical device company with a mission to improve lives one person at a time. We partner with health care providers worldwide to improve patient outcomes and deliver practice-building resources and training. By listening closely to the healthcare providers and patients, we fulfill the needs of today while focusing on the opportunities of tomorrow through innovation and strategic investment.

Cooper operates through two business segments, CooperVision and CooperSurgical. Our two business segments elevate standards of care with products and services in the fields of vision, fertility and women's health. For financial information relating to these business segments, refer to Note 12. Business Segment Information in Item 8. Financial Statements and Supplementary Data of this Annual Report.

CooperVision is a global manufacturer providing products for contact lens wearers. CooperVision develops, manufactures and markets a broad range of single-use, two-week and monthly contact lenses, featuring advanced materials and optics. CooperVision designs its products to address vision challenges such as astigmatism, presbyopia and myopia with a broad collection of spherical, toric and multifocal contact lenses. CooperVision offers contact lenses in materials like silicone hydrogel Aquaform technology. CooperVision also manufactures and markets myopia management products, including the internally developed MiSight 1 day lens, as well as other specialty eyecare products such as orthokeratology (ortho-k) and scleral lenses. In November 2019, the MiSight 1 day lens became the first and only product approved by the United States Food and Drug Administration (FDA) for slowing the progression of myopia in children aged 8-12 at the initiation of treatment, and in August 2021, CooperVision received Chinese National Medical Products Administration (NMPA) approval for use of the MiSight 1 day lens in China. CooperVision's major manufacturing and distribution facilities are located in Belgium, Costa Rica, Hungary, Puerto Rico, the United Kingdom and the United States, with other smaller facilities in multiple locations around the world.

CooperSurgical offers a broad array of products and services focused on fertility and women's health. We categorize CooperSurgical product sales based on the point of health care delivery, which includes: products used in medical offices, ambulatory surgery centers and hospitals primarily by women's health providers including Obstetricians/Gynecologists (OB/GYN); and fertility products and services used primarily in fertility clinics. Our portfolio encompasses more than 600 products and services. Our medical devices are used in gynecology and obstetrics, including but not limited to surgical products, contraception and labor and delivery as well as cord blood and cord tissue storage services. Our fertility portfolio encompasses medical devices supporting the in vitro fertilization (IVF) process, egg and sperm donation, cryopreservation, and genomic services (including genetic testing). CooperSurgical has established its market presence and distribution system by developing products and acquiring companies, products and services that complement its business model. CooperSurgical's major manufacturing, cryostorage and distribution facilities are located in Costa Rica, the Netherlands, the United Kingdom and the United States, with other smaller facilities in multiple locations around the world.

SEGMENT INFORMATION

CooperVision

CooperVision competes in the worldwide soft contact lens market and services three primary regions: the Americas, EMEA (Europe, Middle East and Africa) and Asia Pacific. The two major product categories of contact lenses sold by CooperVision are:

- Toric and multifocal lenses, including lenses that, in addition to correcting near- and farsightedness, address more complex visual defects such as astigmatism, myopia and presbyopia by adding optical properties of cylinder and axis, which correct for irregularities in the shape of the cornea; and

- Spherical lenses, including lenses that correct near- and farsightedness uncomplicated by more complex visual defects, myopia management lenses, which slow the progression of and correct myopia in age-appropriate children, and other specialty lenses.

In order to achieve a comfortable and healthier lens wearing experience, products are sold with recommended wearing and replacement schedules, often referred to as modalities, with the primary modalities being single-use lenses designed for one-day use and frequent replacement (FRP) lenses designed for two-week and monthly replacement. CooperVision offers spherical, toric, multifocal and toric multifocal lens products in most modalities and in a wide range of lens parameters.

CooperVision Product Modalities

Frequent replacement lenses

Under the Biofinity brand, CooperVision markets monthly silicone hydrogel spherical (including Biofinity Energys), toric, multifocal and toric multifocal (made-to-order) lens products. Our Biofinity brand is CooperVision's highest grossing product. CooperVision also markets two-week silicone hydrogel spherical and toric lenses under the Avaira Vitality brand.

Single-use lenses

CooperVision markets single-use silicone hydrogel lenses under our MyDay brand and our clariti 1 day brand. The MyDay brand is our softest line of 1-day silicone hydrogel lenses and offers spherical (including MyDay Energys), toric, and multifocal lenses. The clariti 1-day brand is our most affordable line of silicone hydrogel 1-day lenses and offers spherical, toric, and multifocal lenses. CooperVision also offers traditional single-use hydrogel lenses under our Proclear and Biomedics brands.

CooperVision focuses on supporting the growth of all customers including key accounts (which include optical chains, global retailers, certain buying groups and mass merchandisers) by investing in selling, promotional and advertising activities. Further, we are increasing investment in our distribution and packaging capabilities to support the growth of our business and to continue providing quality service with our industry leading stock keeping unit range and customized offerings.

Market for Contact Lenses

The market for spherical lenses is growing with the addition of new value-added products, such as spherical lenses that may provide improved comfort for contact lens related dryness during lens wear and that add aspherical optical properties, more higher oxygen permeable lenses such as silicone hydrogels, and myopia management contact lenses for children aged 8 to 12 years old. CooperVision believes that there are opportunities for contact lenses to gain market share, particularly in markets where the penetration of contact lenses in the vision correction market is low.

We believe that myopia management opens up an attractive new market for contact lenses. With MiSight, we offer the only FDA approved[1] and first Chinese NMPA approved product to slow the progression of, and correct, myopia in age-appropriate children. This is a critical differentiator as the proactive management of myopia becomes standard-of-care within the eye care community to help reduce the progression of myopia in children, along with reducing the risks of long-term eye health problems associated with myopia such as cataracts, retinal detachment, and macular degeneration. We are investing to develop this new market by educating eye care practitioners, patients and their families, which increases awareness.

CooperVision is focused on greater worldwide market penetration of recently introduced products, and we continue to expand our presence in existing and emerging markets, both organically and through acquisitions.

CooperSurgical

CooperSurgical focuses on advancing fertility and women's health through a diversified portfolio including fertility products and services, medical devices, cryostorage (such as cord blood and cord tissue storage) and contraception. We offer quality products, innovative technologies and superior services to health care professionals and patients worldwide. CooperSurgical collaborates with health care professionals to identify products and new technologies to bring to market. The result is a broad portfolio of products and services that are intended to aid in the delivery of improved clinical outcomes for patients and are routinely used by health care professionals in the diagnosis and treatment of a wide spectrum of women's health and reproductive issues.

CooperSurgical distributes its products and services through OB/GYN and medical offices, hospital and ambulatory surgery centers and fertility clinics, as well as direct-to-consumer. A focus area for CooperSurgical is key accounts, which include large group practices, integrated delivery networks and certain buying groups within the office/surgical business and fertility clinic networks within the fertility business. We believe our portfolio of offerings and focus on service, quality and clinical education will help increase our share of business within these key account groups.

Since its inception in 1990, CooperSurgical has established its market presence and distribution system by developing products and acquiring products and companies that complement its business model. In fiscal 2024, CooperSurgical

[1] MiSight 1 day (omafilcon A) soft (hydrophilic) contact lenses for daily wear are indicated for the correction of myopic ametropia and for slowing the progression of myopia in children with non-diseased eyes, who at the initiation of treatment are 8-12 years of age and have a refraction of -0.75 to -4.00 diopters (spherical equivalent) with ≤ 0.75 diopters of astigmatism. The lens is to be discarded after each removal.

acquired select Cook Medical assets focused primarily on the obstetrics, doppler monitoring, and gynecology surgery markets, a fertility company that specializes in sperm separation devices, and obp Surgical, a U.S.-based medical device company with a suite of single-use cordless surgical retractors with integrated light source and evacuation channels. We expect to continue investing in CooperSurgical's business, including through strategic transactions, with the goal of expanding our integrated solutions model within the areas of fertility and women's health.

CooperSurgical Product Categories

Office/Surgical

CooperSurgical sells a wide variety of innovative medical devices and services used in gynecology and obstetrics, including in labor and delivery, as well as to screen, diagnose and treat women's health and reproductive conditions.

CooperSurgical offers the cryostorage of newborn cord blood and cord tissue, which are potent sources of stem cells that have the potential for treatment and healing. Our newborn stem cell storage services are available in the United States, Canada and Australia.

Paragard is a hormone-free intrauterine device (IUD) offered by CooperSurgical that prevents pregnancy for up to ten years using copper as the only active ingredient. It is the only FDA approved non-hormonal IUD contraceptive option and is exclusively sold in the United States.

Fertility

CooperSurgical has broad product offerings for fertility evaluations and IVF procedures by OB/GYN professionals, reproductive endocrinologists and embryologists. In fertility clinics, our products include media, micro-tools and lab equipment. Additionally, CooperSurgical offers services to clinics and families undergoing assisted reproductive technologies including donor gametes, cryostorage, and genomic services.

Market for Fertility and Women's Health Care

CooperSurgical participates in the market for women's and family health care with its diversified product lines at various points of health care delivery: OB/GYN medical offices, hospitals and surgery centers, and fertility clinics. CooperSurgical's business also includes cryostorage services for gametes, cord blood and cord tissue.

CooperSurgical expects that OB/GYN medical offices and fertility clinics will continue to move away from private practice ownership and toward group practices, private equity, corporate or other ownership. As the consolidation trend continues it will have increased influence over supply chain control, group purchases, value analysis committees, product evaluation and procurement. We believe CooperSurgical's broad product portfolio can benefit in this changing environment as customers look to standardize and consolidate vendors.

Trends specific in the OB/GYN market include:

- The increase in office-based and outpatient procedures, given increased access to care, high patient satisfaction, reduction of healthcare costs and comparative clinical outcomes.
- A focus on reducing pregnancy and childbirth complications.
- The obstetrician being a key contributor to stem cell storage, facilitating the collection of cord blood and cord tissue following delivery in most markets.
- Initial evaluation and treatments for infertility, such as uterine assessment, ovulatory medications and intrauterine insemination (IUI), beginning with the OB/GYN and then transitioning to fertility clinics.

Trends specific in the fertility market include:

- Infertility rates are increasing globally, and there is a significant unmet need for fertility products and services.
- The maternal age is increasing.
- Patient awareness of, and access to, services is increasing.
- The number of fertility clinics is rising worldwide.

- Single parents by choice and LGBTQIA+ individuals are starting families.
- Improved product offerings such as donor activity and cryopreservation services are becoming available.
- Technology improvements are being developed for both male and female infertility challenges.
- Worldwide disposable income is increasing.

COMPETITION

The markets in which we participate are highly competitive and involve the continual search for technological and scientific innovations. Competitive factors in these markets include technological and scientific advances, product quality and availability, price, customer service including response time and effective communication of product information to clinicians and consumers, and manufacturing processes. Competitors may have greater financial resources, larger research and development budgets, larger sales forces, greater market penetration and/or larger manufacturing capacity. Both CooperVision and CooperSurgical compete predominantly on the basis of product quality and differentiation, technological benefits, price, service levels and reliability.

CooperVision Competition

CooperVision's largest competitors in the worldwide market and its primary competitors in the spherical, toric and multifocal lens categories of that market are Johnson & Johnson Vision Care, Inc., Alcon Inc. and Bausch + Lomb. To a lesser extent, CooperVision also competes with manufacturers of eyeglasses and providers of other forms of vision correction including ophthalmic surgery. We believe that in order to compete successfully in the numerous categories of the contact lens market, companies must offer differentiated products that are priced competitively and manufactured efficiently. CooperVision competes in its markets by producing high, medium and low-volume lenses made with a variety of materials for a broader range of market niches, as well as offering a wide range of lens parameters, leading to a higher rate of successful fitting for practitioners and better visual acuity for patients. Our ability to compete successfully with a full range of silicone hydrogel products is an important factor to achieving success in our business. We also compete based on our customer and professional services.

CooperSurgical Competition

CooperSurgical focuses on selected segments of the fertility and women's health care market with a diversified portfolio including fertility products and services, medical devices, cryostorage (such as cord blood and cord tissue storage) and contraception. CooperSurgical's strategy includes developing and acquiring new solutions to complement our current offerings. In the fertility market, CooperSurgical competes against Vitrolife Group, FujiFilm-Irvine Scientific, Hamilton Thorne, and Fairfax Cryobank and Fairfax EggBank. We also compete with fertility clinics offering their own services. Larger companies such as Johnson & Johnson, Medtronic and Hologic have offerings that compete with our medical device products. In the stem cell storage field, we compete primarily with ViaCord, a division of Revvity, in the United States, as well as other smaller companies globally. With Paragard, we compete with manufacturers of hormonal IUDs including Bayer and AbbVie, Long Acting Reversible Contraceptives including Organon, and other forms of birth control. We are aware of a non-hormonal IUD under development, which may compete with Paragard in the future. Further, the continued consolidation of medical offices and fertility clinics may impact the competition for our products and services.

RESEARCH AND DEVELOPMENT

The Company employs approximately 400 people in research and development. CooperVision's product development and clinical research is supported by internal and external specialists in lens design, formulation science, polymer chemistry, engineering, clinical trials, microbiology and biochemistry. CooperVision's research and development activities primarily include programs to develop new contact lens designs, myopia management, and manufacturing technologies, along with improving formulations and existing products.

CooperSurgical conducts research and development in-house, and works with external specialists when necessary, in mechanical, electrical, biomedical and software engineering, as well as life sciences. CooperSurgical research and development activities are focused on innovating, improving, and advancing our products and services including, instruments, devices, consumables, digital services, and manufacturing technologies.

GOVERNMENT REGULATION

Our products are subject to extensive regulation by the FDA in the United States and a variety of regulatory agencies in other countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. These regulations govern, among other things, the design and development, testing, manufacturing, labeling, storage, record keeping, premarket clearance, approval or certification, post-market vigilance reporting, advertising and promotion, and sales and distribution of medical devices and pharmaceutical products. Failure to comply with the applicable regulations, which are subject to established and new legislation and change, could result in enforcement action by the FDA, or other U.S. or foreign government agencies which may include, among other things, any of the following consequences: warning letters, civil penalties, refusal or withdrawal of approvals or certifications, license suspension or revocation, product recalls, operating restrictions, suspension or shutdown of production, and criminal prosecution.

Regulation in the United States

Medical Devices

Most of our products are medical devices, which must comply with the Federal Food, Drug and Cosmetic Act (FDCA) and the regulations promulgated by the FDA thereunder. The FDA classifies medical devices into one of three classes—Class I, II or III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure the medical device's safety and effectiveness. Both CooperVision and CooperSurgical develop and market medical devices subject to different levels of FDA regulation depending on the classification and risk profile of the device. Class III devices, such as extended wear contact lenses, require extensive premarket testing and approval, while Class I and II devices require lower levels of regulation. The majority of CooperSurgical's products are Class II devices. Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require either premarket notification to the FDA requesting clearance for commercial distribution under Section 510(k) of the FDCA, a premarket approval (PMA) from the FDA, or a de novo classification and request for marketing authorization submitted to and granted by the FDA.

If we are required to obtain a 510(k) clearance for a device that we wish to market, we must submit a premarket notification to the FDA demonstrating that the device is substantially equivalent to a device commercially distributed in the United States before May 28, 1976 (a pre-amendments device), or to a device that was found to be substantially equivalent to a pre-amendments device. If the FDA agrees that the device is substantially equivalent, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is not substantially equivalent to a legally marketed device, the FDA automatically designates the device as a Class III device. The sponsor of a device automatically designated as Class III must either fulfill more rigorous PMA requirements or request a risk-based classification determination for the device in accordance with the de novo process. The de novo process is a pathway to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

A PMA application must be submitted if the device cannot be cleared through the 510(k) premarket notification procedures, or if the device has been previously classified as Class III. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application must be supported by extensive data including, but not limited to, technical, pre-clinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. Prior to commencing human clinical trials, submission of an application for an investigational device exemption (IDE) and receipt of IDE approval from the FDA is required if the device under evaluation presents a significant risk to human health. The process of gathering supporting information leading up to PMA application, and the subsequent FDA review, can take several years.

A majority of the medical devices we currently market have received FDA clearance through the 510(k) process or approval through the PMA process. Because we cannot be assured that any new products we develop, or any product enhancements, will be exempt from the premarket clearance or approval requirements, or will be subject to the shorter 510(k) clearance process rather than the PMA process, significant delays in the introduction of any new products or product enhancements may occur.

After a device is placed on the market, numerous regulatory requirements apply. These include: establishment registration and device listing with the FDA; the FDA's Quality System Regulation (QSR), which requires manufacturers to follow design, testing, production, control, complaint handling, documentation and other quality assurance procedures during the manufacturing process; labeling regulations, which prohibit the promotion of products for uncleared or unapproved or "off-label" uses and impose other restrictions on labeling, advertising and promotion; FDA unique device identifier regulations, which require changes to labeling and packaging; and medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections for cause by the FDA to determine our compliance with the QSR and other regulations.

In the United States, under the FDCA and the FDA's regulatory framework, in vitro diagnostic devices (IVDs) are a type of medical device that can be used in the diagnosis or detection of diseases, such as cancer, or other conditions. The FDA considers Laboratory Developed Tests (LDTs) to be a subset of IVDs that are designed, manufactured, and used within a single laboratory. Furthermore, in May 2024, the FDA issued a final rule to amend its regulations to make explicit that LDTs are devices under the FDCA. Along with this amendment, the FDA is finalizing a policy under which the FDA will provide greater oversight of IVDs offered as LDTs through a phaseout of its general enforcement discretion approach for LDTs over the course of four years, as well as targeted enforcement discretion policies for certain categories of IVDs manufactured by laboratories. As we operate a genetic testing laboratory, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations, we are required to hold a certificate applicable to the type of laboratory tests we perform and to comply with standards applicable to our operations, including test processes, personnel, facilities administration, equipment maintenance, recordkeeping, quality systems and proficiency testing. We have current certification under CLIA to perform testing at our New Jersey facility. In addition to federal certification requirements of laboratories under CLIA, licensure is required and maintained for our laboratory under state law.

Human cells, tissues, and cellular and tissue-based products

We currently operate as a provider of donated reproductive tissue (eggs and sperm) for fertility treatments, fertility cryopreservation services and newborn stem cell storage. Eggs and sperm are regulated by the FDA as human cells, tissues, and cellular and tissue-based products (HCT/Ps). In addition, Section 361 of the Public Health Service Act (PHSA) authorizes the FDA to issue regulations with respect to HCT/Ps. To be regulated as a "361 HCT/P", the product must, among other things, be minimally manipulated and intended only for homologous uses. HCT/Ps regulated as 361 HCT/Ps are subject to requirements relating to registering facilities and listing products with the FDA, and stringent requirements for processing, storing, labeling and distributing HCT/Ps, including required labeling information, screening and testing for tissue donor eligibility, record keeping and adverse event reporting, among other applicable requirements and laws. 361 HCT/Ps do not require 510(k) clearance, PMA approval, submission of a Biologics License Application, or other premarket authorization from the FDA before marketing. We believe our HCT/Ps are regulated as 361 HCT/Ps.

Pharmaceutical Products

In the United States, the FDA regulates pharmaceutical products under the FDCA and its implementing drug regulations. Although Paragard is a drug-device combination product, the FDA has determined that the primary mode of action for Paragard is the drug component and the product is therefore regulated by the FDA's Center for Drug Evaluation and Research under applicable drug regulations. The process required by the FDA before a drug may be marketed in the United States generally involves numerous and time-consuming steps, including preclinical laboratory tests, human clinical trials, FDA reviews, and facility inspections.

Any drug products manufactured or distributed by us pursuant to NDA approvals are subject to continuing regulation by the FDA as the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. After approval of an NDA, most changes to the approved product, such as adding new indications, manufacturing changes or other labeling claims, are subject to further testing requirements and prior FDA review and approval. Drug manufacturers and their subcontractors are also required to maintain compliance with cGMPs and other requirements, including requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain ongoing compliance. In addition, the FDA closely regulates the marketing, promotion and distribution of pharmaceutical products. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Foreign Regulation

Health authorities in foreign countries regulate Cooper's clinical studies and medical device sales. Even if the FDA has cleared or approved a product in the United States, the regulatory agencies or notified bodies in other countries must approve or certify new products and product modifications before they may be marketed in those countries. The regulations vary widely from country to country, although there is a trend towards harmonization of quality system standards among the European Union (EU), United States, Canada and various other industrialized countries. Medical devices marketed or sold in the EU must meet the CE mark requirements and maintain certain certifications. CooperVision maintains ISO 13485 certification and CE marks for its products and CooperSurgical maintains ISO 13485 certification and CE marks for medical devices and ISO 15189 certification for the genomics laboratories. The ISO 13485 Quality Management System certification is now also required for registration of products in Asia Pacific and Latin American

countries, among many other requirements for registration in these countries. In order to maintain these quality benchmarks, the Company is subjected to rigorous biannual reassessment audits of its quality systems and procedures.

The EU rules below are generally applicable in the European Economic Area (EEA) which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland, while the majority of the United Kingdom now operates under a separate regulatory regime following the United Kingdom's withdrawal from the EU on January 31, 2020.

Medical Device and In Vitro Diagnostic Medical Device Regulation in the EU

Until May 25, 2021, medical devices sold in the EU were regulated by the Medical Device Directive (the EU MDD), which has been repealed and replaced by the EU MDR). Similarly, the EU has adopted the IVDR, which repealed and replaced the In Vitro Diagnostic Medical Device Directive (the EU IVDD) and became applicable on May 26, 2022. The majority of our current certificates have been granted under the EU MDD and the EU IVDD. Due to the unattainable nature of the deadlines for recertification of medical devices under the EU MDR and the EU IVDR, EU institutions have extended the transition periods for devices certified in accordance with the previous Directives, including the EU MDD and the EU IVDD, through legislative amendments of the transitional provisions of the EU MDR and EU IVDR. Therefore, devices lawfully placed on the market pursuant to the EU MDD and EU IVDD may generally continue to be made available on the market or put into service provided that the requirements of transitional provisions are fulfilled. Pursuing marketing of medical devices (including IVDs) in the EU will require that our devices be certified under the new regimes set forth in the EU MDR and the EU IVDR.

In the EU, the safety and performance of medical devices (including IVDs) are evaluated by the designated notified bodies via the submission of technical dossiers, depending on the product classifications. A declaration of conformity to the MDD or MDR is drawn out as a basis for European conformity marking (CE Mark). All medical devices placed on the EU market must meet general safety and performance requirements, including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

Compliance with the general safety and performance requirements is also a prerequisite for CE mark, without which medical devices cannot be marketed or sold in the EU. To demonstrate compliance with the general safety and performance requirements, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its risk classification. With certain exceptions, a conformity assessment procedure requires the intervention of notified bodies, which are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. Typically, satisfactory completion of an audit and examinations of a product's technical dossiers and the manufacturer's quality system is required before the issuance of a certificate by the notified body. This certificate, along with the Declaration of Conformity, are then used by the manufacturer as basis for CE mark.

Throughout the term of the certificate, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements.

In addition, all manufacturers placing medical devices on the market in the EU are subject to various other regulations, including compliance with the EU medical device vigilance system, directives and requirements regarding the advertisement and promotion of medical devices and inspections rights of regulatory authorities.

Laboratory Developed Test Regulation in the EU

In the EU, LDTs were exempt from the regulations that govern medical devices and IVDs under certain conditions. In order to fall within this exemption under the EU IVDD, medical devices, including LDTs, had to be designed and used within such health institutions (which may include hospitals, laboratories and public health institutions that support the healthcare system and/or address patient needs but do not treat or care for patients directly) on a non-industrial scale, without being released into the market. While the legal framework for applying the exemption under the EU IVDD to LDTs was not entirely clear, the EU IVDR may provide greater clarity on the regulation of LDTs.

Our current and future tests will need to be assessed against the EU IVDR requirements. We will be required to comply with various certification and documentation criteria, and we will be subject to conformity assessments and audits by EU notified body and inspections by regulatory authorities.

Medical Devices and In Vitro Diagnostic Medical Devices Regulations in the United Kingdom

Following the United Kingdom's withdrawal from the EU, commonly referred to as Brexit, EU laws no longer apply directly in Great Britain (England, Wales and Scotland). Under the terms of the Ireland/Northern Ireland Protocol agreed between the EU and United Kingdom, many EU laws, including those relating to medical devices and IVDs do still apply in Northern Ireland.

In Great Britain, the legislative regime currently continues to be based on the requirements set out in the EU MDD, the Active Implantable Medical Devices Directive (EU AIMDD), and the EU IVDD. However, substantial reforms to the Great Britain regulatory regime for medical devices and IVDs are currently being developed to improve patient safety. Most of the reforms are to align with EU MDR requirements, but the Medicines and Healthcare products Regulatory Agency (MHRA) also intends to introduce unique requirements such as post market surveillance, software, and Artificial Intelligence from mid-2025.

Medical Device and In Vitro Diagnostic Medical Device Regulation in Asia Pacific

As in other regions, securing regulatory approvals in Asia Pacific is a critical aspect of commercializing our products. While medical device regulations in the Asia Pacific are based on similar regulatory fundamentals (such as risk-based classification of devices) as other regions, navigating the regulatory landscape in Asia Pacific is extremely complex. Medical device regulation in Asia Pacific differs significantly country by country, requiring specific regulatory affairs expertise in each country, as well as country-based regulatory strategies. The regulatory framework maturity in Asia Pacific is widely varied ranging from well-established to emerging, approval timelines can be lengthy and unpredictable and there is less access to and engagement with regulators compared to other markets. Several key Asia Pacific markets require regulatory approval in other countries prior to registration, increasing the time from completion of product development to product launch. For example, in China, manufacturers must provide proof of home country approval (such as the United States or EU) as part of the regulatory registration/approval process.

The NMPA regulates medical devices in China. Medical devices in China are classified by risk into Class I (lowest risk), Class II or Class III (highest risk). China requires physical testing (known as 'type testing') of medical device samples by in-country testing centers to confirm compliance with specifications and standards, both pre- and post-market. Additionally, NMPA generally requires in-country clinical trials to support new product registrations, rather than relying on foreign clinical data.

In Japan, the primary regulation governing medical devices is the Pharmaceutical and Medical Device Act (PMD Act). The Ministry of Health, Labor and Welfare (MHLW) and the Pharmaceutical and Medical Device Agency (PMDA) regulate medical devices. The PMDA evaluates the safety and effectiveness of medical devices prior to granting marketing authorization or approval, and monitors post-market safety of approved devices. The PMDA is also the Quality Management System (QMS) Inspection Authority. Medical devices are placed into one of four risk classes based on potential risk, with Class I being the lowest potential risk and Class IV being the highest. Contact lenses, for example, are regulated as Class III devices and require premarket approval (registration), an expensive and lengthy process depending on the application category. A novel or new medical device application will generally require local clinical trial data, extending the time to approval. The registration process in Japan requires a QMS application and inspection. Additionally, separate from the registration process, a Foreign Manufacturer Registration is required before a company can import medical devices manufactured outside Japan.

Japan and Australia participate in the Medical Device Single Audit Program, which allows for the acceptance of QMS audit reports from other participating Regulatory Authorities, including the FDA.

Other Health Care Regulation

We are subject to various federal, state and foreign laws to prevent fraud and abuse in the healthcare industry and protect personal health-related information, including the following:

- state, federal and similar foreign anti-kickback laws, which generally prohibit payments and other forms of remuneration to induce or in return for the purchase, lease, order or arranging for the purchase, lease or order of a product or service;
- the federal physician self-referral law, known as the Stark Law, which generally prohibits physicians from referring Medicare or Medicaid patients to receive designated health services from an entity which the physician, or a member of the physician's immediate family, has a financial interest in;
- the federal False Claims Act, which prohibits any individual or entity from presenting or causing to be presented false claims for payment to the federal government;

- federal and state laws that prohibit executing, or attempting to execute, a scheme to obtain money from any healthcare benefit program under false pretenses;
- the Physician Payments Sunshine Act and similar state and foreign laws that require medical device and pharmaceutical manufacturers to disclose financial relationships with health care professionals and teaching hospitals; and
- data privacy and security laws and regulations, such as the HIPAA and the EU GDPR, which are intended to protect the collection, use, access to, confidentiality and security of health-related and other personal information.

Coverage and Reimbursement

Market acceptance and sales of our CooperSurgical products to our customers, who primarily consist of hospitals and surgery centers, OB/GYN medical offices and fertility clinics, will depend on the availability of payor coverage and the adequacy of reimbursement, for the procedures using our products, by government insurance programs and other third-party payors. Payor coverage and reimbursement for procedures using medical devices in the United States and international markets vary significantly by country. With respect to drug coverage and reimbursement, third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of drugs, in addition to their safety and efficacy. We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industry to reduce the costs of products and services.

Healthcare Reform

In the United States and foreign countries, there has been, and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates. We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that state, federal and foreign governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. Passed in March 2010, the Patient Protection and Affordable Care Act (the ACA) substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical, medical device and clinical laboratory industries. Additionally, there has recently been heightened scrutiny by governmental authorities, individual hospitals, and third-party payors over product prices, which has resulted in proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025).

In the EU, regulations have been adopted which are intended to boost cooperation among EU member states in assessing health technologies, including certain high-risk medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas.

Other Laws and Regulations

We are subject to numerous federal, state, local and foreign environmental laws, including provisions that regulate the discharge of materials into the environment, laws applicable to our facilities, products or manufacturing processes, including evolving regulations regarding the use of hazardous substances or chemicals in our products, and laws related to the protection of the environment, environmental health and safety regulations, Restriction of Hazardous Substances (RoHS) in electrical and electronic equipment in the EU, and Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH).

We are subject to various other federal, state and foreign laws related to the manufacturing and distribution of our products and to our international operations, including export control and trade compliance laws.

4F

NEVADA STATE BOARD OF PHARMACY

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

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Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: Hill-Rom, Inc.

Physical Address: 1069 State Route 46E

City: Batesville State: IN Zip: 47006

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

City: Dublin State: OH Zip: 43017

Telephone: (843)740-8795 Website: www.hillrom.com

Name of Designated Representative (DR): Steven Bennett

Licensing Company Email: licensure@cardinalhealth.com DR Email: steven_bennett@baxter.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Clinics		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

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

Provide explanation below:

Hill-Rom Manufacturing, Inc. ("Company") is a subsidiary of a publicly held entity. Baxter International, Inc. ("Corporate Parent"). From time to time, both Company and Corporate Parent are involved in litigation or investigations as part of ongoing business operations. Please see Corporate Parent's SEC filings for a description of litigation and other reported activity.

Original Signature (electronic, copies or stamps not accepted)

9/25/2024
Date

Baxter Healthcare Corporation Disclosures

The corporate owner of the applicant facility is Baxter Healthcare Corporation. Accordingly, as part of this application we have provided disclosures pertaining to state disciplinary actions and charges against Baxter Healthcare Corporation, as well as the specific individuals listed on the application. We cannot answer application questions with respect to all owners and shareholders, given that Baxter Healthcare Corporation is a subsidiary of Baxter International Inc., a publicly traded company listed on the New York Stock Exchange. We also cannot answer with respect to all Baxter Healthcare Corporation employees given the scope of Baxter's US operations.

FDA-related information regarding specific Baxter Healthcare Corporation facilities (e.g., inspection history and enforcement actions) can be found on the FDA website.

State Disciplinary Actions

Utah, License # 12435996-1710, 2023

On February 17, 2023, The Utah Board of Pharmacy issued a citation for failure to timely notify the Board of the change in designated representative at the Baxter Byhalia, MS location. Baxter paid the fine and is waiting for the final signed order.

Utah, Pharmacy Class C License # 9451291-1710, 2022

On May 31, 2022, The Utah Department of Commerce issued a Citation and Order due to a failure to file a timely notification of the change in the designated representative at the Baxter - Hayward (W. Winton) location. Baxter resolved the matter and paid a reduced fine.

Idaho, Out of State Mail Service Pharmacy License # 36855MS, 2022

On March 3, 2022, The Idaho Board of Pharmacy issued an Order and Stipulation for violations stemming from an expired non-resident PIC registration. The registration has since been approved by the Board. Baxter has signed the Stipulation and paid the required fine.

Alabama, Permit #194460, 2022

On May 3, 2022, The Alabama Board of Pharmacy issued a citation for failure to notify the Board of the change in designated representative at the Baxter – Hayward (W. Winton location). Baxter resolved the matter and paid the required fine.

Georgia, Wholesaler Pharmacy License # PHWH001754, 2017

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the

settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice. This issue is unrelated to Baxter's pharmacy or wholesale activities.

Baxter disclosed this issue on a renewal application for a Georgia wholesale license for its Marion, NC facility, and in October 2017, the state of Georgia issued a disciplinary order against that license (PHWH001754) based on the disclosure.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities. Iowa,

Nonresident Pharmacy License # 4127, 2014

The Iowa Board of Pharmacy (the "Iowa Board") issued a Stipulation for Baxter's Omaha, Nebraska pharmacy due to improperly delegating final verification of prescriptions for peritoneal dialysis solutions to a pharmacy technician. The Omaha facility is licensed in Nebraska under a Delegated Dispensing Permit, and utilized multiple quality checks, including retrospective pharmacist review, to ensure proper dispensing of peritoneal dialysis products to patients. Upon request by the Iowa Board, Baxter promptly modified its operations to ensure pharmacist verification of all orders. Baxter has signed the Stipulation and paid the required fine.

Montana, License #2152, 2010

The Montana Board of Pharmacy (the "Montana Board") issued a Stipulation for violations stemming from the failure of Baxter to notify the Montana Board in the requisite time frame of a change in the designated Person-in-Charge for the Waukegan, IL facility. Baxter has signed the Stipulation and paid the required fine.

Alabama, License #191639, 2009

The Alabama Board of Pharmacy found the Buford, GA facility was in violation of Code of Alabama (1975) Section 34-23-32. The facility continued distribution operations during the time between the valid license expired and when the expired license was renewed. Baxter Healthcare renewed the license, signed a Consent Order and paid the applicable fine.

Florida, Non-Resident Drug Manufacturer Permit No.: 26:4672, 2009

The Florida Department of Health (the "Florida Department") alleged that Baxter (Memphis, TN) sold prescription drugs to an unpermitted facility in Florida in violation of Section 499.005(15), F.S. Specifically, the Florida Department alleged that Baxter sold prescription drugs to Invivo at an unpermitted location. Baxter entered into a settlement agreement, whereby it neither admitted nor denied the allegations, and paid a fine.

Louisiana, License #3691, 2008

Louisiana Board of Wholesale Drug Distributors conducted a routine inspection of the facility operated by Baxter's third-party logistics provider. Inspectors concluded Baxter (Round Lake, IL)

violated Louisiana Administrative Code 46:XCI.311.D, which requires a licensee to maintain copies of current licenses for its customers who are authorized to obtain and possess legend drugs and devices. Baxter obtained customer licenses, signed a Consent Order, and paid the applicable fine.

Missouri, License #2005002668, 2005

The Missouri Board of Pharmacy (the "Missouri Board") issued a restricted drug distributor license to the facility located in Memphis, TN. The Missouri Board determined the facility violated Section 338.333.1 and 338.337.1 RSMo because the facility shipped legend drugs and/or medical devices into the state without being properly licensed. The proper license was obtained. The probationary period was successfully completed on October 21, 2007 and the restriction on the license was removed.

State Non-Disciplinary Settlements for Memphis Facility

Florida, License #s 26:506 (Memphis, TN) and 26:384 (Marion, NC), 2015

In June 2015, the Florida Department of Business and Professional Regulation (the "Department") sent Notices of Violation to Baxter alleging the shipment of prescription

drugs to a Baptist Health South Florida, Inc. ("Baptist"), prior to Baptist receiving its permit to operate as a restricted prescription drug distributor — health care entity. Baxter had shipped products to the Baptist address under the valid medical license of the Medical Director, in reliance on a document evidencing the Medical Director's intent that he serve as the purchaser of the product. In August 2015, Baxter and the Department resolved the matter via a non-disciplinary settlement.

Other Actions: Dismissed Charge of Drug Law Violation

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities, or the facility that is the subject of this application.

Question #3: Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?

- **Response**: **Yes**. Hill-Rom Manufacturing, Inc. ("Company") is a subsidiary of a publicly held entity. Baxter International, Inc. ("Corporate Parent"). From time to time, both Company and Corporate Parent are involved in litigation or investigations as part of ongoing business operations. Please see Corporate Parent's SEC filings for a description of litigation and other reported activity.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Indiana

Parent Company (if any): See org chart attached - Ultimate parent company is Baxter International, Inc. (publicly traded)

Corporation Name: Hill-Rom, Inc.

Mailing Address: 1069 State Route 46E

City: Batesville State: IN Zip: 47006

Telephone: 614.757.8789 Email: licensure@cardinalhealth.com

Contact Person Name: LaToyia Martin

Date of SEC Registration: 03/21/2994 | SEC Registration Number: 0000010456 | Stock Exchange Symbol: BAX

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Hill-Rom, Inc.

Facility Name

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

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

9/25/2024

Date

Board Use Only	Date Received: 9/26/24	Amount: $1000-ck#10903911

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
HILL-ROM, INC.
Business Trade Names:
(1) Hill-Rom (2) Hill-Rom Co. Inc. (3) Hill-Rom Company (4) Hill-Rom Company Inc. (5) Hill-Rom Holdings, Inc. (6) Hill-Rom Manufacturing, Inc. (7) Hill-Rom Services, Inc.

1069 State Route 46 East
Batesville, IN 47006
Registration Number: 1824206
FEI Number*: 1824206
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
BAXTER HEALTHCARE CORPORATION[6]
One Baxter Parkway
Deerfield, IL US 60015
Owner/Operator Number: 1417572[7]

Official Correspondent:
Julie Carolan
One Baxter Parkway
Deerfield, IL 60015
Phone: 224-9086010

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1417572&OwnerOperatorName=&ProductCode=&DeviceName=&Propri
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Page Last Updated: 09/02/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

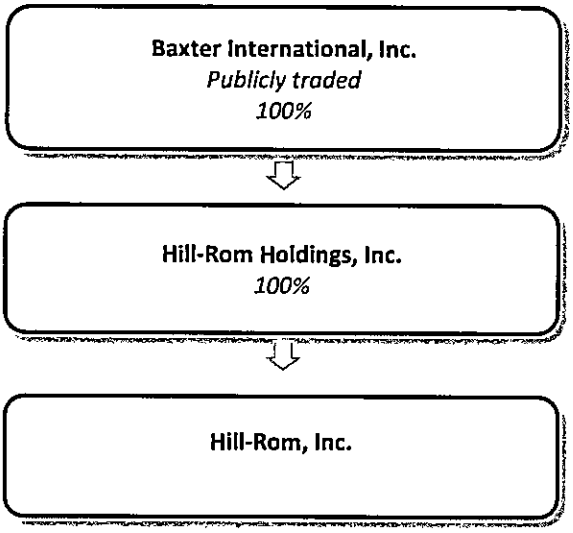
U.S. Department of Health & Human Services

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1417572&OwnerOperatorName=&ProductCode=&DeviceName=&Propri

Hill-Rom Manufacturing, Inc.

Organizational Chart



Hill-Rom, Inc. Top Suppliers

Plexus
Plot 87 Lebuhraya
Kampung Jawa
11900 Bayan Lepas
Penang, Malaysia W67

Central Steel
525 Township Ave
Cincinnati, OH 45216

TiMOTION
1535 Center Park Drive
Charlotte, NC 28217

Winstronics
3817 Spinnaker Ct
Fremont, CA 94538

Corporate Officer List

Officer Name	Title	Company	Business Address	Business Phone Number
Reazur Rasul	President and Director	Hill-Rom, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-6990
Karen L. Leets	Vice President and Treasurer	Hill-Rom, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-2000
James William Borzi	SVP, Chief Supply Chain Officer	Hill-Rom, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-2100
Ellen K. Bradford	SVP and Corporate Secretary	Hill-Rom, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-3086

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

HILL-ROM COMPANY, INC.

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on December 22, 1981, and was in existence or authorized to transact business in the State of Indiana on January 06, 2025.

I further certify this Domestic For-Profit Corporation has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, January 06, 2025

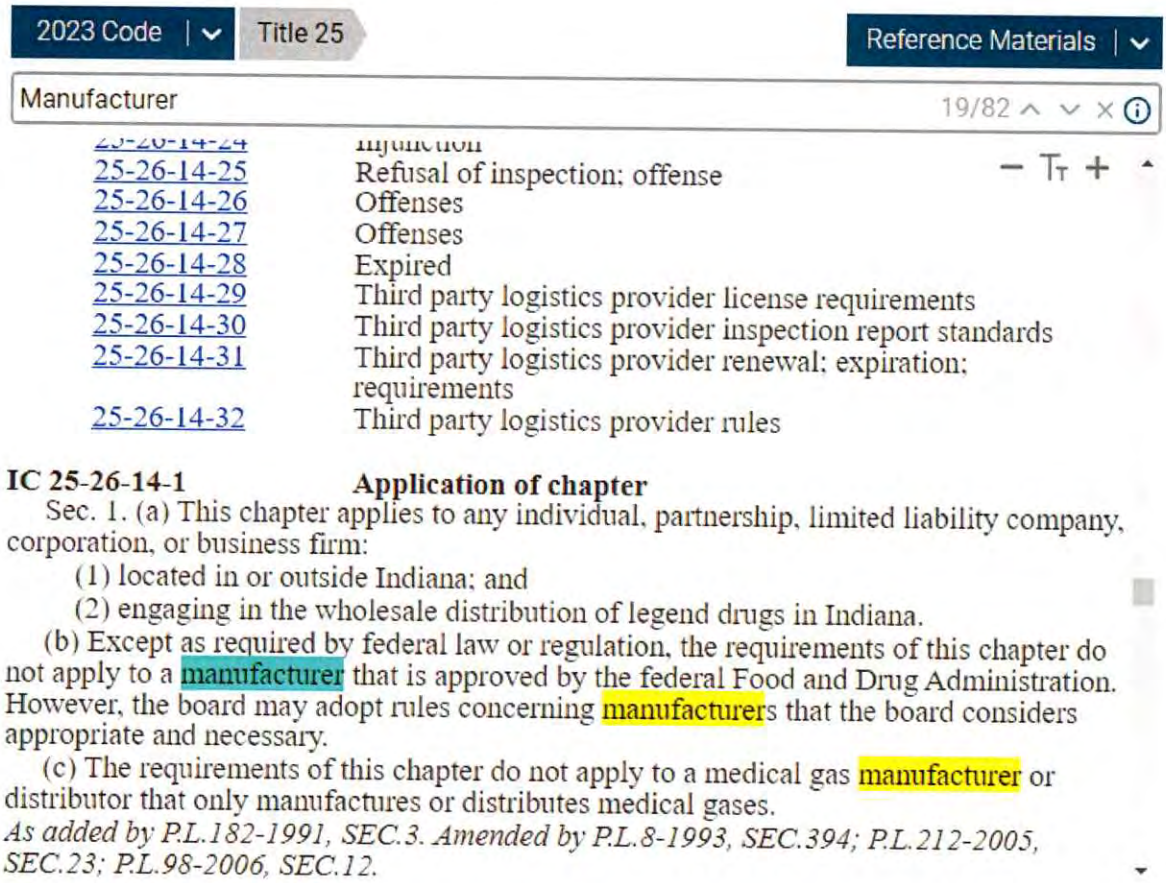
Diego Morales

DIEGO MORALES
SECRETARY OF STATE

198112-634 / 20254161560
All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate
Expires on February 05, 2025.

Indiana Pharmacy law is defined in Title 25 and specifically exempts Drug Manufacturers approved by the FDA from licensing requirements for Wholesale Drug Distributors. If the manufacturer distributes Controlled Substances, they would then be required to get a controlled substance permit.

Please see below reference to 2023 Indiana Code:



2023 Code | Title 25 | Reference Materials

Manufacturer 19/82

25-26-14-24	Injunction
25-26-14-25	Refusal of inspection; offense
25-26-14-26	Offenses
25-26-14-27	Offenses
25-26-14-28	Expired
25-26-14-29	Third party logistics provider license requirements
25-26-14-30	Third party logistics provider inspection report standards
25-26-14-31	Third party logistics provider renewal; expiration; requirements
25-26-14-32	Third party logistics provider rules

IC 25-26-14-1 Application of chapter

Sec. 1. (a) This chapter applies to any individual, partnership, limited liability company, corporation, or business firm:

(1) located in or outside Indiana; and

(2) engaging in the wholesale distribution of legend drugs in Indiana.

(b) Except as required by federal law or regulation, the requirements of this chapter do not apply to a manufacturer that is approved by the federal Food and Drug Administration. However, the board may adopt rules concerning manufacturers that the board considers appropriate and necessary.

(c) The requirements of this chapter do not apply to a medical gas manufacturer or distributor that only manufactures or distributes medical gases.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.394; P.L.212-2005, SEC.23; P.L.98-2006, SEC.12.

https://iga.in.gov/laws/2023/ic/titles/25

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
08/27/2024

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Chicago IL Office 200 East Randolph Chicago IL 60601 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Baxter International Inc and All Affiliates, Divisions, and Subsidiaries thereof including Baxter Healthcare Corp and Hillrom Holdings, Inc. One Baxter Parkway Deerfield IL 60015-4633 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B: Illinois Union Insurance Company	27960
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570107836082 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY5782024	09/01/2024	09/01/2025	EACH OCCURRENCE	$2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$50,000
	X Contractual Liability						MED EXP (Any one person)	$25,000
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$4,000,000
	POLICY X PRO-JECT LOC						PRODUCTS - COMP/OP AGG	Excluded
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 20158 24	09/01/2024	09/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$5,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
B	X UMBRELLA LIAB X OCCUR			XEUG27981604009	09/01/2024	09/01/2025	EACH OCCURRENCE	$5,000,000
	EXCESS LIAB CLAIMS-MADE			SIR applies per policy terms & conditions			AGGREGATE	$5,000,000
	DED X RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			MWC11550217	09/01/2024	09/01/2025	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N / N/A (Mandatory in NH)			All Other States			E.L. EACH ACCIDENT	$2,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$2,000,000
							E.L. DISEASE-POLICY LIMIT	$2,000,000
A	Excess Workers Compensation			MWXS82924 Workers Comp Excess IL CE SIR applies per policy terms & conditions	09/01/2024	09/01/2025	EL Each Accident EL Disease - Policy EL Disease - Ea Emp	$1,500,000 $1,500,000 $1,500,000

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

For General liability, Products Liability and Automobile liability Additional insured status is provided to all parties Baxter is required by written contract to name as additional insured(s), including, where required by written contract, on a primary and non-contributory basis. Such status is limited to the operations of Baxter under said contract, subject to the liability and indemnity terms of the contract and subject to the terms and conditions of the policy.
For General liability, Products Liability, Automobile liability and Workers' Compensation where required by written contract, waiver of subrogation is provided. Such waiver is limited to the operations of Baxter under said contract, subject to the liability and indemnity terms of the contract and subject to the terms and conditions of the policy.

CERTIFICATE HOLDER

Baxter International, Inc. and All Affiliates, Divisions and Subsidiaries thereof including Baxter Healthcare Corp. and Hillrom Holdings, Inc.
One Baxter Parkway
Deerfield IL 60015-4633 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570107836082

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AGENCY CUSTOMER ID: 10224186
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Baxter International Inc and All
POLICY NUMBER: See Certificate Number: 570107836082	
CARRIER: See Certificate Number: 570107836082 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
A	Products Liability			MWZY31692224 SIR applies per policy terms & conditions	09/01/2024	09/01/2025	Each Occurrence	$5,000,000
							Products - Comp/Op Agg	$5,000,000

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AGENCY CUSTOMER ID: 10224186
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Baxter International Inc and All
POLICY NUMBER: See Certificate Number: 570107836082	
CARRIER: See Certificate Number: 570107836082 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

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

Additional Description of Operations / Locations / Vehicles:

For General liability and Products Liability where required by written contract, aggregate limits apply on a per project basis.
Excess/Umbrella liability follows form over the General Liability, Automobile liability and Workers' Compensation policies.

ACORD 101 (2008/01)
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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 285075582

Application/License No. _____

HILL-ROM, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1069 State Route 46 East, Batesville, IN 47006 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 30, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of August, 2024.

APPLICANT/PRINCIPAL
HILL-ROM, INC.

COMPANY

Eileen K. Bradford
Authorized Representative

SURETY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Tara A. Maquinto, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness K. Hannigan

Witness Darionya Wright

Countersigned by

N/A
Nevada Resident Agent

Posted February 20, 2020

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual. SURETY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8211823-285057

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aaron D. Griffin; Aerie Walton; Bartlomiej Siepierski; Christina L. Sandoval; Christopher P. Troha; Corinne Chapman; Dartonya Wright; Derek J. Elston; James B. McTaggart, Jean Torres; Jennifer L. Jakaitis; Jessica B. Dempsey; Judith A. Lucky-Eftimov; Kristin L. Hannigan; Melissa L. Fortier; Nicholas Kertesz; Richard Casas; Robert Nachreiner; Roger Paraison, Samantha Chierici; Sandra M. Winsted; Susan A. Welsh; Tara A. Maquinto; Therese M. Jackson

all of the city of Chicago state of IL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 10th day of May, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 10th day of May, 2024 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 27th day of August, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG HILL-ROM, INC. MDEG License # (if applicable) N/A
Physical Address 1069 State Road 46 EAST
City Batesville State IN Zip 47006
Mailing Address (if different from physical address) 7000 Cardinal Pl, Attn: QRA
City Dublin State OH Zip 43017
Telephone 843-740-8795 Website
Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First STEVEN Middle MICHAEL Last BENNETT
Alias(es, nicknames, name changes, etc.) STEVE
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X
Mailing Address [redacted]
City DILLSBORO State IN Zip [redacted]
Telephone [redacted] Email steven_bennett@baxter.com
Are you a citizen of the United States? ☒ Yes ☐ No

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

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

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

School Name: IUPUI (Purdue)			From - To (MM/YY – MM/YY): 1992 – 1995
Address	City: INDIANAPOLIS	State: IN	Zip
Diploma/Degree obtained, if any: BS – Electrical Engineering Technology			
School Name: IUPUI (PURdue)			From - To (MM/YY – MM/YY): 1989 – 1992
Address	City: Indianapolis	State: IN	Zip
Diploma/Degree obtained, if any: AAS Electrical Engineering Technology			
School Name: Regis College			From - To (MM/YY – MM/YY): 1985 – 1988
Address	City: Denver	State: CO	Zip
Diploma/Degree obtained, if any: ## AAS – Biomedical Electronics			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18 – Curre	[redacted]	Dillsboro	IN	[redacted]
4/17 – 11/18		Germantown	KY	
9/12 – 3/17		Wanship	UT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name: Baxter			From - To (MM/YY – MM/YY): 01/22 – Current
Business Address: 1125E. Pearl St.	City: Bakesville	State: IN	Zip: 47006
Phone: 812-931-0126	Title: PLant Manager		Number of Employed Hours: 5,200
Description of Duties: Responsible for all Manufacturing Operations in Bakesville			

Business Name: HILLROM			From - To (MM/YY – MM/YY): 09/18 – 12/21
Business Address: 1125E. Pearl St.	City: Bakesville	State: IN	Zip: 47006
Phone: 812-931-0126	Title: Executive Director Operations		Number of Employed Hours: 6720
Description of Duties: Responsible for all manufacturing operation and Distribution from Bakesville			

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Steven M Bennett
Original Signature (electronic, copies or stamps not accepted)

7-29-2024
Date

I, Steven M. Bennett, **certify that as the MDEG Administrator for** MDEG Administrator as noted above — HILL-ROM, INC 1069 State road 46 East, Batesville, IN 47006 **that I (initial that you have read and meet the following requirements):**

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

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

Steven M. Bennett
Print Name (First, Last)

Steven M Bennett
Original Signature (electronic, copies or stamps not accepted)

7-29-2024
Date

Board Use Only	Date Received: 9/26/24

Employee List

Steven Bennett - Plant Manager

Reazur Rasul - President and Director

Karen L. Leets - Vice President and Treasurer

James William Borzi - SVP, Chief Supply Chain Officer

Ellen K. Bradford - SVP and Corporate Secretary

EXHIBIT A

BAXTER HEALTHCARE CORPORATION

ORDINARY COURSE OF BUSINESS

SIGNATURE AUTHORITY TABLE

(updated September 2017)

JOB CLASSIFICATION	FINANCIAL LIMITATION
Chief Executive Officer, Executive Vice President or any Senior Vice President	**No limitations**
Global Franchise Unit Head	**Up to $10 Million**
Vice President (including General Manager)	**Up to $5 Million**
Director	**Up to $1 Million**

BAXTER HEALTHCARE CORPORATION

DELEGATION OF AUTHORITY

As contemplated by the resolutions adopted by the Board of Directors of Baxter Healthcare Corporation, a Delaware corporation ("the Corporation"), effective September 15, 2017 ("Resolutions"), a copy of such Resolutions is attached hereto, the undersigned Ellen K. Bradford, Vice President and Secretary, an Authorized Employee of Baxter Healthcare Corporation, hereby delegates to Keegan Chamberlain, Director of Quality Management, and LaToyia Martin, Manager, Quality Compliance, employees of Cardinal Health 200 LLC, the authority to sign for all documents, applications, submissions and other related instruments required for the state pharmacy, wholesale distribution, and manufacturing licenses and legally required permits filed on behalf of Baxter Healthcare Corporation.

This delegation of authority shall be effective until December 31, 2024 and is subject to revocation by any officer of Baxter Healthcare Corporation at any time and shall occur automatically when Keegan Chamberlain or LaToyia Martin ceases to be an employee of Cardinal Health 200 LLC.

The undersigned further approves and ratifies any and all actions taken by Keegan Chamberlain and LaToyia Martin prior to this date, solely in connection with the execution of the above-referenced matters.

Effective: April 13, 2023

Baxter Healthcare Corporation

Ellen K. Bradford

Ellen K. Bradford
Vice President and Secretary

BAXTER HEALTHCARE CORPORATION

RESOLUTIONS FOR SIGNING AUTHORITY

September 15, 2017

RESOLVED, that the Corporation's elected officers and employees of the Corporation having the job classifications set forth in Exhibit A (each an "Authorized Signatory") are authorized and directed to sign any documents relating to matters within the Authorized Signatory's respective job responsibilities, commonly necessary and incidental to the Corporation's business and the execution of which is in the best interest of the Corporation;

FURTHER RESOLVED, that each Authorized Signatory shall have the authority to execute such documents that are within the financial limitations as set forth on Exhibit A, which may be updated from time to time without further resolution;

FURTHER RESOLVED, that any Authorized Signatory is authorized to delegate signing authority ("Delegation") to another individual with such limitations as the Authorized Signatory may establish from time to time, provided however, that any such Delegation shall be in writing in the form of Delegation provided by the office of the Secretary of the Corporation and shall be subject to any limits set forth therein by the Authorized Signatory;

FURTHER RESOLVED, that when signing authority is delegated, an original of any such Delegation shall be delivered to the Secretary of the Corporation to be retained as a part of the permanent records of the Corporation;

FURTHER RESOLVED, that the Secretary or an Assistant Secretary of the Corporation is authorized to attest to the signatures of the Authorized Signatories and affix the seal of the Corporation to such documents, however such documents shall be the binding obligation of the Corporation without the necessity of attestation or affixing of the corporate seal; and

FURTHER RESOLVED, that these resolutions supercede and replace resolutions adopted on November 7, 2008, and July 21, 2014 but any documents signed pursuant to the superceded resolutions remain valid until their expiration and any actions taken by an Authorized Signatory that would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of the foregoing resolutions are hereby authorized, ratified, confirmed and approved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 12, 2024

Baxter International Inc.

(Exact name of registrant as specified in its charter)

Delaware		
(State or other jurisdiction of incorporation)		
1-4448		**36-0781620**
(Commission File Number)		(I.R.S. Employer Identification No.)
One Baxter Parkway, Deerfield, Illinois		**60015**
(Address of principal executive offices)		(Zip Code)

(224) 948-2000
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d 2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $1.00 par value	BAX (NYSE)	New York Stock Exchange Chicago Stock Exchange
0.4% Global Notes due 2024	BAX 24	New York Stock Exchange
1.3% Global Notes due 2025	BAX 25	New York Stock Exchange
1.3% Global Notes due 2029	BAX 29	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter):

☐ Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act: ☐

Item 1.01 Entry into a Material Definitive Agreement.

On August 12, 2024, Baxter International Inc., a Delaware corporation (the "Company"), entered into an Equity Purchase Agreement (the "Purchase Agreement") with Spruce Bidco I, Inc., a Delaware corporation, Spruce Bidco II, Inc., a Delaware corporation, Spruce Bidco I Limited, an Irish corporation, and CP Spruce Holdings, S.C.Sp, a Luxembourg special limited partnership (société en commandite spéciale) having its registered office at 2 avenue Charles de Gaulle, L-1653 Luxembourg and registered with the Luxembourg Trade and Companies Register (Registre de Commerce et des Sociétés, Luxembourg) under number B288011, represented by its managing general partner (associé commandité gérant) CP VIII Spruce GP S.à r.l., a Luxembourg private limited liability company (société à responsabilité limitée) having its registered office at 2 avenue Charles de Gaulle, L-1653 Luxembourg and registered with the Luxembourg Trade and Companies Register (Registre de Commerce et des Sociétés, Luxembourg) under number B287936 (collectively "Buyer"), which are affiliates of certain investment funds managed by global investment firm Carlyle (NASDAQ: CG), to sell, or cause its applicable subsidiaries to sell, all of the issued and outstanding equity interests of Vantive Health LLC, a Delaware limited liability company (the "KidneyCo"), Vantive Mexico LLC, a Delaware limited liability company (the "US-Mexico Holdco"), Gambro Renal Products, Inc., a Delaware corporation (the "Gambro Subsidiary"), RTS Worldwide Holdings Inc., a Delaware corporation (the "RTS Holdco" and, together with KidneyCo, the US-Mexico Holdco and the Gambro Subsidiary, the "US Corps"), Vantive Holding B.V., a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) incorporated under the laws of the Netherlands (the "Dutch Holdco"), Vantive Health GmbH, a Swiss limited liability company (the "Swiss Holdco"), and a Jersey entity that will be formed as contemplated by, and in accordance with, the Purchase Agreement (the "Jersey Newco" and, together with the Dutch Holdco and the Swiss Holdco, the "Non-US Entities" and together with the US Corps, the "Divested Entities"), to Buyer for an aggregate purchase price of $3.8 billion in cash, subject to certain closing cash, working capital and debt adjustments (the "Transaction"). Under the terms of the Purchase Agreement, subject to the aforementioned adjustments, the Company will receive approximately $3.5 billion in cash with net after-tax proceeds currently estimated to be approximately $3 billion.

Pursuant to the Purchase Agreement, following the closing of the Transaction (the "Closing"), Buyer and the Divested Entities and their respective subsidiaries will operate the renal care and acute therapies business previously operated by the Company (the "Vantive Business"). Post-Closing, the Company will be focused on medical products and therapies, healthcare systems and technologies and pharmaceuticals. Pursuant to the Purchase Agreement, the Company will retain (i) the manufacture and sale of saline solutions and (ii) the plastics operations of the Company and its subsidiaries at the Company's Mountain Home, Arkansas facility.

The Transaction is subject to the satisfaction of certain closing conditions, including: (i) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended; (ii) competition clearances in the European Union ("EU"), Brazil, Canada, China, Japan, Mexico and certain other jurisdictions; (iii) foreign direct investment filings in certain EU member states; (iv) approval from the European Commission under the Foreign Subsidiaries Regulation; (v) the absence of any law or order enjoining or otherwise prohibiting the Transaction; (vi) the accuracy of the representations and warranties of the Company or Buyer, as applicable; (vii) completion of a pre-closing reorganization in all material respects; (viii) compliance of the other party with its covenants in all material respects; and (ix) the execution of certain ancillary agreements. These agreements include: (a) a manufacturing and supply agreement, pursuant to which the Company and the Divested Entities will provide each other with certain dialysis-related products, other products, product components and fulfillment services; (b) a long-term master services agreement, pursuant to which the Company will provide the Divested Entities with certain products and services related to biological indicators and reference standards; (c) a distribution agreement, pursuant to which the Company will provide the Divested Entities with certain saline products; (d) a transition services agreement, pursuant to which the Company and the Divested Entities will provide each other with certain transitional services; and (e) an intellectual property agreement providing for the assignment of certain intellectual property to the Vantive Business and certain licensing arrangements between the Company and the Divested Entities regarding certain intellectual property relevant for their respective businesses, each in accordance with the Purchase Agreement. The Transaction is currently expected to close in late 2024 or early 2025.

The Purchase Agreement contains certain representations and warranties that are customary for a transaction of this type. The Purchase Agreement also contains certain covenants, including, among others, customary covenants by the Company to conduct the business of the Divested Entities in the ordinary course between execution of the Purchase Agreement and the Closing.

The Purchase Agreement contains customary termination rights, including if the Closing has not occurred on or prior to February 12, 2025 (the "Initial Outside Date"), subject to two potential extensions by either party until August 12, 2025 under certain circumstances.

The Purchase Agreement provides that Buyer will be required to pay the Company a termination fee of $180,000,000 if the Purchase Agreement is terminated by: (i) either the Company or Buyer because the Transaction has not been completed by the Initial Outside Date (subject to certain extension rights as set forth in the Purchase Agreement), in a circumstance in which the Company would then have been entitled to terminate the Purchase Agreement because (x) Buyer breached any of its covenants or other agreements contained in this Agreement, or any of its representations and warranties are untrue, which breach or failure to be true results in the failure of the related closing condition to be satisfied, subject to a cure period in certain circumstances (a "Terminable Breach") or (y) if all of the closing conditions have been and continue to be satisfied or have been waived (other than those conditions that by their nature only can be satisfied at the Closing), Buyer fails to consummate the Closing in accordance with the terms thereof, and the Company has provided written confirmation to Buyer following the date on which the Closing is required to occur that all closing conditions have been satisfied or waived but Buyer fails to consummate the Closing in accordance with the Purchase Agreement (a "Financing Failure"); or (ii) the Company if there is a Terminable Breach or the Closing is not consummated due to a Financing Failure.

Pursuant to the Purchase Agreement, (i) effective as of the applicable closing date, each outstanding and unvested equity award or cash-based retention award granted to a Transferred Business Employee (as defined in the Purchase Agreement), other than (x) stock option awards that are underwater as of such date and (y) any portion of such outstanding and unvested equity awards that remain outstanding at the applicable closing date and eligible for payout on the terms provided in the applicable award agreement for retirement eligible participants (each, an "LTIP Award"), will vest on a pro rata basis, with such pro rata portion computed based on the number of calendar days elapsed from the start of the vesting period applicable to such LTIP Award through the applicable closing date, relative to the total number of calendar days in such vesting period, (ii) any such accelerated portion will be settled within the time period set forth in the applicable award agreement (such treatment described in clauses and (i) and (ii), the "LTIP Award Treatment") and (iii) Buyer will grant cash-based replacement awards in respect of the forfeited portion of each such LTIP Award (excluding stock option awards) in accordance with the terms and conditions of the Purchase Agreement.

The foregoing description of the Purchase Agreement and the transactions contemplated thereby, including the Transaction, is only a summary, does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Purchase Agreement, which is filed as Exhibit 2.1 to this Current Report on Form 8-K and incorporated herein by reference. The Purchase Agreement has been filed to provide investors with information regarding its terms. It is not intended to provide any other factual information about the Company, the Divested Entities, Buyer or their respective subsidiaries or affiliates. In particular, the assertions embodied in the representations and warranties and certain covenants contained in the Purchase Agreement are qualified by information in confidential disclosure schedules provided by the Company in connection with the signing of the Purchase Agreement. These confidential disclosure schedules contain information that modifies, qualifies and creates exceptions to the representations and warranties and certain covenants set forth in the Purchase Agreement. Moreover, certain representations and warranties in the Purchase Agreement were used for the purpose of allocating risk between the Company and Buyer, rather than establishing matters as facts. Accordingly, investors should not rely on the representations, warranties and covenants or any description thereof as characterizations of the actual state of facts or condition of the Company, the Divested Entities, Buyer or their respective subsidiaries or affiliates or businesses.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

In accordance with the terms and conditions of the Purchase Agreement, effective as of Closing, Chris Toth will cease serving as Executive Vice President and Group President, Kidney Care, and as an executive officer of the Company and will be entitled to receive the LTIP Award Treatment in respect of his outstanding and unvested LTIP Awards as described in Item 1.01 of this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On August 13, 2024, the Company and Buyer issued a joint press release, which is attached hereto as Exhibit 99.1 and incorporated into this Item 7.01 by reference. In addition, on August 13, 2024, the Company posted to the "Investors" section of its website a presentation, attached hereto as Exhibit 99.2, in connection with the Transaction announcement.

The information contained in this Item 7.01 and Exhibits 99.1 and 99.2 shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of such section, nor will such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description of Exhibits
2.1	Equity Purchase Agreement, dated August 12, 2024, by and among Baxter International Inc., Spruce Bidco I, Inc., Spruce Bidco II, Inc., Spruce Bidco I Limited and CP Spruce Holdings, S.C.Sp.
99.1	Joint Press Release, dated August 13, 2024
99.2	Investor Presentation, dated August 13, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, and the documents referred to herein, include "forward-looking statements" within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act that involve risks and uncertainties. Forward-looking statements provide current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact. These statements by their nature address matters that are uncertain to different degrees. Use of the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "seeks," "intends," "evaluates," "pursues," "anticipates," "continues," "designs," "impacts," "affects," "forecasts," "target," "outlook," "initiative," "objective," "designed," "priorities," "goal," or the negative of those words or other similar expressions may identify forward-looking statements, although not all forward-looking statements contain such words. These forward-looking statements are based on certain assumptions and analyses made in light of the Company's experience and perception of historical trends, current conditions, and expected future developments as well as other factors that the Company believes are appropriate in the circumstances. While these statements represent the Company's judgment on what the future may hold, and the Company believes these judgments are reasonable, these statements are not guarantees of any events or financial results. Whether actual future results and developments will conform to expectations and predictions is subject to a number of risks and uncertainties, including the following factors, many of which are beyond our control: (i) the inability to obtain, or delays in obtaining, any required regulatory approvals or other consents for the Transaction, or failure to consummate or delay in consummating the Transaction for other reasons; (ii) the risk that a condition to closing of the Transaction may not be satisfied; (iii) the occurrence of any event, change or other circumstances that could give rise to the termination of the Purchase Agreement; (iv) the outcome of any legal proceedings that may be instituted following announcement of the Transaction; (v) the failure of Buyer to obtain the financing required to consummate the Transaction; (vi) the failure to retain key management and employees of the Vantive Business before the Closing; (vii) potential unfavorable reactions to the Transaction by customers, competitors, suppliers, employees and Company stockholders; (viii) the risk that the expected benefits of the Transaction (including with respect to the Company's capital allocation plans) are not realized in full or at all or on the timeline expected; (ix) each party's ability to satisfy its respective obligations under the manufacturing and supply agreement, transition services agreement, long-term master services agreement, intellectual property agreement, distribution agreement, and other ancillary agreements entered into in connection with the Transaction; and (x) other risks identified in the Company's most recent filings on Form 10-K and Form 10-Q and other U.S. Securities and Exchange Commission ("SEC") filings, all of which are available on the Company's website. Actual results may differ materially from those projected in the forward-looking statements, which are more fully discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. These forward-looking statements are not exclusive and are in addition to other factors discussed elsewhere in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. Further, other unknown or unpredictable factors could also have material adverse effects on future results. Any forward-looking statement in this Current Report on Form 8-K, and the documents referred to herein, speaks only as of the date on which it is made. Except as required by law, the Company assumes no obligation, and expressly disclaim any obligation, to update or revise any forward-looking statements, whether as a result of new information or future events.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BAXTER INTERNATIONAL INC.

Date: August 13, 2024

By: /s/ Joel Grade
Name: Joel Grade
Title: Executive Vice President and Chief Financial Officer

EQUITY PURCHASE AGREEMENT

by and among

BAXTER INTERNATIONAL INC.,

SPRUCE BIDCO I INC.,

SPRUCE BIDCO II INC.,

SPRUCE BIDCO I LIMITED

and

CP SPRUCE HOLDINGS, S.C.Sp

Dated as of August 12, 2024

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EQUITY PURCHASE AGREEMENT

THIS EQUITY PURCHASE AGREEMENT (including the exhibits and schedules hereto, each as amended or restated from time to time, this "Agreement"), dated as of August 12, 2024 (the "Execution Date"), is made by and among Spruce Bidco I, Inc., a Delaware corporation ("US Bidco I"), Spruce Bidco II, Inc., a Delaware corporation ("US Bidco II"), Spruce Bidco I Limited, an Irish corporation ("Irish Bidco"), and CP Spruce Holdings, S.C.Sp, a Luxembourg special limited partnership (*société en commandite spéciale*) having its registered office at 2 avenue Charles de Gaulle, L-1653 Luxembourg and registered with the Luxembourg Trade and Companies Register (*Registre de Commerce et des Sociétés, Luxembourg*) under number B288011, represented by its managing general partner (*associé commandité gérant*) CP VIII Spruce GP S.à r.l., a Luxembourg private limited liability company (*société à responsabilité limitée*) having its registered office at 2 avenue Charles de Gaulle, L-1653 Luxembourg and registered with the Luxembourg Trade and Companies Register (*Registre de Commerce et des Sociétés, Luxembourg*) under number B287936 ("Lux Bidco"), and Baxter International Inc., a Delaware corporation ("Seller" or "BII"). Buyer and Seller are sometimes referred to herein individually as a "Party" and collectively as the "Parties." Except as otherwise indicated herein, capitalized terms used but not defined herein shall have the meanings set forth in Exhibit A.

RECITALS

WHEREAS, Vantive Health LLC, a Delaware limited liability company (the "KidneyCo"), Vantive Mexico LLC, a Delaware limited liability company (the "US-Mexico Holdco"), Gambro Renal Products, Inc., a Delaware corporation (the "Gambro Subsidiary"), RTS Worldwide Holdings Inc., a Delaware corporation (the "RTS Holdco" and, together with KidneyCo, the US-Mexico Holdco and the Gambro Subsidiary, the "US Corps"), Vantive Holding B.V., a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) incorporated under the laws of the Netherlands (the "Dutch Holdco"), Vantive Health GmbH, a Swiss limited liability company (the "Swiss Holdco"), and the "Jersey NewCo" contemplated by Section 1.1(a) of the Seller Disclosure Letter (the "Jersey Newco" and, together with the Dutch Holdco and the Swiss Holdco, the "Non-US Entities" and together with the US Corps, and subject to any changes contemplated by Section 1.1 of this Agreement, the "Companies," and each, a "Company"), and each of their Subsidiaries (including the Transferred Subsidiaries and the Deferred Market Entities and together with the Companies, the "Vantive Group Entities"), together with Seller and certain of its other Subsidiaries, are engaged in the Business;

WHEREAS, on the terms and subject to the conditions set forth herein, prior to or as of the Closing, Seller and certain of its Subsidiaries will take (or have already taken, as applicable) the steps set forth in Section 1.1(a) of the Seller Disclosure Letter, including (a) the transfer of the applicable Excluded Assets by the Vantive Group Entities to Seller or certain of its Subsidiaries (other than the Vantive Group Entities) and the assumption of the Excluded Liabilities by Seller or certain of its Subsidiaries (otber than the Vantive Group Entities) and (b) the transfer of certain Transferred Assets by Seller or certain of its Subsidiaries to the applicable Vantive Group Entity and the assumption of the Assumed Liabilities by the applicable Vantive Group Entity (other than the Transferred Assets and Assumed Liabilities in each of the jurisdictions listed on Section 1.1(b) of the Seller Disclosure Letter (each, a "Deferred Vantive Local Business")) (collectively, the "Pre-Closing Reorganization");

WHEREAS, Seller directly or indirectly owns all of the issued and outstanding equity securities of all of the US Corps (the "US Interests") and the Non-US Entities (the "Non-US Interests" and, together with the US Interests, and subject to any changes contemplated by Section 1.1 of this Agreement, the "Interests");

WHEREAS, BII desires to sell, or cause its applicable Subsidiary to sell, to Buyer, and Buyer desires to purchase from BII or its applicable Subsidiary, the US Interests and the Non-US Interests, in each case upon the terms and subject to the conditions set forth in this Agreement;

WHEREAS, Seller desires for it and its Subsidiaries to sell to Buyer, and Buyer desires to purchase from Seller and its applicable Subsidiaries, the Deferred Vantive Local Businesses (whether by Buyer or its designee directly acquiring (a) the Transferred Assets and Assumed Liabilities of the applicable Deferred Vantive Local Business or (b) the equity interests of a Deferred Market Entity formed by Seller or its Subsidiaries for purposes of transferring the applicable Deferred Vantive Local Business), in each case, upon the terms and subject to the conditions set forth in this Agreement and the executed Business Transfer Agreements and/or Share Transfer Agreements, as applicable;

WHEREAS, in connection with the Transactions, at the Closing, certain of the Parties and/or their applicable Subsidiaries will enter into a manufacturing and supply agreement substantially in the form attached hereto as Exhibit B (the "Supply Agreement");

WHEREAS, in connection with the Transactions, at the Closing, certain of the Parties and/or their applicable Subsidiaries will enter into (a) a transition services agreement substantially in the form attached hereto as Exhibit C (the "Transition Services Agreement"), (b) an intellectual property agreement substantially in the form attached hereto as Exhibit D (the "Intellectual Property Agreement"), (c) a distribution agreement to be entered into based upon the terms and subject to the conditions set forth in the Distribution Agreement Term Sheet attached hereto as Exhibit E (the "Distribution Agreement Term Sheet") and (d) a long term master services agreement to be entered into based upon the terms and subject to the conditions set forth in the Long Term Master Services Agreement Term Sheet attached hereto as Exhibit F (the "LTMSA Term Sheet");

WHEREAS, in connection with the Transactions, following the Closing, certain of the Parties and/or their applicable Subsidiaries will enter into certain business transfer agreement(s), substantially in the form attached hereto as Exhibit G (the "Business Transfer Agreement") and certain share transfer agreement(s), substantially in the form attached hereto as Exhibit K (the "Share Transfer Agreement"), pursuant to which Seller and/or the applicable Subsidiaries of Seller will transfer each Deferred Vantive Local Business to Buyer and/or the applicable Subsidiaries of Buyer, in each case upon the terms and subject to the conditions set forth in the applicable Business Transfer Agreement and/or Share Transfer Agreement; and

WHEREAS, Buyer and Seller desire to make certain representations, warranties, covenants and agreements in connection with this Agreement and the Transactions.

NOW, THEREFORE, in consideration of the premises, and of the representations, warranties, covenants and agreements contained herein, the Parties, intending to be legally bound, agree as follows:

ARTICLE I

PURCHASE AND SALE; CLOSING; CLOSING DELIVERIES

Section 1.1 Purchase and Sale. Upon the terms and subject to the conditions set forth in this Agreement, and in reliance on the representations, warranties and covenants contained herein, (a) at the Closing, Seller agrees to sell, assign, convey, transfer and deliver, or cause its applicable Subsidiary to sell, assign, convey, transfer and deliver, to Buyer, and Buyer agrees to purchase and accept from Seller or its applicable Subsidiary, the US Interests and the Non-US Interests, in each case free and clear of any Liens, other than any Liens solely arising under or relating to applicable securities Laws, any of the Organizational Documents of the US Corps or the Non-US Entities, respectively, or this Agreement, in the order and manner further specified in Annex A to this Agreement (the transfers contemplated by clauses (a) and (b) and Annex A, collectively the "Closing Steps"), and (b) at the applicable Local Closing, Seller shall or shall cause its applicable Subsidiaries to convey, transfer, assign and deliver to Buyer or its designee the applicable Deferred Vantive Local Business, free and clear of all Liens, other than Permitted Liens, in accordance with the terms and conditions set forth herein and in the applicable Business Transfer Agreement and/or Share Transfer Agreement, in the case of the foregoing clauses (a) and (b) collectively, for an aggregate cash amount equal to the Closing Cash Consideration, payable in accordance with Section 1.3 and subject to adjustment pursuant to Section 1.4. The Closing Steps contemplated by Section 1.1(a) shall in each case be made in accordance with Annex A. Buyer shall not make changes to Annex A without Seller's consent (not to be unreasonably withheld, conditioned or delayed); provided, that Seller may withhold such consent if, in Seller's reasonable determination after consultation with Buyer, such change would be reasonably likely to (x) result in any non-*de minimis* cost or Tax or generate any non-*de minimis* Liability or obligation to Seller or any of its Subsidiaries as of the action taken pursuant to change Annex A or thereafter, including following Closing (but Seller may not withhold such consent if Buyer agrees to fully reimburse Seller or its applicable Subsidiaries or fully indemnify them for, as applicable, any such non-*de minimis* cost or Tax or any such non-*de minimis* Liability or obligation), or (y) prevent or materially delay the Closing; provided, further, that Buyer acknowledges and agrees that any change made in accordance with this Section 1.1 that causes any representation and warranty of Seller to be untrue as of the Closing shall not constitute a breach of this Agreement or a breach of the condition precedent set forth in Section 5.2(a) unless such breach is an intentional and material breach that is not curable or, if curable, is not cured by Seller within thirty (30) days after written notice thereof is given by Buyer to Seller. The Parties shall reasonably cooperate in connection with the (i) implementation of any changes to Annex A that were made in accordance with this Section 1.1 and (ii) execution of any resulting changes required to be made to this Agreement, and Buyer shall reasonably consider any comments from Seller on any such changes.

Section 1.2 Time and Place of Closing.

(a) The closing of the purchase and sale of the Interests (excluding any transactions to be consummated at any Local Closing) (the "Closing") will take place remotely, via electronic exchange of documents on the date that is the fifth (5th) Business Day following the day on which the last to be satisfied or waived of the conditions set forth in Article V (other than those conditions that by their nature are to be satisfied or waived at the Closing, but subject to the satisfaction or waiver of those conditions) has been satisfied or waived in accordance with this Agreement, but subject to the continued fulfillment or, to the extent permitted by applicable Law, waiver of those conditions at the Closing (the date on which such satisfaction or waiver occurs, the "Initial Satisfaction Date"); provided, that, notwithstanding anything to the contrary in the foregoing provisions of this Section 1.2(a), (i) in the event the Initial Satisfaction Date occurs (A) on or after the fifteenth (15th) day of such calendar month and (B) no less than five (5) Business Days prior to the last day of such calendar month, then, at Seller's written election, the Closing shall take place on the last Business Day of such calendar month, or (ii) the Closing may occur at such other date, time or place (or by means of remote communication) as the Parties mutually agree in writing; in each case subject to the continued fulfillment or, to the extent permitted by applicable Law, waiver of all conditions at the Closing Date; provided, further, that in no event will Closing occur prior to October 15, 2024 without Buyer's or Seller's prior written consent (the date on which the Closing actually occurs, the "Closing Date"); it being understood that the transfer of the equity interests of Dutch Holdco shall take effect in accordance with the execution of the deed of transfer, substantially in the form set forth in Exhibit H-3 (the "Deed of Transfer"), which shall be executed at the offices of Stibbe N.V., Beethovenplein 10, 1077 WM Amsterdam, the Netherlands (the "Deed of Transfer"). The Closing will be effective as of 12:01 a.m. Eastern Time on the Closing Date (the "Effective Time"). On or promptly following the Initial Satisfaction Date, Seller shall notify Buyer (x) that all conditions set forth in Section 5.1 and Section 5.2 (other than those that, by their nature, are to be satisfied at the Closing) have been satisfied and (y) of the actual date of the Closing Date determined pursuant to this Section 1.2(a) (such notice, the "Closing Date Confirmation"); provided that the Closing Date Confirmation shall be delivered to Buyer no later than five (5) Business Days prior to the Closing Date.

(b) Subject to Section 1.6, the transfer of legal title of the Deferred Vantive Local Businesses to Buyer or its designee (whether by Buyer or its designee directly acquiring (i) the Transferred Assets and Assumed Liabilities of the applicable Deferred Vantive Local Business or (ii) the equity interests of the applicable Deferred Market Entity) shall be deferred until after the Closing until such time as set forth in the applicable Business Transfer Agreement and/or Share Transfer Agreement (each, a "Local Closing," and the date of such Local Closing, a "Local Closing Date").

Section 1.3 Deliveries at Closing.

(a) By Seller. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Seller shall deliver or cause to be delivered to Buyer and the Dutch Notary (as applicable):

(i) (A) an instrument of sale, assignment and transfer with respect to the US Interests (other than those that are shares), substantially in the form set forth in Exhibit H-1, conveying such US Interests to Buyer free and clear of any Liens, other than any Liens solely arising under or relating to applicable securities Laws, any of the Organizational Documents of the applicable US Corps or this Agreement (the "Instruments of Assignment"), and (B) a share transfer form with respect to those US Interests that are shares, substantially in the form set forth in Exhibit H-2, conveying such US Interests to Buyer free and clear of any Liens, other than any Liens solely arising under or relating to applicable securities Laws, any of the Organizational Documents of the applicable US Corps or this Agreement (the "Share Transfer Forms");

(ii) if applicable, a shareholder resolution of Dutch Holdco to accept the resignation of the managing directors (*bestuurders*) of Dutch Holdco as Buyer may request in writing no later than ten (10) Business Days prior to the Closing Date and to appoint the new managing directors of Dutch Holdco as designated in writing by Buyer no later than ten (10) Business Days prior to the Closing Date, in each case effective as of the Closing Date;

(iii) the shareholders' register of Dutch Holdco;

(iv) the legalized powers of attorney duly executed by the applicable Subsidiary of Seller and Dutch Holdco to execute the Deed of Transfer on behalf of such Subsidiary of Seller and Dutch Holdco, including a confirmation with respect to the authority of such Subsidiary of Seller to give the relevant power of attorney and its execution by such Subsidiary of Seller;

(v) a duly executed amended and restated operating agreement of each of KidneyCo and the US-Mexico Holdco, in each case in the form or substantially the form provided to Seller by Buyer at least ten (10) Business Days prior to the Closing, evidencing effective as of the Closing: (A) the withdrawal of Seller or its applicable Subsidiary as a member, (B) the transfer of the applicable US Interests to Buyer in accordance with Section 1.1 and Annex A and (C) the admission of Buyer as a member of each such Company; provided that neither Seller nor its applicable Subsidiary shall be party to such agreement for any purpose and shall have no liability thereunder, except for compliance with the express provisions of this Section 1.3(a)(v);

(vi) in relation to Swiss Holdco, (A) a member resolution of Swiss Holdco (*Gesellschafterbeschluss*) approving the transfer of the shares in Swiss Holdco, (B) a resolution of the board of managing directors (*Geschäftsführerbeschluss*) approving the update of the quota ledger combined with the register of beneficial owners of Swiss Holdco, (C) a transfer instrument relating to the transfer of the shares in Swiss Holdco substantially in the form set forth in Exhibit H-4 (the "Swiss Transfer Form"), duly signed by the applicable Subsidiary of Seller, (D) an updated quota ledger combined with the register of beneficial owners of Swiss Holdco evidencing the new member of Swiss Holdco following the transfer of the shares in Swiss Holdco and the ultimate beneficial owner notified by Irish Bidco and (E) if applicable, written resignations of the managing directors of Swiss Holdco;

(vii) in relation to Jersey Newco, (A) a duly executed stock transfer form substantially in the form set forth in Exbibit H-5 (the "Jersey Stock Transfer Form") relating the applicable shares in Jersey Newco (the "Jersey Shares"), (B) an updated register of the members of Jersey NewCo showing Irish Bidco as the holder of the Jersey Shares, (C) any existing share certificate for the Jersey Shares in the name of the applicable Subsidiary of Seller for cancellation, (D) a new share certificate in the name of Irish Bidco in relation to the Jersey Shares, (E) if applicable, duly executed resignation letters in a form reasonably acceptable to Seller and Buyer of the current directors of Jersey Newco as Buyer may request in writing no later than ten (10) Business Days prior to the Closing Date, (F) if applicable, duly executed letters of acceptance from

4G

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Hill-Rom Company, Inc.

Physical Address: 1889 E. Maule Ave., Suite C

City: Las Vegas State: NV Zip: 89119

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

City: Dublin State: OH Zip: 43017

Telephone: 702.429.8434 Website: www.hillrom.com

Name of Designated Representative (DR): Michael Simpson

Licensing Company Email: Licensure@CardinalHealth.com DR Email: Michael_Simpson@Baxter.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
■ Others: Clinics		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Baxter Healthcare Corporation Disclosures

The corporate owner of the applicant facility is Baxter Healthcare Corporation. Accordingly, as part of this application we have provided disclosures pertaining to state disciplinary actions and charges against Baxter Healthcare Corporation, as well as the specific individuals listed on the application. We cannot answer application questions with respect to all owners and shareholders, given that Baxter Healthcare Corporation is a subsidiary of Baxter International Inc., a publicly traded company listed on the New York Stock Exchange. We also cannot answer with respect to all Baxter Healthcare Corporation employees given the scope of Baxter's US operations.

FDA-related information regarding specific Baxter Healthcare Corporation facilities (e.g., inspection history and enforcement actions) can be found on the FDA website.

State Disciplinary Actions

Utah, License # 12435996-1710, 2023

On February 17, 2023, The Utah Board of Pharmacy issued a citation for failure to timely notify the Board of the change in designated representative at the Baxter Byhalia, MS location. Baxter paid the fine and is waiting for the final signed order.

Utah, Pharmacy Class C License # 9451291-1710, 2022

On May 31, 2022, The Utah Department of Commerce issued a Citation and Order due to a failure to file a timely notification of the change in the designated representative at the Baxter - Hayward (W. Winton) location. Baxter resolved the matter and paid a reduced fine.

Idaho, Out of State Mail Service Pharmacy License # 36855MS, 2022

On March 3, 2022, The Idaho Board of Pharmacy issued an Order and Stipulation for violations stemming from an expired non-resident PIC registration. The registration has since been approved by the Board. Baxter has signed the Stipulation and paid the required fine.

Alabama, Permit #194460, 2022

On May 3, 2022, The Alabama Board of Pharmacy issued a citation for failure to notify the Board of the change in designated representative at the Baxter – Hayward (W. Winton location). Baxter resolved the matter and paid the required fine.

Georgia, Wholesaler Pharmacy License # PHWH001754, 2017

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the

settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice. This issue is unrelated to Baxter's pharmacy or wholesale activities.

Baxter disclosed this issue on a renewal application for a Georgia wholesale license for its Marion, NC facility, and in October 2017, the state of Georgia issued a disciplinary order against that license (PHWH001754) based on the disclosure.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities. Iowa,

Nonresident Pharmacy License # 4127, 2014

The Iowa Board of Pharmacy (the "Iowa Board") issued a Stipulation for Baxter's Omaha, Nebraska pharmacy due to improperly delegating final verification of prescriptions for peritoneal dialysis solutions to a pharmacy technician. The Omaha facility is licensed in Nebraska under a Delegated Dispensing Permit, and utilized multiple quality checks, including retrospective pharmacist review, to ensure proper dispensing of peritoneal dialysis products to patients. Upon request by the Iowa Board, Baxter promptly modified its operations to ensure pharmacist verification of all orders. Baxter has signed the Stipulation and paid the required fine.

Montana, License #2152, 2010

The Montana Board of Pharmacy (the "Montana Board") issued a Stipulation for violations stemming from the failure of Baxter to notify the Montana Board in the requisite time frame of a change in the designated Person-in-Charge for the Waukegan, IL facility. Baxter has signed the Stipulation and paid the required fine.

Alabama, License #191639, 2009

The Alabama Board of Pharmacy found the Buford, GA facility was in violation of Code of Alabama (1975) Section 34-23-32. The facility continued distribution operations during the time between the valid license expired and when the expired license was renewed. Baxter Healthcare renewed the license, signed a Consent Order and paid the applicable fine.

Florida, Non-Resident Drug Manufacturer Permit No.: 26:4672, 2009

The Florida Department of Health (the "Florida Department") alleged that Baxter (Memphis, TN) sold prescription drugs to an unpermitted facility in Florida in violation of Section 499.005(15), F.S. Specifically, the Florida Department alleged that Baxter sold prescription drugs to Invivo at an unpermitted location. Baxter entered into a settlement agreement, whereby it neither admitted nor denied the allegations, and paid a fine.

Louisiana, License #3691, 2008

Louisiana Board of Wholesale Drug Distributors conducted a routine inspection of the facility operated by Baxter's third-party logistics provider. Inspectors concluded Baxter (Round Lake, IL)

violated Louisiana Administrative Code 46:XCI.311.D, which requires a licensee to maintain copies of current licenses for its customers who are authorized to obtain and possess legend drugs and devices. Baxter obtained customer licenses, signed a Consent Order, and paid the applicable fine.

Missouri, License #2005002668, 2005

The Missouri Board of Pharmacy (the "Missouri Board") issued a restricted drug distributor license to the facility located in Memphis, TN. The Missouri Board determined the facility violated Section 338.333.1 and 338.337.1 RSMo because the facility shipped legend drugs and/or medical devices into the state without being properly licensed. The proper license was obtained. The probationary period was successfully completed on October 21, 2007 and the restriction on the license was removed.

State Non-Disciplinary Settlements for Memphis Facility

Florida, License #s 26:506 (Memphis, TN) and 26:384 (Marion, NC), 2015

In June 2015, the Florida Department of Business and Professional Regulation (the "Department") sent Notices of Violation to Baxter alleging the shipment of prescription

drugs to a Baptist Health South Florida, Inc. ("Baptist"), prior to Baptist receiving its permit to operate as a restricted prescription drug distributor — health care entity. Baxter had shipped products to the Baptist address under the valid medical license of the Medical Director, in reliance on a document evidencing the Medical Director's intent that he serve as the purchaser of the product. In August 2015, Baxter and the Department resolved the matter via a non-disciplinary settlement.

Other Actions: Dismissed Charge of Drug Law Violation

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities, or the facility that is the subject of this application.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Indiana

Parent Company (if any): See org chart enclosed - ultimate parent company is Baxter International, Inc.

Corporation Name: HILL-ROM COMPANY, INC.

Mailing Address: 1 Baxter Pkwy

City: Deerfield State: IL Zip: 60015

Telephone: 614.757.8789 Email: licensure@cardinalhealth.com

Contact Person Name: LaToyia Martin

Date of SEC Registration: 03/21/2994	SEC Registration Number: 0000010456	Stock Exchange Symbol: BAX

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Hill-Rom Company Inc.

Facility Name

LaToyia M. Martin

Print Name of Authorized Person Submitting Application

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

03/03/2025

Date

Board Use Only	Date Received: 3/5/25	Amount: $1000 CC

Officer List

Officer Name	Title	Company	Business Address	Business Phone Number	Percentage of Ownership
Reazur Rasul	President and Director	Hill-Rom Company, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-6990	0%
Karen L. Leets	SVP & Treasurer	Hill-Rom Company, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-2000	0%
James William Borzi	EVP, Chief Supply Chain Officer	Hill-Rom Company, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-2100	0%
Ellen K. Bradford	SVP and Corporate Secretary	Hill-Rom Company, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-3086	0%

Hill-Rom Company, Inc.
Top Suppliers

1. **Sur-Seal Corp**
   6156 Selman Rd
   Cincinnati, OH 45248

2. **Flextronics Sales & Marketing North Asia**
   Labuan Financial Parks Complex Unit 7
   Labuan, Malaysia 87000

3. **Plexus Xiamen Co LTD**
   No 6 Xiangxing 2 Rd
   Xiamen, Fujian, China 361006

4. **Zeus Battery Products**
   191 Covington Dr
   Bloomingdale, IL 60108

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

HILL-ROM COMPANY, INC.

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on December 22, 1981, and was in existence or authorized to transact business in the State of Indiana on January 06, 2025.

I further certify this Domestic For-Profit Corporation has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, January 06, 2025

Diego Morales

DIEGO MORALES
SECRETARY OF STATE

198112-634 / 20254161560

All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate

Expires on February 05, 2025.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

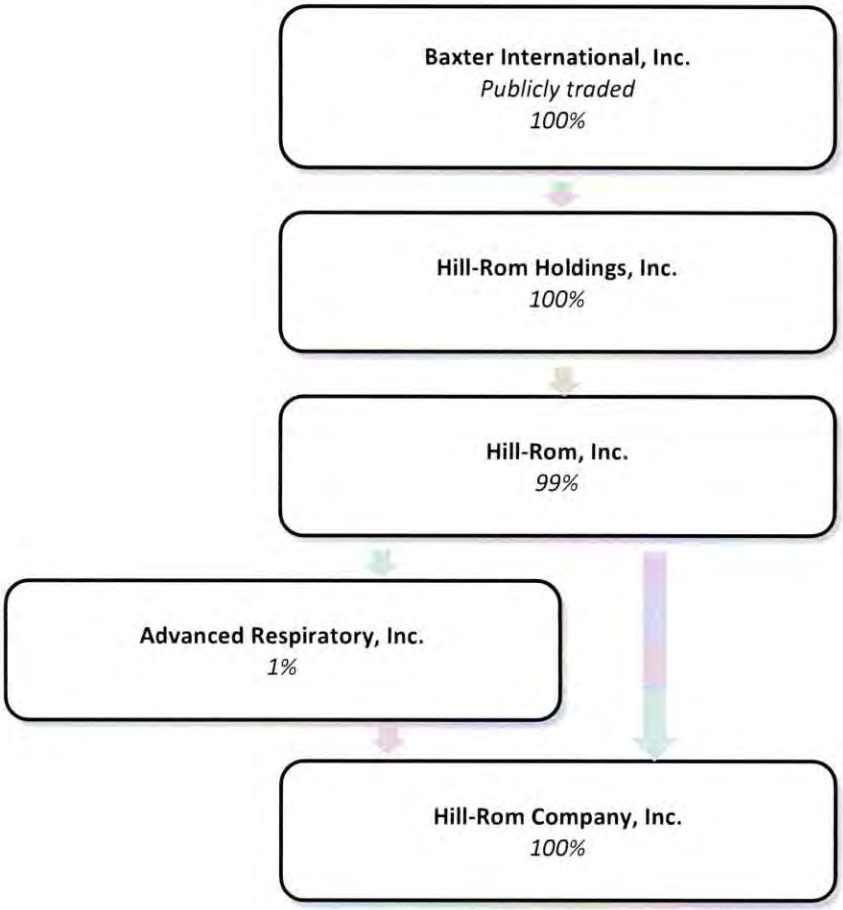
I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **HILL-ROM COMPANY, INC.** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/18/1986, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/06/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502065420705
You may verify this certificate online at https://www.nvsilverflume.gov/home

Hill-Rom Company, Inc. Organizational Chart



CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 08/27/2024

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Chicago IL Office 200 East Randolph Chicago IL 60601 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Baxter International Inc and All Affiliates, Divisions, and Subsidiaries thereof including Baxter Healthcare Corp and Hillrom Holdings, Inc. One Baxter Parkway Deerfield IL 60015-4633 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B: Illinois Union Insurance Company	27960
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570107836082 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR X Contractual Liability GEN'L AGGREGATE LIMIT APPLIES PER: POLICY X PRO-JECT LOC OTHER:			MWZY5782024	09/01/2024	09/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$2,000,000 $50,000 $25,000 $2,000,000 $4,000,000 Excluded
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY X HIRED AUTOS ONLY SCHEDULED AUTOS X NON-OWNED AUTOS ONLY			MWTB 20158 24	09/01/2024	09/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$5,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION			XEUG27981604009 SIR applies per policy terms & conditions	09/01/2024	09/01/2025	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		MWC11550217 All Other States	09/01/2024	09/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $2,000,000 $2,000,000 $2,000,000
A	Excess Workers Compensation			MWXS82924 Workers Comp Excess IL CE SIR applies per policy terms & conditions	09/01/2024	09/01/2025	EL Each Accident EL Disease - Policy EL Disease - Ea Emp	$1,500,000 $1,500,000 $1,500,000

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

For General liability, Products Liability and Automobile liability Additional insured status is provided to all parties Baxter is required by written contract to name as additional insured(s), including, where required by written contract, on a primary and non-contributory basis. Such status is limited to the operations of Baxter under said contract, subject to the liability and indemnity terms of the contract and subject to the terms and conditions of the policy.
For General liability, Products Liability, Automobile liability and Workers' Compensation where required by written contract, waiver of subrogation is provided. Such waiver is limited to the operations of Baxter under said contract, subject to the liability and indemnity terms of the contract and subject to the terms and conditions of the policy.

CERTIFICATE HOLDER

Baxter International, Inc. and All Affiliates, Divisions and Subsidiaries thereof including Baxter Healthcare Corp. and Hillrom Holdings, Inc.
One Baxter Parkway
Deerfield IL 60015-4633 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc

Holder Identifier :

Certificate No : 570107836082

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AGENCY CUSTOMER ID: 10224186
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Baxter International Inc and All
POLICY NUMBER: See Certificate Number: 570107836082	
CARRIER: See Certificate Number: 570107836082 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
A	Products Liability			MWZY31692224 SIR applies per policy terms & conditions	09/01/2024	09/01/2025	Each Occurrence	$5,000,000
							Products - Comp/Op Agg	$5,000,000

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The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 10224186
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Baxter International Inc and All
POLICY NUMBER	
See Certificate Number: 570107836082	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570107836082	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

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

Additional Description of Operations / Locations / Vehicles:

For General liability and Products Liability where required by written contract, aggregate limits apply on a per project basis.
Excess/Umbrella liability follows form over the General Liability, Automobile liability and Workers' Compensation policies.

ACORD 101 (2008/01)
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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 285077265

Application/License No. _____

HILL-ROM, COMPANY INC., doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1889 E. Maule, #C Las Vegas, NV 89119, as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY, a corporation organized under the laws of the state of MA and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 11, 2025.

(Applicant/Principal; Address of Applicant/Principal; Surety Company; State of Incorporation; Address of Surety; Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th **day of** February, **20** 25.

APPLICANT/PRINCIPAL
HILL-ROM, COMPANY INC.

Sarah Padgett
Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Tara A. Maquinto, **Attorney-in-fact**
print name

SIGNED and SEALED in the presence of:

Heather C. Dalin
Witness

Kristen M Myer
Witness

SIGNED and SEALED in the presence of:

RJ-P
Witness Roger Paraison

Corinne Chapman
Witness Corinne Chapman

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual. SURETY

POWER OF ATTORNEY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8213091-285057

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aaron D. Griffin; Aerie Walton; Bartlomiej Siepierski; Christina L. Sandoval; Corinne Chapman; Dartonya Wright; Derek J. Elston; Jean Torres; Jennifer L. Jakaitis; Jessica B. Dempsey; Judith A. Lucky-Eftimov; Kristin L. Hannigan; Melissa L. Fortier; Nicholas Kertesz; Richard Casas; Robert Nachreiner; Roger Paraison; Samantha Chierici; Sandra M. Winsted; Susan A. Welsh; Tara A. Maquinto

all of the city of Chicago state of IL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 6th day of February, 2025.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 6th day of February, 2025 before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 11th day of February, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/24

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Hill-Rom Company, Inc.
Las Vegas, Nevada
Employee List

1. Michael Simpson
2. Michael Swartz
3. Russell Freeman
4. Lino Pacheco
5. Andres Montalvo
6. David Castillo
7. Patrick Hernandez
8. Robert Samuels

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Hill-Rom Company, Inc. MDEG License # (if applicable) New app

Physical Address 1889 E. Maule Ave, Ste C

City Las Vegas State NV Zip 89119

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

City Dublin State OH Zip 43017

Telephone 702-429-8434 Website www.hillrom.com

Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First MICHAEL Middle _____ Last SIMPSON

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

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

Mailing Addres [redacted]

City LAS VEGAS State NV Zip [redacted]

Telephone 702-429-8434 Email michael_simpson@baxter.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Miami University - Middletown		09/79 - 05/82	
Address	**City**	**State**	**Zip**
4200 N UNIVERSITY BLVD	MIDDLETOWN	OH	45042
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
MESA COLLEGE		09/78 - 05/79	
Address	**City**	**State**	**Zip**
1100 NORTH AVE.	GRAND JUNCTION	CO	81501
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
SPRINGBORO HIGH SCHOOL		09/76 - 05/ 78	
Address	**City**	**State**	**Zip**
1675 S MAIN ST	SPRINGBORO	OH	45066
Diploma/Degree obtained, if any			
DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
WAYNESVILLE HIGH SCHOOL		09/74 - 05/76	
Address	**City**	**State**	**Zip**
735 DAYTON RD	WAYNESVILLE	OH	45068
Diploma/Degree obtained, if any			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2015 - PRESENT	[redacted]	LAS VEGAS	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
HILL-ROM CO INC			05/2012 - present
Business Address	**City**	**State**	**Zip**
1889 EAST MAULE AVE STE C	LAS VEGAS	NV	89119
Phone	**Title**		**Number of Employed Hours**
7024298434	SERVICE OPERATIONS SUPERVISOR		40+ PER WEEK
Description of Duties			
Direct supervision of service technicians, to drive traininig, customer satisfaction and continuous improvement.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Michael Sy
Original Signature (electronic, copies or stamps not accepted)

2-13-2025
Date

I, Michael Simpson, **certify that as the MDEG Administrator for**

Hill-Rom Company, Inc.,

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

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

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

Michael Simpson
Print Name (First, Last)

Michael Simpson
Original Signature (electronic, copies or stamps not accepted)

2-13-2025
Date

Board Use Only	Date Received: 3/5/25

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 1-4448

Baxter

Baxter International Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**36-0781620**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
One Baxter Parkway, Deerfield, Illinois	**60015**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code 224.948.2000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock, $1.00 par value	BAX (NYSE)	New York Stock Exchange
1.3% Global Notes due 2025	BAX 25	New York Stock Exchange
1.3% Global Notes due 2029	BAX 29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files) Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), based on the assumption for the purpose of this computation only that all of the registrant's directors and executive officers are affiliates, was approximately $17 billion. The number of shares of the registrant's common stock, $1.00 par value, outstanding as of February 13, 2025 was 511,624,996.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive 2024 proxy statement for use in connection with its Annual Meeting of Stockholders expected to be held on May 6, 2025 are incorporated by reference into Part III of this report.

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PART I

Item 1. *Business.*

Company Overview

Baxter International Inc., through its subsidiaries, provides a broad portfolio of essential healthcare products, including sterile intravenous (IV) solutions; infusion systems and devices; parenteral nutrition therapies; inhaled anesthetics; generic injectable pharmaceuticals; surgical hemostat and sealant products, advanced surgical equipment; smart bed systems; patient monitoring and diagnostic technologies; and respiratory health devices. These products are used by hospitals, nursing homes, rehabilitation centers, ambulatory surgery centers, doctors' offices, kidney dialysis centers and patients at home under physician supervision. Our global footprint and the critical nature of our products and services play a key role in expanding access to healthcare in emerging and developed countries. As of December 31, 2024, after giving effect to the recent sale of our Kidney Care business (as discussed below), we manufactured products in over 20 countries and sold them in over 100 countries.

Baxter International Inc. was incorporated under Delaware law in 1931. As used in this report, "Baxter International" means Baxter International Inc. and "we", "our" or "us" means Baxter International and its consolidated subsidiaries, unless the context otherwise requires.

Recent Strategic Actions

In mid-2022, our Board of Directors authorized a strategic review of our business portfolio, with the goal of increasing stockholder value. As part of that review process, we identified and evaluated a range of potential strategic actions, including opportunities for sales and other separation transactions. In January 2023, following the completion of that review, we announced a number of planned strategic actions, as discussed below, which are intended to enhance our operational effectiveness, accelerate innovation and drive additional stockholder value. We completed the last of these strategic actions on January 31, 2025 in connection with the sale of our Kidney Care business.

Sale of Kidney Care Business

On August 12, 2024, we entered into an Equity Purchase Agreement (EPA) with certain affiliates of Carlyle Group Inc. (Carlyle) to sell our Kidney Care business. That business, which is now known as Vantive Health LLC (Vantive) is comprised of our former Kidney Care segment and provides chronic and acute dialysis therapies and services, including peritoneal dialysis, hemodialysis, continuous renal replacement therapies, and other organ support therapies. On January 31, 2025, we completed the sale of our Kidney Care business to Carlyle for an aggregate purchase price of $3.80 billion in cash, subject to certain closing cash, working capital and debt adjustments. After giving effect to certain adjustments, we received approximately $3.71 billion pre-tax cash proceeds at closing of the transaction with the net after tax proceeds currently estimated to be approximately $3.4 billion, subject to certain post-closing adjustments. We determined that our Kidney Care business met the criteria to be classified as held-for-sale in August 2024, and we also concluded that it met the conditions to be reported as a discontinued operation at that time. Accordingly, our Kidney Care business is reported in discontinued operations in the accompanying consolidated financial systems, and our prior period results have been adjusted to reflect discontinued operations presentation.

Implementation of New Operating Model and Resulting Segment Change

Our reportable segments were previously comprised of the following geographic segments related to our legacy Baxter business: Americas (North and South America), EMEA (Europe, Middle East and Africa) and APAC (Asia Pacific), and a global segment for the Hill-Rom Holdings, Inc. (Hillrom) business we acquired in December 2021. In the third quarter of 2023, we completed the implementation of a new operating model intended to simplify and streamline our operations and better align our manufacturing and supply chain to our commercial activities. Under this operating model, our business is currently comprised of three reportable segments: Medical Products & Therapies, Healthcare Systems & Technologies, and Pharmaceuticals. Our segment reporting was changed during the third quarter of 2023 to align with our new operating model, and all periods presented are under the new operating model.

Sale of BPS Business

On September 29, 2023, we completed the sale of our BioPharma Solutions (BPS) business and received cash proceeds of $3.96 billion from that transaction. The results of operations and cash flows of our BPS business, including the $2.88 billion pre-tax gain ($2.59 billion net of tax) from the sale of that business and the related cash proceeds received, are reported as discontinued operations in the accompanying consolidated financial statements. We used substantially all of the after-tax proceeds from this transaction to repay certain of our debt obligations, including $514 million of commercial paper borrowings and $2.28 billion of long-term debt that we repaid during the fourth quarter of 2023, as well as €750 million of senior notes that we repaid during the second quarter of 2024.

Business Segments and Products

We currently manage our global operations based on three reportable segments: Medical Products & Therapies, Healthcare Systems & Technologies and Pharmaceuticals.

The Medical Products & Therapies segment includes sales of our sterile IV solutions, infusion systems, administration sets, parenteral nutrition therapies and surgical hemostat, sealant and adhesion prevention products. The Healthcare Systems & Technologies segment includes sales of our connected care solutions and collaboration tools, including smart bed systems, patient monitoring systems and diagnostic technologies, respiratory health devices and advanced equipment for the surgical space, including surgical video technologies, precision positioning devices and other accessories. The Pharmaceuticals segment includes sales of specialty injectable pharmaceuticals, inhaled anesthetics and drug compounding services.

For financial information about our segments, see Note 18 in Item 8 of this Annual Report on Form 10-K.

Business Strategy

Our business strategy is focused on driving sustainable growth and innovation aligned with our mission to save and sustain lives and our vision to transform healthcare with a customer focus to help improve patient outcomes, enhance workflow efficiency, and enable cost-effective care. Our diversified and broad portfolio of medical products that treat acute or chronic conditions and our global presence are core components of our strategy as we work to achieve these objectives. We are focused on key strategic pillars as part of our pursuit of industry leading performance: innovation; operational efficiency; and capital allocation.

Innovation

Our innovation strategy, which encompasses both organic and inorganic initiatives, is focused on accelerating our sales growth through the introduction of new connected care and core therapy offerings. Connected care offerings include devices or software that can digitally connect, communicate and/or analyze data to help transform healthcare and improve patient outcomes, and we are continuing to build out our connected care portfolio offerings, which includes smart bed systems, infusion pumps, patient monitoring and diagnostic technologies, respiratory health devices and advanced equipment for the surgical space. Our core therapy product offerings include pharmaceuticals and consumable medical products designed to address essential patient and provider needs across the continuum of care.

As part of this strategy, we are prioritizing investments that drive innovation in product areas where we believe we have compelling opportunities to better serve patients and healthcare professionals, particularly in markets with higher growth rates. We are working to accelerate the pace at which we bring these advances to market to support our future growth. We are in the midst of launching (or have recently launched) several new products, geographic expansions and line extensions in areas such as smart pump technology, hospital pharmaceuticals and nutritionals, surgical sealants, smart beds, respiratory vests and more. These comprise a mix of entirely new product offerings and meaningful improvements to existing technologies.

Portfolio Optimization

Our strategy also involves active portfolio management in the interest of maximizing value for Baxter stockholders and best positioning Baxter for long-term success. The recent Kidney Care sale has given us enhanced flexibility to deploy (or in some cases redeploy) capital toward opportunities that seek to accelerate our growth objectives,

whether as a result of innovation or expanding our portfolio geographically or as a result of channel expansion or market development activities.

Operational Excellence

As discussed above under "Recent Strategic Actions," in the third quarter of 2023, we implemented a new operating model intended to simplify and streamline our operations and better align our manufacturing and supply chain to our commercial activities. We believe these changes will allow us to be a more integrated and nimble organization that can respond more effectively to operational challenges and changes in the macroeconomic environment while enhancing our ability to drive innovation in our product portfolio. We also continue to focus on increasing efficiencies through automation and digitization. We intend to continue to actively manage our cost structure and strive to commit resources to the highest value uses. Such high value activities include supporting innovation, actively managing the portfolio, expanding patient access and accelerating growth for our stockholders.

Maintaining Disciplined and Balanced Capital Allocation

Subject to market conditions and our investment grade targets, our capital allocation strategies currently include the following:

- debt repayments to support our deleveraging commitments;
- active portfolio management through the identification of attractive acquisition and divestiture transactions, including the recent divestitures of our BPS and Kidney Care businesses; and
- returning capital to stockholders through dividends, while balancing any returns with other strategic actions we take. We also intend to reinstate share repurchases over the longer term.

We paid down $3.65 billion of net debt during 2024 and through February 21, 2025 using proceeds from the sales of our BPS and Kidney Care businesses, and we are committed to retaining our investment grade rating, including taking actions toward achieving a net leverage target of approximately 3.0x by the end of 2025 through ongoing debt repayment and financing activities. During this deleveraging period, we currently intend to continue paying a dividend (which we reduced in November 2024), not make any share repurchases and be highly selective with respect to any potential acquisitions.

Sales and Distribution

We have our own direct sales force and also make sales to and through independent distributors, drug wholesalers acting as sales agents and specialty pharmacy or other alternate site providers. In the United States, third parties, such as Cardinal Health, Inc., warehouse and ship a significant portion of our products through their distribution centers. These centers are generally stocked with adequate inventories to facilitate prompt customer service. Sales and distribution methods include frequent contact by sales and customer service representatives, automated communications via various electronic purchasing systems, circulation of catalogs and merchandising bulletins, direct-mail campaigns, trade publication presence and advertising.

Sales are made and products are distributed on a direct basis or through independent distributors or sales agents in more than 100 countries as of December 31, 2024, giving effect to the sale of our Kidney Care business.

International Operations

A significant portion of our revenues are generated outside of the United States and thoughtful geographic expansion remains a key component of our strategy. Our international presence includes operations in Europe, the Middle East, Africa, Asia-Pacific, Latin America and Canada. We are subject to certain risks inherent in conducting business outside the United States. For more information on these risks, see the information under the captions "Risks Relating to Our Business—We are subject to risks associated with doing business globally" and "—Changes in foreign currency exchange rates and interest rates have had, and may in the future have, an adverse effect on our results of operations, financial condition, cash flows and liquidity" in Item 1A. Risk Factors of this Annual Report on Form 10-K.

For financial information about our foreign and domestic revenues and segment information, see Note 18, in Item 8 of this Annual Report on Form 10-K. For more information regarding foreign currency exchange risk, refer to the

discussion under the caption entitled "Financial Instrument Market Risk" in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report on Form 10-K.

Contractual Arrangements

Our products are sold through contracts with customers, both within and outside the United States. Some of these contracts have terms of more than one year and place limits on our ability to increase prices. In the case of hospitals, governments and other facilities, these contracts may specify minimum quantities of a particular product or categories of products to be purchased by the customer.

In keeping with the increased emphasis on cost-effectiveness in healthcare delivery, many hospitals and other customers of medical products in the United States have joined group purchasing organizations (GPOs), or formed integrated delivery networks (IDNs), to enhance purchasing power. GPOs and IDNs negotiate pricing arrangements with manufacturers and distributors and the negotiated prices are made available to members. We have purchasing agreements with several of the major GPOs in the United States, which are subject to renewal from time to time. GPOs may have agreements with more than one supplier for certain products. Accordingly, in these cases, we face competition from other suppliers even where a customer is a member of a GPO under contract with us, which may constrain our ability to secure negotiated price increases. Purchasing power is similarly consolidated in many other countries. For example, public contracting authorities often act as the purchasing entities for the hospitals and other customers of medical products in their region and many hospitals and other customers have joined joint procurement entities and buying consortia. The result is that demand for healthcare products is increasingly concentrated across our markets globally. Additionally, our contractual pricing arrangements with GPOs, IDNs and public contracting authorities can sometimes limit our ability to increase prices in order to offset raw materials or component price increases or otherwise. Some of these agreements contain failure to supply clauses with varying remedies, inclusive of limited termination rights.

Raw Materials and Component Parts

Raw materials and component parts essential to our business are purchased from numerous suppliers worldwide in the ordinary course of business. While many of these materials are generally available, we have experienced and may in the future experience shortages of supply. Additionally, certain of these materials are secured from single source suppliers or on a spot basis and not pursuant to a contractual arrangement.

In an effort to manage risk associated with raw materials and component supply, we work closely with our suppliers to help ensure availability and continuity of supply while maintaining high quality and reliability. We also seek to develop new and alternative sources of supply where beneficial to our overall raw materials procurement strategy. Refer to Item 1A. Risk Factors of this Annual Report on Form 10-K for further information regarding risks related to the supply chain, raw materials and component parts (including with respect to the qualification of any new or alternative supplier).

We are not always able to recover cost increases for raw materials and component parts through customer pricing due to contractual limits, where applicable, and market forces. For example, during 2022 and 2023, our profit margins were adversely impacted because we were unable to fully offset all related cost increases resulting from the high inflationary environment through customer pricing adjustments or other pricing actions. Additionally, our profit margins were negatively impacted in the fourth quarter of 2024 (and may continue to be negatively impacted in the short term) because we were unable to fully offset the increased supply chain costs associated with our ongoing North Cove recovery efforts (including as a result of importing additional product from outside the United States to support IV solutions demand). We seek to utilize long-term supply contracts with some suppliers to help maintain continuity of supply and manage the risk of price increases. Our ability to do so in the face of limited supply of certain raw materials and component parts and inflationary environment has been and may in the future be limited.

Competition and Healthcare Cost Containment

Our businesses benefit from a number of competitive advantages, including the breadth and depth of our product offerings and our strong relationships with customers, including hospitals and clinics, GPOs, IDNs, physicians and patients, many of whom self-administer home-based therapies that we supply. We also benefit from efficiencies and cost advantages resulting from shared manufacturing facilities and the technological advantages of our products.

Although no single company competes with us in all of our businesses, we face substantial competition in each of our segments from international and domestic healthcare, medical products and pharmaceutical companies and providers of all sizes, and these competitors often differ across our businesses. In addition, global and regional competitors continue to expand their manufacturing capacity and sales and marketing channels. We believe customer purchasing decisions are primarily focused on cost-effectiveness, price, service, product performance and technological innovation. There has been consolidation in our customer base and by our competitors, which has resulted and continues to result in pricing and market pressures.

1. Global efforts toward healthcare cost containment continue to exert pressure on product pricing. Governments around the world use various mechanisms to control healthcare expenditures, such as price controls, the formation of public contracting authorities, product formularies (lists of recommended or approved products), and competitive tenders which require the submission of a bid to sell products. Sales of our products are dependent, in part, on the availability of reimbursement by government agencies and healthcare programs, as well as insurance companies and other private payers. In the United States, the federal government and many states have adopted or proposed initiatives relating to Medicaid and other health programs that may limit reimbursement or increase rebates that we and other providers are required to pay to the state. In addition to government regulation, managed care organizations in the United States, which include medical insurance companies, medical plan administrators, health-maintenance organizations, hospital and physician alliances and pharmacy benefit managers, continue to put pressure on the price and usage of healthcare products. Managed care organizations seek to contain healthcare expenditures, and their purchasing strength has been increasing due to their consolidation into fewer, larger organizations and a growing number of enrolled patients. We face similar issues outside of the United States. In Europe and Latin America, for example, the government provides healthcare at low cost to patients, and controls its expenditures by purchasing products through public tenders, collective purchasing, regulating prices, setting reference prices in public tenders or limiting reimbursement or patient access to certain products. Additionally, China has been implementing volume-based procurement policies and a series of centralized reforms on both a national and regional basis which have resulted in significant price cuts for pharmaceuticals and medical consumables. For further discussion, refer to Item 1A. Risk Factors of this Annual Report on Form 10-K.

Intellectual Property

Patents and other proprietary rights are essential to our business. We rely on patents, trademarks, copyrights, trade secrets, know-how and confidentiality agreements to develop, maintain and strengthen our competitive position. We own numerous patents and trademarks throughout the world and have entered into license arrangements relating to various third-party patents and technologies. Products manufactured by us are sold primarily under our own trademarks and trade names. Some products distributed by us are sold under our trade names, while others are sold under trade names owned by our suppliers or partners. Trade secret protection of unpatented confidential and proprietary information is also important to us. We maintain certain details about our processes, products and technology as trade secrets and generally require employees, consultants, and business partners to enter into confidentiality agreements. These agreements may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, and business partners use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our policy is to protect our products and technology through patents and trademarks on a worldwide basis. This protection is sought in a manner that balances the cost of such protection against obtaining the greatest value for us. We also recognize the need to promote the enforcement of our patents and trademarks and take commercially reasonable steps to enforce our patents and trademarks around the world against potential infringers, including judicial or administrative action where appropriate.

We operate in an industry susceptible to significant patent litigation. At any given time, we are involved as either a plaintiff or defendant in a number of patent infringement and other intellectual property-related actions. Such litigation can result in significant royalty or other payments or result in injunctions that can prevent the sale of products. For more information on patent and other litigation, see Note 8 in Item 8 of this Annual Report on Form 10-K.

Research and Development

We believe our investment in research and development (R&D), consistent with our portfolio optimization and capital allocation strategies, will help fuel our future growth and our ability to remain competitive. Accordingly, we continue to focus our investment on select R&D programs to enhance future growth through clinical differentiation. Expenditures for our R&D activities were $590 million in 2024, $518 million in 2023, and $450 million in 2022. These expenditures include costs associated with R&D activities performed at our R&D centers located around the world, which include facilities in Belgium, India, Italy, Malta and the United States, as well as in-licensing, milestone and reimbursement payments made to partners for R&D work performed at non-Baxter locations. As discussed above in under "Recent Strategic Actions," in the third quarter of 2023, we implemented a new operating model intended to simplify and streamline our operations, including with respect to our R&D activities. We are also working to create a more resilient supply chain and better align our manufacturing footprint and supply chain to our commercial activities. These activities may result in the consolidation of one or more R&D facilities.

For more information on our R&D activities, refer to the discussion under the caption entitled "Strategic Objectives" in Item 7. Management's Discussion of Analysis and Financial Condition and Results of Operations of this Annual Report on Form 10-K.

Quality Management

Our continued success depends upon the quality of our products. Quality management plays an essential role in determining and meeting customer requirements, helping to prevent defects, facilitating continuing improvement of our processes, products and services, and helping to assure the safety and efficacy of our products. Our quality system enables the design, development, manufacturing, packaging, sterilization, handling, distribution and labeling of our products to help ensure that they conform to customer requirements. In order to consistently improve the effectiveness and efficiency of our quality system, various measurement, monitoring and analysis methods, such as management reviews and internal, external and vendor audits, are employed at local and central levels.

Each product that we market is required to meet specific quality standards, both in packaging and in product integrity and quality. If any of those is determined to be compromised at any time, we endeavor to take corrective and preventive actions designed to ensure compliance with regulatory requirements and to meet customer expectations. For more information on corrective actions taken by us, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7. Management's Discussion of Analysis and Financial Condition and Results of Operations of this Annual Report on Form 10-K.

Corporate Responsibility

Driven by our mission to save and sustain lives, Baxter's corporate responsibility strategy focuses on addressing corporate responsibility matters that affect our patients, customers, employees, communities and other critical stakeholders worldwide. Advancing our corporate responsibility goals contributes to business, social and economic value, including attraction and retention of employees, enhanced operational efficiency and implementation of enterprise risk management strategies, among others.

In 2021, we launched our 2030 Corporate Responsibility Commitment featuring strategic goals for focused action. Our Commitment is anchored by three pillars - Empower our Patients, Protect our Planet and Champion our People and Communities. The 2030 Corporate Responsibility Commitment and Goals highlight Baxter's corporate responsibility focus and help to further advance our corporate responsibility performance. We expect to announce a refreshed Corporate Responsibility commitment and goal set after the issuance of our 2024 Corporate Responsibility Report (to be issued in June 2025), either in a separate announcement or as part of the 2025 Corporate Responsibility Report. This timing should allow for a new, permanent CEO to have the opportunity to review and contribute to our commitment and goals and to reflect recent operational and other developments (including the recent Kidney Care sale). Our progress against our current goals and commitments is published annually in our Corporate Responsibility Report which is available on our website under "Our Story-Corporate Responsibility." The Corporate Responsibility Report is not incorporated by reference into this Annual Report on Form 10-K or any other document filed with the SEC.

Government Regulation

As a medical products company, our operations and many of the products manufactured or sold by us are subject to extensive regulation by numerous government agencies, both within and outside the United States. The Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) and the Medicines &

Healthcare products Regulatory Agency (MHRA) in Europe, the National Medical Products Administration (NMPA) in China and other government agencies, inside and outside of the United States, administer requirements covering the testing, safety, effectiveness, manufacturing, labeling, promotion and advertising, distribution and post-market surveillance of our products. We must obtain specific clearance, approval or other marketing authorization from FDA and non-U.S. regulatory authorities before we can market and sell most of our products in a particular country. Even after we obtain regulatory authorization to market a product, additional regulatory authorization may be necessary to maintain the product in the market, including additional 501(k) clearances, new drug approval (NDA) supplements, and other regulatory submissions. In addition, the raw materials, manufacturing facilities, processes and quality systems used in the manufacture of a product are subject to continued review by FDA and other regulatory authorities globally. State agencies in the United States also regulate our facilities, operations, employees, products and services within their respective states. We, along with our facilities, are subject to periodic inspections and possible administrative and legal actions by FDA and other regulatory agencies inside and outside the United States. Such actions may include warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. As situations require, we take steps to ensure the safety and efficacy of our products, such as removing products from the market that are found not to meet applicable requirements and improving the effectiveness of quality systems. For more information on compliance actions taken by us, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7. Management's Discussion of Analysis and Financial Condition and Results of Operations of this Annual Report on Form 10-K.

We are also subject to various laws inside and outside the United States concerning our relationships with healthcare professionals and government officials, price reporting and regulation, the promotion, sales and marketing of our products and services, the importation and exportation of products, the operation of our facilities and the distribution of products. In the United States, we are subject to the oversight of FDA, Office of the Inspector General within the Department of Health and Human Services (OIG), the Center for Medicare/Medicaid Services (CMS), the Department of Justice (DOJ), Environmental Protection Agency, Department of Defense and Customs and Border Protection in addition to others. We supply products and services to healthcare providers that are reimbursed by federally funded programs such as Medicare. As a result, our activities are subject to regulation by CMS and enforcement by OIG and DOJ. In each jurisdiction outside the United States, our activities are subject to regulation by government agencies including the EMA and MHRA in Europe, NMPA in China and other agencies in other jurisdictions. Many of the agencies enforcing these laws have increased their enforcement activities with respect to healthcare companies in recent years. These actions appear to be part of a general trend toward increased enforcement activity globally.

Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. Our environmental policies require compliance with all applicable environmental regulations and contemplate, among other things, appropriate capital expenditures for environmental protection.

Human Capital Management

As of December 31, 2024, after giving effect to the Kidney Care sale, we employed approximately 38,000 people globally, with approximately 15,000 employees in the United States and approximately 23,000 employees outside of the United States. Our employees set the foundation for our ability to achieve our strategic objectives. They contribute to our success and are instrumental in driving operational execution and our ability to deliver strong financial performance, advancing innovation and maintaining a strong quality and compliance program across our organization.

The success and growth of our business depends in large part on our ability to attract, retain and develop talented and high-performing employees at all levels of our organization with a myriad of backgrounds and experiences, including the individuals who comprise our global workforce as well as executive officers and other key personnel. To succeed in a competitive labor market, we have developed recruitment and retention strategies, objectives and measures that we focus on as part of the overall management of our business. These strategies, objectives and measures form our human capital management framework and are advanced through the following programs, policies and initiatives:

- **Competitive Pay and Benefits.** Our compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate

employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance.

- **Health and Safety.** Health and safety are firmly rooted across our global footprint. We aim for a zero-harm workplace and prioritize the elimination of risks and incident precursors to drive improvement. In 2024, Baxter focused on employee engagement, hazard identification and accelerated technology deployment to better understand and address top health and safety risk areas. We have continued to mobilize our hazard identification program for our operational workforce, in concert with a centralized corrective action tracking tool. These improvements have enabled us to harvest actionable insights, support ergonomic evaluations and implement safety control technology for improved operation of our powered industrial vehicles.
- **Recruitment, Training and Development.** We use recruitment vehicles to attract talent to our organization and we prioritize learning opportunities that foster a growth mindset. Our formal offerings include a tuition reimbursement program, an e-learning platform known as BaxU and virtual workshops that support our culture, strategy and the development of crucial skills. To assess the impact of the investments we make in our people, and to help us consistently improve our human resources programs, we regularly conduct anonymous surveys of our global workforce to seek feedback on a variety of topics including confidence in our leadership, competitiveness of our compensation and benefits packages, career growth opportunities and improvements on how we can make our company an employer of choice. Administered and analyzed by an independent third-party, the survey results are reviewed by our senior leaders, which include our executive officers. Summaries of select surveys are also provided to our Board of Directors. The results of this engagement survey are also shared with individual managers, who are then tasked with taking action based on their employees' anonymous feedback.

Available Information

We make available free of charge on our website at www.baxter.com our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), as soon as reasonably practicable after electronically filing or furnishing such material with the Securities and Exchange Commission. These reports are also available free of charge via EDGAR through the Securities and Exchange Commission website (www.sec.gov). In addition, our Corporate Governance Guidelines, Code of Conduct, and the charters for the committees of our Board of Directors are available on our website at www.baxter.com under "Our Story — Our Governance." All the foregoing materials will be made available to stockholders in print upon request by writing to: Corporate Secretary, Baxter International Inc., One Baxter Parkway, Deerfield, Illinois 60015: Information contained on our website shall not be deemed incorporated into, or to be a part of, this Annual Report on Form 10-K.

Item 1A. *Risk Factors.*

In addition to the other information in this Annual Report on Form 10-K, stockholders or prospective investors should carefully consider the following risk factors for a description of the principal risks that we face. If any of the events described below occurs, our business, results of operations, financial condition, cash flows, future growth prospects and stock price could suffer. Further, other unknown or unpredictable factors could also have material adverse effects on our future results.

Risk Factors Summary

This summary of risks below is intended to provide an overview of the risks we face and should not be considered a substitute for the more detailed risk factors discussed immediately following this summary.

Risks Relating to Our Strategic Actions

- We are exposed to risks as a result of our strategic actions, including the recent sale of our Kidney Care business.
- We may continue to experience difficulties with our ongoing integration of Hillrom or fail to realize the anticipated benefits of the Hillrom acquisition.
- If our business strategy and development activities are unsuccessful, our business, results of operations, financial condition and cash flows could be adversely affected.

Risks Relating to Our Financial Performance and Our Common Stock

- Global economic conditions, including inflation and supply chain disruptions, have adversely affected, and could continue to adversely affect, our operations.
- Our operating results and financial condition have fluctuated and may in the future continue to fluctuate.
- We may not achieve our financial goals.
- Our common stock price has fluctuated significantly and may continue to do so.
- Our significant indebtedness requires us to use a substantial amount of our cash flow for debt service and could constrain our flexibility in responding to unanticipated or adverse business conditions and adversely affect our business, results of operations, financial condition and cash flows.
- Changes in foreign currency exchange rates and interest rates have had, and may in the future have, an adverse effect on our results of operations, financial condition, cash flows and liquidity.
- Future material impairments in the value of our goodwill, intangible assets and other long-lived assets, would negatively affect our operating results.
- We cannot guarantee that in the future we will not further reduce the amount of dividends we pay.

Risks Relating to Our Business

- If we are unable to successfully introduce or monetize new and existing products or services, or fail to keep pace with changing consumer preferences and needs or advances in technology, our business, results of operations, financial condition and cash flows could be adversely affected.
- Issues with quality management or product quality could, among other things, have an adverse effect on our business or cause a loss of customer confidence in us or our products.
- There is substantial competition in the product markets in which we operate and the risk of declining demand and pricing pressures could adversely affect our business, results of operations, financial condition and cash flows.
- If we fail to attract, develop, retain and engage key employees, including a permanent Chief Executive Officer (CEO) and other members of our senior management, our business may suffer.
- Pandemics and other public health emergencies, or the fear thereof, have had, and may in the future have, a material adverse effect on our business.

Risks Relating to Our Operations

- Segments of our business are significantly dependent on major contracts with GPOs, IDNs, and certain other distributors and purchasers.
- We may not be successful in achieving expected operating efficiencies and sustaining or improving operating expense reductions and may experience business disruptions and adverse tax consequences associated with restructuring, realignment and cost reduction activities.
- If we are unable to obtain sufficient components or raw materials on a timely basis or for a cost-effective price or if we experience other manufacturing, sterilization, supply or distribution difficulties, our business, results of operations, financial condition and cash flows may be adversely affected.
- Breaches and breakdowns affecting our information technology systems or protected information, including from obsolescence, cyber security breaches and data leakage, could have a material adverse effect on us.
- Incorporating artificial intelligence, machine learning and other emerging technologies into our products, services and operations exposes us to legal and regulatory risks and could result in reputational harm or have other adverse consequences to our business, financial condition or results of operations.

- Climate change, or legal, regulatory or market measures to address climate change, could adversely affect our business, results of operations, financial condition and cash flows.
- Our commitments, goals and disclosures related to corporate responsibility matters, and the perception of our activities in these areas, may adversely impact the company, including through reputational harm.
- We are subject to risks associated with doing business globally.
- A portion of our workforce is unionized, and we could face labor disruptions that would interfere with our operations.

Risks Relating to Legal and Regulatory Matters

- We are subject to a number of laws and regulations, and we are susceptible to a changing regulatory environment.
- Increasing regulatory focus on, and expanding laws relating to, privacy, artificial intelligence and cybersecurity could impact our business and expose us to increased liability.
- If reimbursement or other payment for our current or future products is reduced or modified in the United States or in foreign countries or there are changes to policies with respect to pricing, taxation or rebates, our business could suffer.
- We could be subject to fines or damages and possible exclusion from participation in federal or state healthcare programs if we fail to comply with the laws and regulations applicable to our business.
- If we are unable to protect or enforce our patents or other proprietary rights, or if we become subject to claims or litigation alleging infringement of the patents or other proprietary rights of others, our competitiveness and business prospects may be materially damaged.
- Changes in tax laws or exposure to additional income tax liabilities may have a negative impact on our operating results.
- We are party to a number of pending lawsuits and other disputes which may have an adverse impact on our business, results of operations, financial condition and cash flows.
- Our Amended and Restated By-Laws could limit our stockholders' ability to choose their preferred judicial forum for disputes with us or our directors, officers, or employees.

Risks Relating to Our Recent and Ongoing Strategic Actions

We are exposed to risks as a result of our strategic actions, including the recent sale of our Kidney Care business.

Our businesses have begun to face, and will continue to face, material challenges in connection with the sale of our Kidney Care business and the other strategic actions we have undertaken (including the implementation of a simplified operating model and the ongoing simplification of our manufacturing footprint). The success of the sale of our Kidney Care business depends on, among other things, our ability to effectively transition the Kidney Care business to Carlyle in a manner that: minimizes disruption to our customers, employees, other personnel and operations; realizes the expected tax benefits; avoids potential liabilities or claims; and enables us to achieve related cost savings initiatives. The Kidney Care sale may result in challenges such as: the diversion of management's attention from our ongoing business concerns and any newly identified strategic initiatives; attracting, retaining and motivating key management and other employees; retaining existing, or attracting new, business and operational relationships, including with customers, suppliers, employees and other counterparties; maintaining our relationships with regulators; the potential for disputes or litigation with Carlyle or Vantive, as applicable, arising from the transaction, the EPA or the various agreements (including a transition services agreement and a manufacturing and supply agreement) that we entered into with Vantive in connection with the Kidney Care closing (as further described below) and liabilities and obligations otherwise related to the transaction, the EPA or the other agreements described in this paragraph; the potential for exposure related to certain pre-closing Kidney Care liabilities we retained; the potential for adverse tax consequences or changes in tax laws or

regulations that could affect our remaining businesses; the potential for regulatory actions or investigations related to the transaction or the businesses involved; and potential negative reactions from the financial markets, ratings agencies, customers, employees, other personnel or other stakeholders.

In addition, in the last few years, we have undertaken other strategic and business transformation actions (including the divestiture of our BPS business, the acquisition of Hillrom and cost reduction initiatives) that have entailed changes across our organizational structure, senior leadership, culture, functional alignment, outsourcing and other areas. These actions pose risks in the form of personnel capacity constraints and institutional knowledge loss that has led to, and could in the future lead to, missed performance of financial targets (including those related to cost savings initiatives) and harm to our reputation.

In connection with the closing of the Kidney Care sale, we entered into certain agreements as described above (including a transition services agreement and a manufacturing and supply agreement). These agreements provide for the performance of services, and the provision of certain dialysis-related products, other products and product components, by each company for the benefit of the other for a period of time. If Vantive is unable to satisfy its obligations under these agreements, including its supply and indemnification obligations, we could incur losses. Additionally, in the event that Vantive asserts claims for breaches of any of these agreements, our indemnity obligations and other liabilities to Vantive under these agreements could be significant. These arrangements could also lead to disputes over rights to certain shared property and rights and over the allocation of costs and revenues for products and operations. Our inability to effectively manage these activities and related events could adversely affect our business, financial condition or results of operations.

We have incurred, and will continue to incur, significant expenses in connection with the sale of our Kidney Care business. For example, we will continue to incur the costs of providing transition services, products and product components to Vantive under the agreements described above and other stranded costs that we will no longer be able to share with the Kidney Care business and which we may not be able to fully offset. Such expenses have been significant, and may continue to grow. In addition, the anticipated benefits of the sale are based on a number of assumptions, some of which may prove incorrect, and we cannot predict with certainty when the expected benefits will occur, or the extent to which they will be achieved. As a result, even with the completed sale of the Kidney Care business, we may not achieve some or all of the anticipated strategic, financial, operational or other benefits in the expected timeframe, or at all, which could adversely impact our business, results of operations, financial condition and cash flows. Further, the sale of the Kidney Care business results in a smaller, less diversified company, with more limited and concentrated businesses than before the transaction, which may leave us more vulnerable to changing market conditions.

Additionally, until the market has fully analyzed our valuation following the sale of the Kidney Care business, the price of our common stock may continue to fluctuate even after a sufficient amount of time has passed for the market to fully analyze our valuation following the sale of the Kidney Care business. Our common stock may not match some holders' investment strategies or meet minimum criteria for inclusion in stock market indices or portfolios, causing certain investors to sell their shares, which could in turn lead to declines in the trading price of such stock. Furthermore, with the sale having decreased the diversification of our revenues, costs and cash flows, our operations, cash flows, working capital, effective tax rate and financing requirements may be subject to increased volatility, and our ability to fund capital expenditures and investments, pay dividends and meet debt obligations and other liabilities may be diminished.

We may continue to experience difficulties with our ongoing integration of Hillrom or fail to realize the anticipated benefits of the Hillrom acquisition.

During 2021, we completed the acquisition of Hillrom. The success of this acquisition depends on, among other things, our ability to complete the integration of Hillrom in a manner that facilitates growth opportunities, realizes anticipated cost and revenue synergies and achieves certain previously communicated net leverage targets without adversely affecting current revenues and investments in future growth. If we are not able to successfully achieve these objectives (including completing the ongoing integration), the anticipated benefits of the Hillrom acquisition may not be realized fully, or at all, or may take longer to realize than expected.

There is a significant degree of difficulty and management distraction inherent in the process of integrating an acquisition. The integration of Hillrom into our operations is complex and time-consuming and certain aspects have taken longer than originally anticipated and have required more effort than was originally planned. Challenges associated with our integration efforts are also heightened due to the other strategic actions we have recently completed (including the sale of our Kidney Care business). This has resulted in, and may continue to result in, additional expenses and other difficulties as we work to complete the integration, including challenges consolidating certain operations and functions (including regulatory and other corporate functions), integrating technologies

(including differing information technology systems and processes), organizations, procedures, policies and operations and addressing differences in the business cultures of the two companies, any of which could adversely affect our ability to achieve the anticipated benefits of the acquisition. The integration process and other disruptions resulting from the Hillrom acquisition and our recently completed strategic initiatives also disrupt our ongoing businesses and could cause inconsistencies in standards, controls, procedures and policies that adversely affect our relationships with market participants, employees, regulators and others with whom we have business or other dealings. Any failure to successfully or cost-effectively integrate Hillrom could have a material adverse effect on our business and cause reputational harm.

If our business strategy and development activities are unsuccessful, our business, results of operations, financial condition and cash flows could be adversely affected.

While we remain committed to deleveraging, we expect to engage in significant business development activities over the longer term in a manner that is consistent with our net leverage targets, including evaluating acquisitions, joint development opportunities, technology licensing arrangements and other opportunities, such as potential divestitures and targeted market exits as we look to optimize our product portfolio and improve our operating margins. These activities may result in substantial investment of our resources. Our success developing products, expanding into new markets and optimizing our market presence from such activities will depend on a number of factors, including our ability to find suitable opportunities or partners for acquisition, investment, alliance or divestiture; competition from other companies in the industries in which we operate that are seeking similar opportunities; whether we are able to complete an acquisition, investment, alliance or divestiture on terms that are satisfactory to us or at all; the strength of the underlying technology and products of any of the other parties involved in a transaction, as well as their ability to execute their business strategies; any intellectual property and litigation related to any other party's products or technology; and our ability to successfully integrate the acquired company, business, product, technology or research into our existing operations (or to divest such company, business, product, technology or research from our existing operations), including the ability to adequately fund acquired in-process R&D projects and to maintain adequate controls over the combined operations. Certain of these activities are subject to antitrust and competition laws, which could impact our ability to pursue strategic transactions and could result in mandated divestitures in the context of proposed acquisitions. Additionally, certain divestitures could result in negative market or regulatory reactions. If we are unsuccessful in our business development activities, we may not realize the intended benefits of such activities, including that acquisition and integration or divestiture costs may be greater than expected or the possibility that the expected return on investment, synergies and accretion will not be realized or will not be realized within the expected timeframes. For more information, see Note 3 in Item 8 of this Annual Report on Form 10-K.

Risks Relating to Our Financial Performance and Our Common Stock

Global economic conditions, including inflation and supply chain disruptions, have adversely affected, and could continue to adversely affect, our operations.

General global economic downturns and macroeconomic trends, including heightened inflation, capital markets volatility, interest rate and currency rate fluctuations, changes in monetary policy and economic slowdown or recession, have resulted in, and may continue to result in, unfavorable conditions that negatively affect demand for our products and exacerbate other risks described in this "Risk Factors" section that affect our business, results of operations, financial condition and cash flows. Both domestic and international markets have been experiencing significant inflationary pressures in recent years and inflation rates in the U.S., as well as in other countries in which we operate, are currently expected to continue at elevated levels for the near term. In addition, increases in interest rates and volatility in currency exchange rates have negatively impacted, and may continue to negatively impact, our results of operations. See "Risks Relating to Our Financial Performance and Our Common Stock – Changes in foreign currency exchange rates and interest rates have had, and may in the future have, an adverse effect on our results of operations, financial condition, cash flows and liquidity".

We have experienced significant challenges to our global supply chain in recent periods, including production delays and interruptions, increased costs and shortages of raw materials and component parts (including resins and electromechanical devices), heightened inventory levels to reduce the risk of patient supply disruption and higher transportation and labor costs, resulting from significant weather events (including Hurricane Helene), elevated inflation levels, disruptions to certain ports of call around the world, the war in Ukraine, the conflict in the Middle East and other geopolitical events. Due to the nature of our products, which include dense consumable medical products such as IV fluids, and the geographic locations of our manufacturing, storage and distribution facilities, which were further consolidated in anticipation of the recent Kidney Care sale and which often require us to transport our products long distances, we may be more susceptible to increases in freight costs and other supply

4H

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Hill-Rom Company, Inc.

Physical Address: 1430 Greg St., Suite 508

City: Sparks State: NV Zip: 89431

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

City: Dublin State: OH Zip: 43017

Telephone: 775.331.1335 Website: www.hillrom.com

Name of Designated Representative (DR): Jay Dacuycuy

Licensing Company Email: licensure@cardinalhealth.com DR Email: Jay_Dacuycuy@Baxter.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
■ Others: Clinics		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Baxter Healthcare Corporation Disclosures

The corporate owner of the applicant facility is Baxter Healthcare Corporation. Accordingly, as part of this application we have provided disclosures pertaining to state disciplinary actions and charges against Baxter Healthcare Corporation, as well as the specific individuals listed on the application. We cannot answer application questions with respect to all owners and shareholders, given that Baxter Healthcare Corporation is a subsidiary of Baxter International Inc., a publicly traded company listed on the New York Stock Exchange. We also cannot answer with respect to all Baxter Healthcare Corporation employees given the scope of Baxter's US operations.

FDA-related information regarding specific Baxter Healthcare Corporation facilities (e.g., inspection history and enforcement actions) can be found on the FDA website.

State Disciplinary Actions

Utah, License # 12435996-1710, 2023

On February 17, 2023, The Utah Board of Pharmacy issued a citation for failure to timely notify the Board of the change in designated representative at the Baxter Byhalia, MS location. Baxter paid the fine and is waiting for the final signed order.

Utah, Pharmacy Class C License # 9451291-1710, 2022

On May 31, 2022, The Utah Department of Commerce issued a Citation and Order due to a failure to file a timely notification of the change in the designated representative at the Baxter - Hayward (W. Winton) location. Baxter resolved the matter and paid a reduced fine.

Idaho, Out of State Mail Service Pharmacy License # 36855MS, 2022

On March 3, 2022, The Idaho Board of Pharmacy issued an Order and Stipulation for violations stemming from an expired non-resident PIC registration. The registration has since been approved by the Board. Baxter has signed the Stipulation and paid the required fine.

Alabama, Permit #194460, 2022

On May 3, 2022, The Alabama Board of Pharmacy issued a citation for failure to notify the Board of the change in designated representative at the Baxter – Hayward (W. Winton location). Baxter resolved the matter and paid the required fine.

Georgia, Wholesaler Pharmacy License # PHWH001754, 2017

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the

settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice. This issue is unrelated to Baxter's pharmacy or wholesale activities.

Baxter disclosed this issue on a renewal application for a Georgia wholesale license for its Marion, NC facility, and in October 2017, the state of Georgia issued a disciplinary order against that license (PHWH001754) based on the disclosure.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities. Iowa,

Nonresident Pharmacy License # 4127, 2014

The Iowa Board of Pharmacy (the "Iowa Board") issued a Stipulation for Baxter's Omaha, Nebraska pharmacy due to improperly delegating final verification of prescriptions for peritoneal dialysis solutions to a pharmacy technician. The Omaha facility is licensed in Nebraska under a Delegated Dispensing Permit, and utilized multiple quality checks, including retrospective pharmacist review, to ensure proper dispensing of peritoneal dialysis products to patients. Upon request by the Iowa Board, Baxter promptly modified its operations to ensure pharmacist verification of all orders. Baxter has signed the Stipulation and paid the required fine.

Montana, License #2152, 2010

The Montana Board of Pharmacy (the "Montana Board") issued a Stipulation for violations stemming from the failure of Baxter to notify the Montana Board in the requisite time frame of a change in the designated Person-in-Charge for the Waukegan, IL facility. Baxter has signed the Stipulation and paid the required fine.

Alabama, License #191639, 2009

The Alabama Board of Pharmacy found the Buford, GA facility was in violation of Code of Alabama (1975) Section 34-23-32. The facility continued distribution operations during the time between the valid license expired and when the expired license was renewed. Baxter Healthcare renewed the license, signed a Consent Order and paid the applicable fine.

Florida, Non-Resident Drug Manufacturer Permit No.: 26:4672, 2009

The Florida Department of Health (the "Florida Department") alleged that Baxter (Memphis, TN) sold prescription drugs to an unpermitted facility in Florida in violation of Section 499.005(15), F.S. Specifically, the Florida Department alleged that Baxter sold prescription drugs to Invivo at an unpermitted location. Baxter entered into a settlement agreement, whereby it neither admitted nor denied the allegations, and paid a fine.

Louisiana, License #3691, 2008

Louisiana Board of Wholesale Drug Distributors conducted a routine inspection of the f[illegible] operated by Baxter's third-party logistics provider. Inspectors concluded Baxter (Round Lake, IL)

violated Louisiana Administrative Code 46:XCI.311.D, which requires a licensee to maintain copies of current licenses for its customers who are authorized to obtain and possess legend drugs and devices. Baxter obtained customer licenses, signed a Consent Order, and paid the applicable fine.

Missouri, License #2005002668, 2005

The Missouri Board of Pharmacy (the "Missouri Board") issued a restricted drug distributor license to the facility located in Memphis, TN. The Missouri Board determined the facility violated Section 338.333.1 and 338.337.1 RSMo because the facility shipped legend drugs and/or medical devices into the state without being properly licensed. The proper license was obtained. The probationary period was successfully completed on October 21, 2007 and the restriction on the license was removed.

State Non-Disciplinary Settlements for Memphis Facility

Florida, License #s 26:506 (Memphis, TN) and 26:384 (Marion, NC), 2015

In June 2015, the Florida Department of Business and Professional Regulation (the "Department") sent Notices of Violation to Baxter alleging the shipment of prescription

drugs to a Baptist Health South Florida, Inc. ("Baptist"), prior to Baptist receiving its permit to operate as a restricted prescription drug distributor — health care entity. Baxter had shipped products to the Baptist address under the valid medical license of the Medical Director, in reliance on a document evidencing the Medical Director's intent that he serve as the purchaser of the product. In August 2015, Baxter and the Department resolved the matter via a non-disciplinary settlement.

Other Actions: Dismissed Charge of Drug Law Violation

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities, or the facility that is the subject of this application.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Indiana

Parent Company (if any): See org chart enclosed - ultimate parent company is Baxter International, Inc.

Corporation Name: HILL-ROM COMPANY, INC.

Mailing Address: 1 Baxter Pkwy

City: Deerfield State: IL Zip: 60015

Telephone: 614.757.8789 Email: licensure@cardinalhealth.com

Contact Person Name: LaToyia Martin

Date of SEC Registration: 03/21/2994	SEC Registration Number: 0000010456	Stock Exchange Symbol: BAX

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of <u>all</u> Officers and Directors.**	✓	✓		
• **List the <u>top four</u> corporation shareholders and their percent ownership.**	✓			
• **List of <u>all</u> corporation shareholders and their percent ownership.**		✓		
• **List of <u>all</u> partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
<u>ONLY</u> Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Hill-Rom Company Inc.

Facility Name

LaToyia M. Martin

Print Name of Authorized Person Submitting Application

LaToyia M. Martin

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

3/6/2025

Date

Board Use Only	Date Received: 3/7/25	Amount: $100.00 ✓

Hill-Rom Company, Inc.
Top Suppliers

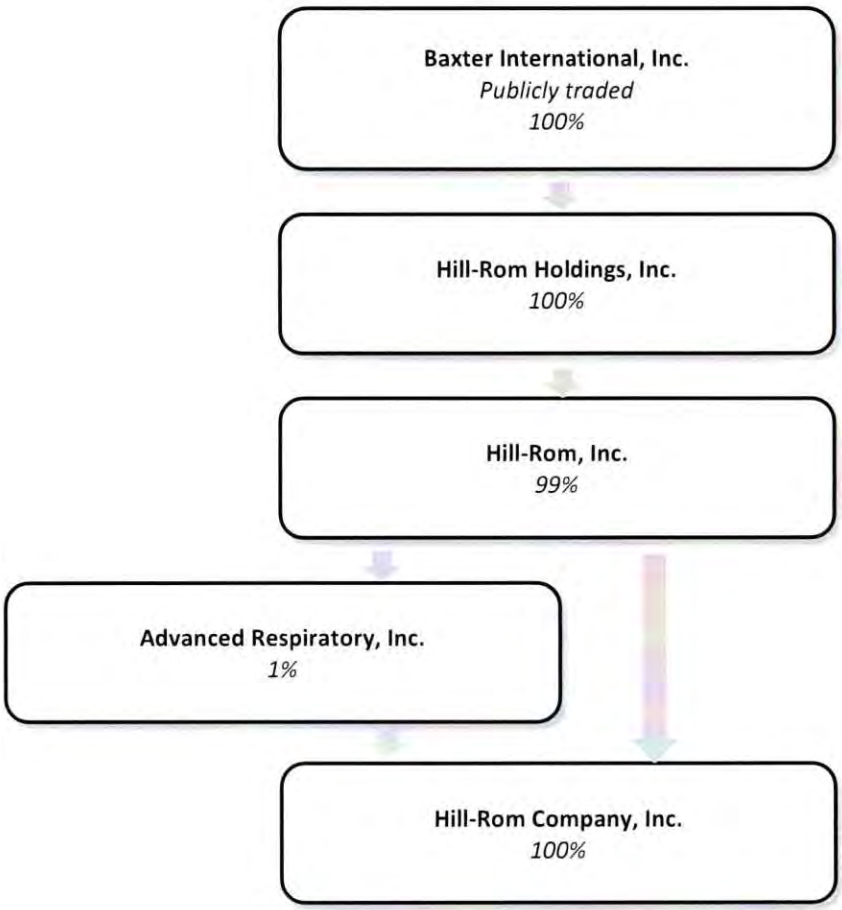
1. **Sur-Seal Corp**
   6156 Selman Rd
   Cincinnati, OH 45248

2. **Flextronics Sales & Marketing North Asia**
   Labuan Financial Parks Complex Unit 7
   Labuan, Malaysia 87000

3. **Plexus Xiamen Co LTD**
   No 6 Xiangxing 2 Rd
   Xiamen, Fujian, China 361006

4. **Zeus Battery Products**
   191 Covington Dr
   Bloomingdale, IL 60108

Hill-Rom Company, Inc. Organizational Chart



State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

HILL-ROM COMPANY, INC.

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on December 22, 1981, and was in existence or authorized to transact business in the State of Indiana on January 06, 2025.

I further certify this Domestic For-Profit Corporation has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, January 06, 2025

Diego Morales

DIEGO MORALES
SECRETARY OF STATE

198112-634 / 20254161560

All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate

Expires on February 05, 2025.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **HILL-ROM COMPANY, INC.** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/18/1986, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/06/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502065420705
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 285077264

Application/License No. _____

HILL-ROM, COMPANY INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1430 Greg St., #508 Sparks, NV 89431 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 11, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of February, 20 25.

APPLICANT/PRINCIPAL
HILL-ROM, COMPANY INC.

Sarah Padgett
Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Tara A. Maquinto, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Roger Paralson

Witness Corinne Chapman

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8213091-285057

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aaron D. Griffin; Aerie Walton; Bartlomiej Siepierski; Christina L. Sandoval; Corinne Chapman; Dartonya Wright; Derek J. Elston; Jean Torres; Jennifer L. Jakaitis; Jessica B. Dempsey; Judith A. Lucky-Eftimov; Kristin L. Hannigan; Melissa L. Fortier; Nicholas Kertesz; Richard Casas; Robert Nachreiner; Roger Paraison; Samantha Chierici; Sandra M. Winsted; Susan A. Welsh; Tara A. Maquinto

all of the city of Chicago state of IL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 6th day of February, 2025.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 6th day of February, 2025 before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 11th day of February, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

LMS-12873 LMIC OCIC WAIC Multi Co 02/24

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 08/27/2024

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

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

PRODUCER
Aon Risk Services Central, Inc.
Chicago IL Office
200 East Randolph
Chicago IL 60601 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Old Republic Insurance Company	24147
INSURER B:	Illinois Union Insurance Company	27960
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Baxter International Inc and All Affiliates, Divisions, and Subsidiaries thereof including Baxter Healthcare Corp and Hillrom Holdings, Inc.
One Baxter Parkway
Deerfield IL 60015-4633 USA

COVERAGES **CERTIFICATE NUMBER:** 570107836082 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR X Contractual Liability GEN'L AGGREGATE LIMIT APPLIES PER: POLICY X PRO-JECT LOC OTHER:			MWZY5782024	09/01/2024	09/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$2,000,000 $50,000 $25,000 $2,000,000 $4,000,000 Excluded
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY X HIRED AUTOS ONLY SCHEDULED AUTOS X NON-OWNED AUTOS ONLY			MWTB 20158 24	09/01/2024	09/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$5,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION			XEUG27981604009 SIR applies per policy terms & conditions	09/01/2024	09/01/2025	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		MWC11550217 All Other States	09/01/2024	09/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $2,000,000 $2,000,000 $2,000,000
A	Excess Workers Compensation			MWXS82924 Workers Comp Excess IL CE SIR applies per policy terms & conditions	09/01/2024	09/01/2025	EL Each Accident EL Disease - Policy EL Disease - Ea Emp	$1,500,000 $1,500,000 $1,500,000

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

For General liability, Products Liability and Automobile liability Additional insured status is provided to all parties Baxter is required by written contract to name as additional insured(s), including, where required by written contract, on a primary and non-contributory basis. Such status is limited to the operations of Baxter under said contract, subject to the liability and indemnity terms of the contract and subject to the terms and conditions of the policy.
For General liability, Products Liability, Automobile liability and Workers' Compensation where required by written contract, waiver of subrogation is provided. Such waiver is limited to the operations of Baxter under said contract, subject to the liability and indemnity terms of the contract and subject to the terms and conditions of the policy.

CERTIFICATE HOLDER

Baxter International, Inc. and All Affiliates, Divisions and Subsidiaries thereof including Baxter Healthcare Corp. and Hillrom Holdings, Inc.
One Baxter Parkway
Deerfield IL 60015-4633 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570107836082

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AGENCY CUSTOMER ID: 10224186
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Baxter International Inc and All
POLICY NUMBER: See Certificate Number: 570107836082	
CARRIER: See Certificate Number: 570107836082 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
A	Products Liability			MWZY31692224 SIR applies per policy terms & conditions	09/01/2024	09/01/2025	Each Occurrence	$5,000,000
							Products - Comp/Op Agg	$5,000,000

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AGENCY CUSTOMER ID: 10224186
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Baxter International Inc and All
POLICY NUMBER: See Certificate Number: 570107836082	
CARRIER: See Certificate Number: 570107836082 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

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

Additional Description of Operations / Locations / Vehicles:

For General liability and Products Liability where required by written contract, aggregate limits apply on a per project basis.
Excess/Umbrella liability follows form over the General Liability, Automobile liability and Workers' Compensation policies.

ACORD 101 (2008/01)
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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Hill-Rom Company, Inc. MDEG License # (if applicable) _____

Physical Address 1430 GREG ST #508

City SPARKS State NV Zip 89431

Mailing Address (if different from physical address) ~~N/A~~ 7000 Cardinal Place, Attn: QRA

City Dublin State OH Zip 43017

Telephone 800.445.3730 Website www.baxter.com

Licensing Company Email jay_dacuycuy@baxter.com

Section 2: Personal Information

First JAY Middle _____ Last DACUYCUY

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

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

Mailing Address [redacted]

City West Sacramento State CA Zip [redacted]

Telephone [redacted] Email Jay_Dacuycuy@baxter.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)
California State University, Stanislaus			09/92-06/95
Address	**City**	**State**	**Zip**
1 University Cir	Turlock	CA	95382
Diploma/Degree obtained, if any			
MBA			

School Name			From - To (MM/YY – MM/YY)
California State University, Stanislaus			09/87-06/91
Address	**City**	**State**	**Zip**
1 University Cir	Turlock	CA	95382
Diploma/Degree obtained, if any			
Bachelor of Science, Business			

School Name			From - To (MM/YY – MM/YY)
Central Catholic High School			09/83-06/87
Address	**City**	**State**	**Zip**
200 S Carpenter Rd,	Modesto	CA	95351
Diploma/Degree obtained, if any			
Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/01-02/25	[redacted]	West Sacramento	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Hill-Rom Company, Inc.				
Business Address		**City**	**State**	**Zip**
830 Riverside Parkway, Ste 90		West Sacramento	CA	95605
Phone	**Title**		**Number of Employed Hours**	
(279) 219-8836	Service Operations Manager		5200	
Description of Duties				
Manages an area that provides medical products in Northern California and Northern Nevada.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/13/2025
Date

I, Jay Dacuycuy, **certify that as the MDEG Administrator for**

Hill-Rom Company, Inc.,

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

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

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

Jay Dacuycuy
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

February 13, 2025
Date

Board Use Only	Date Received: 3/7/25

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 1-4448

Baxter

Baxter International Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	36-0781620
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
One Baxter Parkway, Deerfield, Illinois	60015
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code 224.948.2000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock, $1.00 par value	BAX (NYSE)	New York Stock Exchange
1.3% Global Notes due 2025	BAX 25	New York Stock Exchange
1.3% Global Notes due 2029	BAX 29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files) Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), based on tha assumption for the purpose of this computation only that all of the registrant's directors and executive officers are affiliates, wes approximately $17 billion. The number of shares of the registrant's common stock, $1.00 par value, outstanding as of February 13, 2025 was 511,624,996.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive 2024 proxy statement for use in connection with its Annual Meeting of Stockholders expected to be held on May 6, 2025 are incorporated by reference into Part III of this report.

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PART I

Item 1. *Business.*

Company Overview

Baxter International Inc., through its subsidiaries, provides a broad portfolio of essential healthcare products, including sterile intravenous (IV) solutions; infusion systems and devices; parenteral nutrition therapies; inhaled anesthetics; generic injectable pharmaceuticals; surgical hemostat and sealant products, advanced surgical equipment; smart bed systems; patient monitoring and diagnostic technologies; and respiratory health devices. These products are used by hospitals, nursing homes, rehabilitation centers, ambulatory surgery centers, doctors' offices, kidney dialysis centers and patients at home under physician supervision. Our global footprint and the critical nature of our products and services play a key role in expanding access to healthcare in emerging and developed countries. As of December 31, 2024, after giving effect to the recent sale of our Kidney Care business (as discussed below), we manufactured products in over 20 countries and sold them in over 100 countries.

Baxter International Inc. was incorporated under Delaware law in 1931. As used in this report, "Baxter International" means Baxter International Inc. and "we", "our" or "us" means Baxter International and its consolidated subsidiaries, unless the context otherwise requires.

Recent Strategic Actions

In mid-2022, our Board of Directors authorized a strategic review of our business portfolio, with the goal of increasing stockholder value. As part of that review process, we identified and evaluated a range of potential strategic actions, including opportunities for sales and other separation transactions. In January 2023, following the completion of that review, we announced a number of planned strategic actions, as discussed below, which are intended to enhance our operational effectiveness, accelerate innovation and drive additional stockholder value. We completed the last of these strategic actions on January 31, 2025 in connection with the sale of our Kidney Care business.

Sale of Kidney Care Business

On August 12, 2024, we entered into an Equity Purchase Agreement (EPA) with certain affiliates of Carlyle Group Inc. (Carlyle) to sell our Kidney Care business. That business, which is now known as Vantive Health LLC (Vantive) is comprised of our former Kidney Care segment and provides chronic and acute dialysis therapies and services, including peritoneal dialysis, hemodialysis, continuous renal replacement therapies, and other organ support therapies. On January 31, 2025, we completed the sale of our Kidney Care business to Carlyle for an aggregate purchase price of $3.80 billion in cash, subject to certain closing cash, working capital and debt adjustments. After giving effect to certain adjustments, we received approximately $3.71 billion pre-tax cash proceeds at closing of the transaction with the net after tax proceeds currently estimated to be approximately $3.4 billion, subject to certain post-closing adjustments. We determined that our Kidney Care business met the criteria to be classified as held-for-sale in August 2024, and we also concluded that it met the conditions to be reported as a discontinued operation at that time. Accordingly, our Kidney Care business is reported in discontinued operations in the accompanying consolidated financial systems, and our prior period results have been adjusted to reflect discontinued operations presentation.

Implementation of New Operating Model and Resulting Segment Change

Our reportable segments were previously comprised of the following geographic segments related to our legacy Baxter business: Americes (North and South America), EMEA (Europe, Middle East and Africa) and APAC (Asia Pacific), and a global segment for the Hill-Rom Holdings, Inc. (Hillrom) business we acquired in December 2021. In the third quarter of 2023, we completed the implementation of a new operating model intended to simplify and streamline our operations and better align our manufacturing and supply chain to our commercial activities. Under this operating model, our business is currently comprised of three reportable segments: Medical Products & Therapies, Healthcare Systems & Technologies, and Pharmaceuticals. Our segment reporting was changed during the third quarter of 2023 to align with our new operating model, and all periods presented are under the new operating model.

Sale of BPS Business

On September 29, 2023, we completed the sale of our BioPharma Solutions (BPS) business and received cash proceeds of $3.96 billion from that transaction. The results of operations and cash flows of our BPS business, including the $2.88 billion pre-tax gain ($2.59 billion net of tax) from the sale of that business and the related cash proceeds received, are reported as discontinued operations in the accompanying consolidated financial statements. We used substantially all of the after-tax proceeds from this transaction to repay certain of our debt obligations, including $514 million of commercial paper borrowings and $2.28 billion of long-term debt that we repaid during the fourth quarter of 2023, as well as €750 million of senior notes that we repaid during the second quarter of 2024.

Business Segments and Products

We currently manage our global operations based on three reportable segments: Medical Products & Therapies, Healthcare Systems & Technologies and Pharmaceuticals.

The Medical Products & Therapies segment includes sales of our sterile IV solutions, infusion systems, administration sets, parenteral nutrition therapies and surgical hemostat, sealant and adhesion prevention products. The Healthcare Systems & Technologies segment includes sales of our connected care solutions and collaboration tools, including smart bed systems, patient monitoring systems and diagnostic technologies, respiratory health devices and advanced equipment for the surgical space, including surgical video technologies, precision positioning devices and other accessories. The Pharmaceuticals segment includes sales of specialty injectable pharmaceuticals, inhaled anesthetics and drug compounding services.

For financial information about our segments, see Note 18 in Item 8 of this Annual Report on Form 10-K.

Business Strategy

Our business strategy is focused on driving sustainable growth and innovation aligned with our mission to save and sustain lives and our vision to transform healthcare with a customer focus to help improve patient outcomes, enhance workflow efficiency, and enable cost-effective care. Our diversified and broad portfolio of medical products that treat acute or chronic conditions and our global presence are core components of our strategy as we work to achieve these objectives. We are focused on key strategic pillars as part of our pursuit of industry leading performance: innovation; operational efficiency; and capital allocation.

Innovation

Our innovation strategy, which encompasses both organic and inorganic initiatives, is focused on accelerating our sales growth through the introduction of new connected care and core therapy offerings. Connected care offerings include devices or software that can digitally connect, communicate and/or analyze data to help transform healthcare and improve patient outcomes, and we are continuing to build out our connected care portfolio offerings, which includes smart bed systems, infusion pumps, patient monitoring and diagnostic technologies, respiratory health devices and advanced equipment for the surgical space. Our core therapy product offerings include pharmaceuticals and consumable medical products designed to address essential patient and provider needs across the continuum of care.

As part of this strategy, we are prioritizing investments that drive innovation in product areas where we believe we have compelling opportunities to better serve patients and healthcare professionals, particularly in markets with higher growth rates. We are working to accelerate the pace at which we bring these advances to market to support our future growth. We are in the midst of launching (or have recently launched) several new products, geographic expansions and line extensions in areas such as smart pump technology, hospital pharmaceuticals and nutritionals, surgical sealants, smart beds, respiratory vests and more. These comprise a mix of entirely new product offerings and meaningful improvements to existing technologies.

Portfolio Optimization

Our strategy also involves active portfolio management in the interest of maximizing value for Baxter stockholders and best positioning Baxter for long-term success. The recent Kidney Care sale has given us enhanced flexibility to deploy (or in some cases redeploy) capital toward opportunities that seek to accelerate our growth objectives,

whether as a result of innovation or expanding our portfolio geographically or as a result of channel expansion or market development activities.

Operational Excellence

As discussed above under "Recent Strategic Actions," in the third quarter of 2023, we implemented a new operating model intended to simplify and streamline our operations and better align our manufacturing and supply chain to our commercial activities. We believe these changes will allow us to be a more integrated and nimble organization that can respond more effectively to operational challenges and changes in the macroeconomic environment while enhancing our ability to drive innovation in our product portfolio. We also continue to focus on increasing efficiencies through automation and digitization. We intend to continue to actively manage our cost structure and strive to commit resources to the highest value uses. Such high value activities include supporting innovation, actively managing the portfolio, expanding patient access and accelerating growth for our stockholders.

Maintaining Disciplined and Balanced Capital Allocation

Subject to market conditions and our investment grade targets, our capital allocation strategies currently include the following:

- debt repayments to support our deleveraging commitments;
- active portfolio management through the identification of attractive acquisition and divestiture transactions, including the recent divestitures of our BPS and Kidney Care businesses; and
- returning capital to stockholders through dividends, while balancing any returns with other strategic actions we take. We also intend to reinstate share repurchases over the longer term.

We paid down $3.65 billion of net debt during 2024 and through February 21, 2025 using proceeds from the sales of our BPS and Kidney Care businesses, and we are committed to retaining our investment grade rating, including taking actions toward achieving a net leverage target of approximately 3.0x by the end of 2025 through ongoing debt repayment and financing activities. During this deleveraging period, we currently intend to continue paying a dividend (which we reduced in November 2024), not make any share repurchases and be highly selective with respect to any potential acquisitions.

Sales and Distribution

We have our own direct sales force and also make sales to and through independent distributors, drug wholesalers acting as sales agents and specialty pharmacy or other alternate site providers. In the United States, third parties, such as Cardinal Health, Inc., warehouse and ship a significant portion of our products through their distribution centers. These centers are generally stocked with adequate inventories to facilitate prompt customer service. Sales and distribution methods include frequent contact by sales and customer service representatives, automated communications via various electronic purchasing systems, circulation of catalogs and merchandising bulletins, direct-mail campaigns, trade publication presence and advertising.

Sales are made and products are distributed on a direct basis or through independent distributors or sales agents in more than 100 countries as of December 31, 2024, giving effect to the sale of our Kidney Care business.

International Operations

A significant portion of our revenues are generated outside of the United States and thoughtful geographic expansion remains a key component of our strategy. Our international presence includes operations in Europe, the Middle East, Africa, Asia-Pacific, Latin America and Canada. We are subject to certain risks inherent in conducting business outside the United States. For more information on these risks, see the information under the captions "Risks Relating to Our Business—We are subject to risks associated with doing business globally" and "—Changes in foreign currency exchange rates and interest rates have had, and may in the future have, an adverse effect on our results of operations, financial condition, cash flows and liquidity" in Item 1A. Risk Factors of this Annual Report on Form 10-K.

For financial information about our foreign and domestic revenues and segment information, see Note 18, in Item 8 of this Annual Report on Form 10-K. For more information regarding foreign currency exchange risk, refer to the

discussion under the caption entitled "Financial Instrument Market Risk" in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report on Form 10-K.

Contractual Arrangements

Our products are sold through contracts with customers, both within and outside the United States. Some of these contracts have terms of more than one year and place limits on our ability to increase prices. In the case of hospitals, governments and other facilities, these contracts may specify minimum quantities of a particular product or categories of products to be purchased by the customer.

In keeping with the increased emphasis on cost-effectiveness in healthcare delivery, many hospitals and other customers of medical products in the United States have joined group purchasing organizations (GPOs), or formed integrated delivery networks (IDNs), to enhance purchasing power. GPOs and IDNs negotiate pricing arrangements with manufacturers and distributors and the negotiated prices are made available to members. We have purchasing agreements with several of the major GPOs in the United States, which are subject to renewal from time to time. GPOs may have agreements with more than one supplier for certain products. Accordingly, in these cases, we face competition from other suppliers even where a customer is a member of a GPO under contract with us, which may constrain our ability to secure negotiated price increases. Purchasing power is similarly consolidated in many other countries. For example, public contracting authorities often act as the purchasing entities for the hospitals and other customers of medical products in their region and many hospitals and other customers have joined joint procurement entities and buying consortia. The result is that demand for healthcare products is increasingly concentrated across our markets globally. Additionally, our contractual pricing arrangements with GPOs, IDNs and public contracting authorities can sometimes limit our ability to increase prices in order to offset raw materials or component price increases or otherwise. Some of these agreements contain failure to supply clauses with varying remedies, inclusive of limited termination rights.

Raw Materials and Component Parts

Raw materials and component parts essential to our business are purchased from numerous suppliers worldwide in the ordinary course of business. While many of these materials are generally available, we have experienced and may in the future experience shortages of supply. Additionally, certain of these materials are secured from single source suppliers or on a spot basis and not pursuant to a contractual arrangement.

In an effort to manage risk associated with raw materials and component supply, we work closely with our suppliers to help ensure availability and continuity of supply while maintaining high quality and reliability. We also seek to develop new and alternative sources of supply where beneficial to our overall raw materials procurement strategy. Refer to Item 1A. Risk Factors of this Annual Report on Form 10-K for further information regarding risks related to the supply chain, raw materials and component parts (including with respect to the qualification of any new or alternative supplier).

We are not always able to recover cost increases for raw materials and component parts through customer pricing due to contractual limits, where applicable, and market forces. For example, during 2022 and 2023, our profit margins were adversely impacted because we were unable to fully offset all related cost increases resulting from the high inflationary environment through customer pricing adjustments or other pricing actions. Additionally, our profit margins were negatively impacted in the fourth quarter of 2024 (and may continue to be negatively impacted in the short term) because we were unable to fully offset the increased supply chain costs associated with our ongoing North Cove recovery efforts (including as a result of importing additional product from outside the United States to support IV solutions demand). We seek to utilize long-term supply contracts with some suppliers to help maintain continuity of supply and manage the risk of price increases. Our ability to do so in the face of limited supply of certain raw materials and component parts and inflationary environment has been and may in the future be limited.

Competition and Healthcare Cost Containment

Our businesses benefit from a number of competitive advantages, including the breadth and depth of our product offerings and our strong relationships with customers, including hospitals and clinics, GPOs, IDNs, physicians and patients, many of whom self-administer home-based therapies that we supply. We also benefit from efficiencies and cost advantages resulting from shared manufacturing facilities and the technological advantages of our products.

Although no single company competes with us in all of our businesses, we face substantial competition in each of our segments from international and domestic healthcare, medical products and pharmaceutical companies and providers of all sizes, and these competitors often differ across our businesses. In addition, global and regional competitors continue to expand their manufacturing capacity and sales and marketing channels. We believe customer purchasing decisions are primarily focused on cost-effectiveness, price, service, product performance and technological innovation. There has been consolidation in our customer base and by our competitors, which has resulted and continues to result in pricing and market pressures.

1. Global efforts toward healthcare cost containment continue to exert pressure on product pricing. Governments around the world use various mechanisms to control healthcare expenditures, such as price controls, the formation of public contracting authorities, product formularies (lists of recommended or approved products), and competitive tenders which require the submission of a bid to sell products. Sales of our products are dependent, in part, on the availability of reimbursement by government agencies and healthcare programs, as well as insurance companies and other private payers. In the United States, the federal government and many states have adopted or proposed initiatives relating to Medicaid and other health programs that may limit reimbursement or increase rebates that we and other providers are required to pay to the state. In addition to government regulation, managed care organizations in the United States, which include medical insurance companies, medical plan administrators, health-maintenance organizations, hospital and physician alliances and pharmacy benefit managers, continue to put pressure on the price and usage of healthcare products. Managed care organizations seek to contain healthcare expenditures, and their purchasing strength has been increasing due to their consolidation into fewer, larger organizations and a growing number of enrolled patients. We face similar issues outside of the United States. In Europe and Latin America, for example, the government provides healthcare at low cost to patients, and controls its expenditures by purchasing products through public tenders, collective purchasing, regulating prices, setting reference prices in public tenders or limiting reimbursement or patient access to certain products. Additionally, China has been implementing volume-based procurement policies and a series of centralized reforms on both a national and regional basis which have resulted in significant price cuts for pharmaceuticals and medical consumables. For further discussion, refer to Item 1A. Risk Factors of this Annual Report on Form 10-K.

Intellectual Property

Patents and other proprietary rights are essential to our business. We rely on patents, trademarks, copyrights, trade secrets, know-how and confidentiality agreements to develop, maintain and strengthen our competitive position. We own numerous patents and trademarks throughout the world and have entered into license arrangements relating to various third-party patents and technologies. Products manufactured by us are sold primarily under our own trademarks and trade names. Some products distributed by us are sold under our trade names, while others are sold under trade names owned by our suppliers or partners. Trade secret protection of unpatented confidential and proprietary information is also important to us. We maintain certain details about our processes, products and technology as trade secrets and generally require employees, consultants, and business partners to enter into confidentiality agreements. These agreements may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, and business partners use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our policy is to protect our products and technology through patents and trademarks on a worldwide basis. This protection is sought in a manner that balances the cost of such protection against obtaining the greatest value for us. We also recognize the need to promote the enforcement of our patents and trademarks and take commercially reasonable steps to enforce our patents and trademarks around the world against potential infringers, including judicial or administrative action where appropriate.

We operate in an industry susceptible to significant patent litigation. At any given time, we are involved as either a plaintiff or defendant in a number of patent infringement and other intellectual property-related actions. Such litigation can result in significant royalty or other payments or result in injunctions that can prevent the sale of products. For more information on patent and other litigation, see Note 8 in Item 8 of this Annual Report on Form 10-K.

Research and Development

We believe our investment in research and development (R&D), consistent with our portfolio optimization and capital allocation strategies, will help fuel our future growth and our ability to remain competitive. Accordingly, we continue to focus our investment on select R&D programs to enhance future growth through clinical differentiation. Expenditures for our R&D activities were $590 million in 2024, $518 million in 2023, and $450 million in 2022. These expenditures include costs associated with R&D activities performed at our R&D centers located around the world, which include facilities in Belgium, India, Italy, Malta and the United States, as well as in-licensing, milestone and reimbursement payments made to partners for R&D work performed at non-Baxter locations. As discussed above in under "Recent Strategic Actions," in the third quarter of 2023, we implemented a new operating model intended to simplify and streamline our operations, including with respect to our R&D activities. We are also working to create a more resilient supply chain and better align our manufacturing footprint and supply chain to our commercial activities. These activities may result in the consolidation of one or more R&D facilities.

For more information on our R&D activities, refer to the discussion under the caption entitled "Strategic Objectives" in Item 7. Management's Discussion of Analysis and Financial Condition and Results of Operations of this Annual Report on Form 10-K.

Quality Management

Our continued success depends upon the quality of our products. Quality management plays an essential role in determining and meeting customer requirements, helping to prevent defects, facilitating continuing improvement of our processes, products and services, and helping to assure the safety and efficacy of our products. Our quality system enables the design, development, manufacturing, packaging, sterilization, handling, distribution and labeling of our products to help ensure that they conform to customer requirements. In order to consistently improve the effectiveness and efficiency of our quality system, various measurement, monitoring and analysis methods, such as management reviews and internal, external and vendor audits, are employed at local and central levels.

Each product that we market is required to meet specific quality standards, both in packaging and in product integrity and quality. If any of those is determined to be compromised at any time, we endeavor to take corrective and preventive actions designed to ensure compliance with regulatory requirements and to meet customer expectations. For more information on corrective actions taken by us, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7. Management's Discussion of Analysis and Financial Condition and Results of Operations of this Annual Report on Form 10-K.

Corporate Responsibility

Driven by our mission to save and sustain lives, Baxter's corporate responsibility strategy focuses on addressing corporate responsibility matters that affect our patients, customers, employees, communities and other critical stakeholders worldwide. Advancing our corporate responsibility goals contributes to business, social and economic value, including attraction and retention of employees, enhanced operational efficiency and implementation of enterprise risk management strategies, among others.

In 2021, we launched our 2030 Corporate Responsibility Commitment featuring strategic goals for focused action. Our Commitment is anchored by three pillars - Empower our Patients, Protect our Planet and Champion our People and Communities. The 2030 Corporate Responsibility Commitment and Goals highlight Baxter's corporate responsibility focus and help to further advance our corporate responsibility performance. We expect to announce a refreshed Corporate Responsibility commitment and goal set after the issuance of our 2024 Corporate Responsibility Report (to be issued in June 2025), either in a separate announcement or as part of the 2025 Corporate Responsibility Report. This timing should allow for a new, permanent CEO to have the opportunity to review and contribute to our commitment and goals and to reflect recent operational and other developments (including the recent Kidney Care sale). Our progress against our current goals and commitments is published annually in our Corporate Responsibility Report which is available on our website under "Our Story-Corporate Responsibility." The Corporate Responsibility Report is not incorporated by reference into this Annual Report on Form 10-K or any other document filed with the SEC.

Government Regulation

As a medical products company, our operations and many of the products manufactured or sold by us are subject to extensive regulation by numerous government agencies, both within and outside the United States. The Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) and the Medicines &

Healthcare products Regulatory Agency (MHRA) in Europe, the National Medical Products Administration (NMPA) in China and other government agencies, inside and outside of the United States, administer requirements covering the testing, safety, effectiveness, manufacturing, labeling, promotion and advertising, distribution and post-market surveillance of our products. We must obtain specific clearance, approval or other marketing authorization from FDA and non-U.S. regulatory authorities before we can market and sell most of our products in a particular country. Even after we obtain regulatory authorization to market a product, additional regulatory authorization may be necessary to maintain the product in the market, including additional 501(k) clearances, new drug approval (NDA) supplements, and other regulatory submissions. In addition, the raw materials, manufacturing facilities, processes and quality systems used in the manufacture of a product are subject to continued review by FDA and other regulatory authorities globally. State agencies in the United States also regulate our facilities, operations, employees, products and services within their respective states. We, along with our facilities, are subject to periodic inspections and possible administrative and legal actions by FDA and other regulatory agencies inside and outside the United States. Such actions may include warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. As situations require, we take steps to ensure the safety and efficacy of our products, such as removing products from the market that are found not to meet applicable requirements and improving the effectiveness of quality systems. For more information on compliance actions taken by us, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7. Management's Discussion of Analysis and Financial Condition and Results of Operations of this Annual Report on Form 10-K.

We are also subject to various laws inside and outside the United States concerning our relationships with healthcare professionals and government officials, price reporting and regulation, the promotion, sales and marketing of our products and services, the importation and exportation of products, the operation of our facilities and the distribution of products. In the United States, we are subject to the oversight of FDA, Office of the Inspector General within the Department of Health and Human Services (OIG), the Center for Medicare/Medicaid Services (CMS), the Department of Justice (DOJ), Environmental Protection Agency, Department of Defense and Customs and Border Protection in addition to others. We supply products and services to healthcare providers that are reimbursed by federally funded programs such as Medicare. As a result, our activities are subject to regulation by CMS and enforcement by OIG and DOJ. In each jurisdiction outside the United States, our activities are subject to regulation by government agencies including the EMA and MHRA in Europe, NMPA in China and other agencies in other jurisdictions. Many of the agencies enforcing these laws have increased their enforcement activities with respect to healthcare companies in recent years. These actions appear to be part of a general trend toward increased enforcement activity globally.

Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. Our environmental policies require compliance with all applicable environmental regulations and contemplate, among other things, appropriate capital expenditures for environmental protection.

Human Capital Management

As of December 31, 2024, after giving effect to the Kidney Care sale, we employed approximately 38,000 people globally, with approximately 15,000 employees in the United States and approximately 23,000 employees outside of the United States. Our employees set the foundation for our ability to achieve our strategic objectives. They contribute to our success and are instrumental in driving operational execution and our ability to deliver strong financial performance, advancing innovation and maintaining a strong quality and compliance program across our organization.

The success and growth of our business depends in large part on our ability to attract, retain and develop talented and high-performing employees at all levels of our organization with a myriad of backgrounds and experiences, including the individuals who comprise our global workforce as well as executive officers and other key personnel. To succeed in a competitive labor market, we have developed recruitment and retention strategies, objectives and measures that we focus on as part of the overall management of our business. These strategies, objectives and measures form our human capital management framework and are advanced through the following programs, policies and initiatives:

- **Competitive Pay and Benefits.** Our compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate

employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance.

- **Health and Safety.** Health and safety are firmly rooted across our global footprint. We aim for a zero-harm workplace and prioritize the elimination of risks and incident precursors to drive improvement. In 2024, Baxter focused on employee engagement, hazard identification and accelerated technology deployment to better understand and address top health and safety risk areas. We have continued to mobilize our hazard identification program for our operational workforce, in concert with a centralized corrective action tracking tool. These improvements have enabled us to harvest actionable insights, support ergonomic evaluations and implement safety control technology for improved operation of our powered industrial vehicles.
- **Recruitment, Training and Development.** We use recruitment vehicles to attract talent to our organization and we prioritize learning opportunities that foster a growth mindset. Our formal offerings include a tuition reimbursement program, an e-learning platform known as BaxU and virtual workshops that support our culture, strategy and the development of crucial skills. To assess the impact of the investments we make in our people, and to help us consistently improve our human resources programs, we regularly conduct anonymous surveys of our global workforce to seek feedback on a variety of topics including confidence in our leadership, competitiveness of our compensation and benefits packages, career growth opportunities and improvements on how we can make our company an employer of choice. Administered and analyzed by an independent third-party, the survey results are reviewed by our senior leaders, which include our executive officers. Summaries of select surveys are also provided to our Board of Directors. The results of this engagement survey are also shared with individual managers, who are then tasked with taking action based on their employees' anonymous feedback.

Available Information

We make available free of charge on our website at www.baxter.com our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), as soon as reasonably practicable after electronically filing or furnishing such material with the Securities and Exchange Commission. These reports are also available free of charge via EDGAR through the Securities and Exchange Commission website (www.sec.gov). In addition, our Corporate Governance Guidelines, Code of Conduct, and the charters for the committees of our Board of Directors are available on our website at www.baxter.com under "Our Story — Our Governance." All the foregoing materials will be made available to stockholders in print upon request by writing to: Corporate Secretary, Baxter International Inc., One Baxter Parkway, Deerfield, Illinois 60015. Information contained on our website shall not be deemed incorporated into, or to be a part of, this Annual Report on Form 10-K.

Item 1A. *Risk Factors.*

In addition to the other information in this Annual Report on Form 10-K, stockholders or prospective investors should carefully consider the following risk factors for a description of the principal risks that we face. If any of the events described below occurs, our business, results of operations, financial condition, cash flows, future growth prospects and stock price could suffer. Further, other unknown or unpredictable factors could also have material adverse effects on our future results.

Risk Factors Summary

This summary of risks below is intended to provide an overview of the risks we face and should not be considered a substitute for the more detailed risk factors discussed immediately following this summary.

Risks Relating to Our Strategic Actions

- We are exposed to risks as a result of our strategic actions, including the recent sale of our Kidney Care business.
- We may continue to experience difficulties with our ongoing integration of Hillrom or fail to realize the anticipated benefits of the Hillrom acquisition.
- If our business strategy and development activities are unsuccessful, our business, results of operations, financial condition and cash flows could be adversely affected.

Risks Relating to Our Financial Performance and Our Common Stock

- Global economic conditions, including inflation and supply chain disruptions, have adversely affected, and could continue to adversely affect, our operations.
- Our operating results and financial condition have fluctuated and may in the future continue to fluctuate.
- We may not achieve our financial goals.
- Our common stock price has fluctuated significantly and may continue to do so.
- Our significant indebtedness requires us to use a substantial amount of our cash flow for debt service and could constrain our flexibility in responding to unanticipated or adverse business conditions and adversely affect our business, results of operations, financial condition and cash flows.
- Changes in foreign currency exchange rates and interest rates have had, and may in the future have, an adverse effect on our results of operations, financial condition, cash flows and liquidity.
- Future material impairments in the value of our goodwill, intangible assets and other long-lived assets, would negatively affect our operating results.
- We cannot guarantee that in the future we will not further reduce the amount of dividends we pay.

Risks Relating to Our Business

- If we are unable to successfully introduce or monetize new and existing products or services, or fail to keep pace with changing consumer preferences and needs or advances in technology, our business, results of operations, financial condition and cash flows could be adversely affected.
- Issues with quality management or product quality could, among other things, have an adverse effect on our business or cause a loss of customer confidence in us or our products.
- There is substantial competition in the product markets in which we operate and the risk of declining demand and pricing pressures could adversely affect our business, results of operations, financial condition and cash flows.
- If we fail to attract, develop, retain and engage key employees, including a permanent Chief Executive Officer (CEO) and other members of our senior management, our business may suffer.
- Pandemics and other public health emergencies, or the fear thereof, have had, and may in the future have, a material adverse effect on our business.

Risks Relating to Our Operations

- Segments of our business are significantly dependent on major contracts with GPOs, IDNs, and certain other distributors and purchasers.
- We may not be successful in achieving expected operating efficiencies and sustaining or improving operating expense reductions and may experience business disruptions and adverse tax consequences associated with restructuring, realignment and cost reduction activities.
- If we are unable to obtain sufficient components or raw materials on a timely basis or for a cost-effective price or if we experience other manufacturing, sterilization, supply or distribution difficulties, our business, results of operations, financial condition and cash flows may be adversely affected.
- Breaches and breakdowns affecting our information technology systems or protected information, including from obsolescence, cyber security breaches and data leakage, could have a material adverse effect on us.
- Incorporating artificial intelligence, machine learning and other emerging technologies into our products, services and operations exposes us to legal and regulatory risks and could result in reputational harm or have other adverse consequences to our business, financial condition or results of operations.

- Climate change, or legal, regulatory or market measures to address climate change, could adversely affect our business, results of operations, financial condition and cash flows.
- Our commitments, goals and disclosures related to corporate responsibility matters, and the perception of our activities in these areas, may adversely impact the company, including through reputational harm.
- We are subject to risks associated with doing business globally.
- A portion of our workforce is unionized, and we could face labor disruptions that would interfere with our operations.

Risks Relating to Legal and Regulatory Matters

- We are subject to a number of laws and regulations, and we are susceptible to a changing regulatory environment.
- Increasing regulatory focus on, and expanding laws relating to, privacy, artificial intelligence and cybersecurity could impact our business and expose us to increased liability.
- If reimbursement or other payment for our current or future products is reduced or modified in the United States or in foreign countries or there are changes to policies with respect to pricing, taxation or rebates, our business could suffer.
- We could be subject to fines or damages and possible exclusion from participation in federal or state healthcare programs if we fail to comply with the laws and regulations applicable to our business.
- If we are unable to protect or enforce our patents or other proprietary rights, or if we become subject to claims or litigation alleging infringement of the patents or other proprietary rights of others, our competitiveness and business prospects may be materially damaged.
- Changes in tax laws or exposure to additional income tax liabilities may have a negative impact on our operating results.
- We are party to a number of pending lawsuits and other disputes which may have an adverse impact on our business, results of operations, financial condition and cash flows.
- Our Amended and Restated By-Laws could limit our stockholders' ability to choose their preferred judicial forum for disputes with us or our directors, officers, or employees.

Risks Relating to Our Recent and Ongoing Strategic Actions

We are exposed to risks as a result of our strategic actions, including the recent sale of our Kidney Care business.

Our businesses have begun to face, and will continue to face, material challenges in connection with the sale of our Kidney Care business and the other strategic actions we have undertaken (including the implementation of a simplified operating model and the ongoing simplification of our manufacturing footprint). The success of the sale of our Kidney Care business depends on, among other things, our ability to effectively transition the Kidney Care business to Carlyle in a manner that: minimizes disruption to our customers, employees, other personnel and operations; realizes the expected tax benefits; avoids potential liabilities or claims; and enables us to achieve related cost savings initiatives. The Kidney Care sale may result in challenges such as: the diversion of management's attention from our ongoing business concerns and any newly identified strategic initiatives; attracting, retaining and motivating key management and other employees; retaining existing, or attracting new, business and operational relationships, including with customers, suppliers, employees and other counterparties; maintaining our relationships with regulators; the potential for disputes or litigation with Carlyle or Vantive, as applicable, arising from the transaction, the EPA or the various agreements (including a transition services agreement and a manufacturing and supply agreement) that we entered into with Vantive in connection with the Kidney Care closing (as further described below) and liabilities and obligations otherwise related to the transaction, the EPA or the other agreements described in this paragraph; the potential for exposure related to certain pre-closing Kidney Care liabilities we retained; the potential for adverse tax consequences or changes in tax laws or

regulations that could affect our remaining businesses; the potential for regulatory actions or investigations related to the transaction or the businesses involved; and potential negative reactions from the financial markets, ratings agencies, customers, employees, other personnel or other stakeholders.

In addition, in the last few years, we have undertaken other strategic and business transformation actions (including the divestiture of our BPS business, the acquisition of Hillrom and cost reduction initiatives) that have entailed changes across our organizational structure, senior leadership, culture, functional alignment, outsourcing and other areas. These actions pose risks in the form of personnel capacity constraints and institutional knowledge loss that has led to, and could in the future lead to, missed performance of financial targets (including those related to cost savings initiatives) and harm to our reputation.

In connection with the closing of the Kidney Care sale, we entered into certain agreements as described above (including a transition services agreement and a manufacturing and supply agreement). These agreements provide for the performance of services, and the provision of certain dialysis-related products, other products and product components, by each company for the benefit of the other for a period of time. If Vantive is unable to satisfy its obligations under these agreements, including its supply and indemnification obligations, we could incur losses. Additionally, in the event that Vantive asserts claims for breaches of any of these agreements, our indemnity obligations and other liabilities to Vantive under these agreements could be significant. These arrangements could also lead to disputes over rights to certain shared property and rights and over the allocation of costs and revenues for products and operations. Our inability to effectively manage these activities and related events could adversely affect our business, financial condition or results of operations.

We have incurred, and will continue to incur, significant expenses in connection with the sale of our Kidney Care business. For example, we will continue to incur the costs of providing transition services, products and product components to Vantive under the agreements described above and other stranded costs that we will no longer be able to share with the Kidney Care business and which we may not be able to fully offset. Such expenses have been significant, and may continue to grow. In addition, the anticipated benefits of the sale are based on a number of assumptions, some of which may prove incorrect, and we cannot predict with certainty when the expected benefits will occur, or the extent to which they will be achieved. As a result, even with the completed sale of the Kidney Care business, we may not achieve some or all of the anticipated strategic, financial, operational or other benefits in the expected timeframe, or at all, which could adversely impact our business, results of operations, financial condition and cash flows. Further, the sale of the Kidney Care business results in a smaller, less diversified company, with more limited and concentrated businesses than before the transaction, which may leave us more vulnerable to changing market conditions.

Additionally, until the market has fully analyzed our valuation following the sale of the Kidney Care business, the price of our common stock may continue to fluctuate even after a sufficient amount of time has passed for the market to fully analyze our valuation following the sale of the Kidney Care business. Our common stock may not match some holders' investment strategies or meet minimum criteria for inclusion in stock market indices or portfolios, causing certain investors to sell their shares, which could in turn lead to declines in the trading price of such stock. Furthermore, with the sale having decreased the diversification of our revenues, costs and cash flows, our operations, cash flows, working capital, effective tax rate and financing requirements may be subject to increased volatility, and our ability to fund capital expenditures and investments, pay dividends and meet debt obligations and other liabilities may be diminished.

We may continue to experience difficulties with our ongoing integration of Hillrom or fail to realize the anticipated benefits of the Hillrom acquisition.

During 2021, we completed the acquisition of Hillrom. The success of this acquisition depends on, among other things, our ability to complete the integration of Hillrom in a manner that facilitates growth opportunities, realizes anticipated cost and revenue synergies and achieves certain previously communicated net leverage targets without adversely affecting current revenues and investments in future growth. If we are not able to successfully achieve these objectives (including completing the ongoing integration), the anticipated benefits of the Hillrom acquisition may not be realized fully, or at all, or may take longer to realize than expected.

There is a significant degree of difficulty and management distraction inherent in the process of integrating an acquisition. The integration of Hillrom into our operations is complex and time-consuming and certain aspects have taken longer than originally anticipated and have required more effort than was originally planned. Challenges associated with our integration efforts are also heightened due to the other strategic actions we have recently completed (including the sale of our Kidney Care business). This has resulted in, and may continue to result in, additional expenses and other difficulties as we work to complete the integration, including challenges consolidating certain operations and functions (including regulatory and other corporate functions), integrating technologies

(including differing information technology systems and processes), organizations, procedures, policies and operations and addressing differences in the business cultures of the two companies, any of which could adversely affect our ability to achieve the anticipated benefits of the acquisition. The integration process and other disruptions resulting from the Hillrom acquisition and our recently completed strategic initiatives also disrupt our ongoing businesses and could cause inconsistencies in standards, controls, procedures and policies that adversely affect our relationships with market participants, employees, regulators and others with whom we have business or other dealings. Any failure to successfully or cost-effectively integrate Hillrom could have a material adverse effect on our business and cause reputational harm.

If our business strategy and development activities are unsuccessful, our business, results of operations, financial condition and cash flows could be adversely affected.

While we remain committed to deleveraging, we expect to engage in significant business development activities over the longer term in a manner that is consistent with our net leverage targets, including evaluating acquisitions, joint development opportunities, technology licensing arrangements and other opportunities, such as potential divestitures and targeted market exits as we look to optimize our product portfolio and improve our operating margins. These activities may result in substantial investment of our resources. Our success developing products, expanding into new markets and optimizing our market presence from such activities will depend on a number of factors, including our ability to find suitable opportunities or partners for acquisition, investment, alliance or divestiture; competition from other companies in the industries in which we operate that are seeking similar opportunities; whether we are able to complete an acquisition, investment, alliance or divestiture on terms that are satisfactory to us or at all; the strength of the underlying technology and products of any of the other parties involved in a transaction, as well as their ability to execute their business strategies; any intellectual property and litigation related to any other party's products or technology; and our ability to successfully integrate the acquired company, business, product, technology or research into our existing operations (or to divest such company, business, product, technology or research from our existing operations), including the ability to adequately fund acquired in-process R&D projects and to maintain adequate controls over the combined operations. Certain of these activities are subject to antitrust and competition laws, which could impact our ability to pursue strategic transactions and could result in mandated divestitures in the context of proposed acquisitions. Additionally, certain divestitures could result in negative market or regulatory reactions. If we are unsuccessful in our business development activities, we may not realize the intended benefits of such activities, including that acquisition and integration or divestiture costs may be greater than expected or the possibility that the expected return on investment, synergies and accretion will not be realized or will not be realized within the expected timeframes. For more information, see Note 3 in Item 8 of this Annual Report on Form 10-K.

Risks Relating to Our Financial Performance and Our Common Stock

Global economic conditions, including inflation and supply chain disruptions, have adversely affected, and could continue to adversely affect, our operations.

General global economic downturns and macroeconomic trends, including heightened inflation, capital markets volatility, interest rate and currency rate fluctuations, changes in monetary policy and economic slowdown or recession, have resulted in, and may continue to result in, unfavorable conditions that negatively affect demand for our products and exacerbate other risks described in this "Risk Factors" section that affect our business, results of operations, financial condition and cash flows. Both domestic and international markets have been experiencing significant inflationary pressures in recent years and inflation rates in the U.S., as well as in other countries in which we operate, are currently expected to continue at elevated levels for the near term. In addition, increases in interest rates and volatility in currency exchange rates have negatively impacted, and may continue to negatively impact, our results of operations. See "Risks Relating to Our Financial Performance and Our Common Stock – Changes in foreign currency exchange rates and interest rates have had, and may in the future have, an adverse effect on our results of operations, financial condition, cash flows and liquidity".

We have experienced significant challenges to our global supply chain in recent periods, including production delays and interruptions, increased costs and shortages of raw materials and component parts (including resins and electromechanical devices), heightened inventory levels to reduce the risk of patient supply disruption and higher transportation and labor costs, resulting from significant weather events (including Hurricane Helene), elevated inflation levels, disruptions to certain ports of call around the world, the war in Ukraine, the conflict in the Middle East and other geopolitical events. Due to the nature of our products, which include dense consumable medical products such as IV fluids, and the geographic locations of our manufacturing, storage and distribution facilities, which were further consolidated in anticipation of the recent Kidney Care sale and which often require us to transport our products long distances, we may be more susceptible to increases in freight costs and other supply

HILL-ROM COMPANY, INC.

DESIGNATION OF AUTHORITY

WHEREAS, the Board of Directors of Hill-Rom Company, Inc., an Indiana corporation (the "Corporation") and a wholly-owned subsidiary of Baxter International Inc. ("Baxter"), adopted Ordinary Course of Business resolutions on December 13, 2021 (the "Resolution"), a copy of which is attached hereto as Exhibit A; and

WHEREAS, pursuant to the Resolutions, the Corporation's elected officers and employees of the Corporation having the job classifications set forth in Exhibit A of the Resolutions (each an "Authorized Signatory") are authorized and directed to sign any documents relating to matters within the Authorized Signatory's respective job responsibilities, commonly necessary and ineidental to the Corporation's business and the execution of which is in the best interest of the Corporation; and

WHEREAS, capitalized terms used and not otherwise defined herein shall have the meanings ascribed to such terms in the Resolutions.

NOW THEREFORE:

1. In accordance with the Resolutions, the undersigned Authorized Signatory hereby designates the following employees of Cardinal Health 200 LLC, as a Delegation entitled to exercise the signing authority granted to her as an Authorized Signatory in the Resolutions, provided, however, that such signing authority shall be limited to signing all documents, applications, submissions and other related instruments required for the state pharmacy, wholesale distribution, and manufacturing licenses and legally required permits filed on behalf of the Corporation.

NAME	TITLE
Keegan Chamberlain	Directory of Quality Management, Cardinal Health 200 LLC
LaToyia Martin	Manager, Quality Compliance, Cardinal Health 200 LLC

1. The Secretary or any Assistant Secretary is authorized and directed, upon request of any interested party, to certify as to the authority of the foregoing person to exercise the signing authority set forth above in accordance with the Resolutions and this Designation.

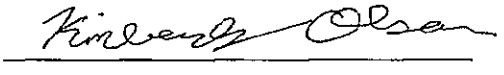
2. The Secretary or any Assistant Secretary is authorized and directed to file this Designation in the minute book of the Corporation.

3. This delegation of authority shall be effective until December 31, 2025 and is subject to revocation by any officer of the Corporation at any time and shall occur automatically when Keegan Chamberlain or LaTovia Martin ceases to be an employee of Cardinal Health 200 LLC.

February 17, 2025.

Effective Date

Hill-Rom Company, Inc.



Kimberly Olson
Assistant Secretary
Authorized Signatory

EXHIBIT A

Hill-Rom, Inc.
Ordinary Course of Business Resolutions
December 13, 2021

ORDINARY COURSE OF BUSINESS RESOLUTIONS

NOW, THEREFORE, BE IT RESOLVED, that the Corporation's elected officers and employees of the Corporation having the job classifications set forth in Exhibit D (each an "Authorized Signatory") are authorized and directed to sign any documents relating to matters within the Authorized Signatory's respective job responsibilities, commonly necessary and incidental to the Corporation's business and the execution of which is in the best interest of the Corporation;

FURTHER RESOLVED, that each Authorized Signatory shall have the authority to execute such documents that are within the financial limitations as set forth on Exhibit D, which may be updated from time to time without further resolution;

FURTHER RESOLVED, that any Authorized Signatory is authorized to delegate signing authority ("Delegation") to another individual with such limitations as the Authorized Signatory may establish from time to time, provided however, that any such Delegation shall be in writing in the form of Delegation provided by the office of the Secretary of the Corporation and shall be subject to any limits set forth therein by the Authorized Signatory;

FURTHER RESOLVED, that when signing authority is delegated, an original of any such Delegation shall be delivered to the Secretary of the Corporation to be retained as a part of the permanent records of the Corporation; and

FURTHER RESOLVED, that the Secretary or an Assistant Secretary of the Corporation is authorized to attest to the signatures of the Authorized Signatories and affix the seal of the Corporation to such documents, however such documents shall be the binding obligation of the Corporation without the necessity of attestation or affixing of the corporate seal.

EXHIBIT D

ORDINARY COURSE OF BUSINESS

SIGNATURE AUTHORITY TABLE

JOB CLASSIFICATION	FINANCIAL LIMITATION
Chief Executive Officer, Executive Vice President or any Senior Vice President	**No limitations**
Global Franchise Unit Head	**Up to $10 Million**

Vice President (including General Manager)	**Up to $5 Million**
Director	**Up to $1 Million**

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NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: Hill-Rom Manufacturing, Inc.

Physical Address: 1020 West County Road F W

City: St. Paul State: MN Zip: 55126

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

City: Dublin State: OH Zip: 43017

Telephone: 800.426.4224 Website: www.hillrom.com

Name of Designated Representative (DR): Christian Kiely

Licensing Company Email: Licensure@CardinalHealth.com DR Email: Christian_Kiely@Baxter.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Clinics		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

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

Provide explanation below:

See attached

LaToyia Martin LaToyia M. [illegible]
Original Signature (electronic, copies or stamps not accepted)

10/31/24
Date

Baxter Healthcare Corporation Disclosures

The corporate owner of the applicant facility is Baxter Healthcare Corporation. Accordingly, as part of this application we have provided disclosures pertaining to state disciplinary actions and charges against Baxter Healthcare Corporation, as well as the specific individuals listed on the application. We cannot answer application questions with respect to all owners and shareholders, given that Baxter Healthcare Corporation is a subsidiary of Baxter International Inc., a publicly traded company listed on the New York Stock Exchange. We also cannot answer with respect to all Baxter Healthcare Corporation employees given the scope of Baxter's US operations.

FDA-related information regarding specific Baxter Healthcare Corporation facilities (e.g., inspection history and enforcement actions) can be found on the FDA website.

State Disciplinary Actions

Utah, License # 12435996-1710, 2023

On February 17, 2023, The Utah Board of Pharmacy issued a citation for failure to timely notify the Board of the change in designated representative at the Baxter Byhalia, MS location. Baxter paid the fine and is waiting for the final signed order.

Utah, Pharmacy Class C License # 9451291-1710, 2022

On May 31, 2022, The Utah Department of Commerce issued a Citation and Order due to a failure to file a timely notification of the change in the designated representative at the Baxter - Hayward (W. Winton) location. Baxter resolved the matter and paid a reduced fine.

Idaho, Out of State Mail Service Pharmacy License # 36855MS, 2022

On March 3, 2022, The Idaho Board of Pharmacy issued an Order and Stipulation for violations stemming from an expired non-resident PIC registration. The registration has since been approved by the Board. Baxter has signed the Stipulation and paid the required fine.

Alabama, Permit #194460, 2022

On May 3, 2022, The Alabama Board of Pharmacy issued a citation for failure to notify the Board of the change in designated representative at the Baxter – Hayward (W. Winton location). Baxter resolved the matter and paid the required fine.

Georgia, Wholesaler Pharmacy License # PHWH001754, 2017

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the

settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice. This issue is unrelated to Baxter's pharmacy or wholesale activities.

Baxter disclosed this issue on a renewal application for a Georgia wholesale license for its Marion, NC facility, and in October 2017, the state of Georgia issued a disciplinary order against that license (PHWH001754) based on the disclosure.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities. Iowa,

Nonresident Pharmacy License # 4127, 2014

The Iowa Board of Pharmacy (the "Iowa Board") issued a Stipulation for Baxter's Omaha, Nebraska pharmacy due to improperly delegating final verification of prescriptions for peritoneal dialysis solutions to a pharmacy technician. The Omaha facility is licensed in Nebraska under a Delegated Dispensing Permit, and utilized multiple quality checks, including retrospective pharmacist review, to ensure proper dispensing of peritoneal dialysis products to patients. Upon request by the Iowa Board, Baxter promptly modified its operations to ensure pharmacist verification of all orders. Baxter has signed the Stipulation and paid the required fine.

Montana, License #2152, 2010

The Montana Board of Pharmacy (the "Montana Board") issued a Stipulation for violations stemming from the failure of Baxter to notify the Montana Board in the requisite time frame of a change in the designated Person-in-Charge for the Waukegan, IL facility. Baxter has signed the Stipulation and paid the required fine.

Alabama, License #191639, 2009

The Alabama Board of Pharmacy found the Buford, GA facility was in violation of Code of Alabama (1975) Section 34-23-32. The facility continued distribution operations during the time between the valid license expired and when the expired license was renewed. Baxter Healthcare renewed the license, signed a Consent Order and paid the applicable fine.

Florida, Non-Resident Drug Manufacturer Permit No.: 26:4672, 2009

The Florida Department of Health (the "Florida Department") alleged that Baxter (Memphis, TN) sold prescription drugs to an unpermitted facility in Florida in violation of Section 499.005(15), F.S. Specifically, the Florida Department alleged that Baxter sold prescription drugs to Invivo at an unpermitted location. Baxter entered into a settlement agreement, whereby it neither admitted nor denied the allegations, and paid a fine.

Louisiana, License #3691, 2008

Louisiana Board of Wholesale Drug Distributors conducted a routine inspection of the facility operated by Baxter's third-party logistics provider. Inspectors concluded Baxter (Round Lake, IL)

violated Louisiana Administrative Code 46:XCI.311.D, which requires a licensee to maintain copies of current licenses for its customers who are authorized to obtain and possess legend drugs and devices. Baxter obtained customer licenses, signed a Consent Order, and paid the applicable fine.

Missouri, License #2005002668, 2005

The Missouri Board of Pharmacy (the "Missouri Board") issued a restricted drug distributor license to the facility located in Memphis, TN. The Missouri Board determined the facility violated Section 338.333.1 and 338.337.1 RSMo because the facility shipped legend drugs and/or medical devices into the state without being properly licensed. The proper license was obtained. The probationary period was successfully completed on October 21, 2007 and the restriction on the license was removed.

State Non-Disciplinary Settlements for Memphis Facility

Florida, License #s 26:506 (Memphis, TN) and 26:384 (Marion, NC), 2015

In June 2015, the Florida Department of Business and Professional Regulation (the "Department") sent Notices of Violation to Baxter alleging the shipment of prescription

drugs to a Baptist Health South Florida, Inc. ("Baptist"), prior to Baptist receiving its permit to operate as a restricted prescription drug distributor — health care entity. Baxter had shipped products to the Baptist address under the valid medical license of the Medical Director, in reliance on a document evidencing the Medical Director's intent that he serve as the purchaser of the product. In August 2015, Baxter and the Department resolved the matter via a non-disciplinary settlement.

Other Actions: Dismissed Charge of Drug Law Violation

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities, or the facility that is the subject of this application.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Indiana

Parent Company (if any): see org chart enclosed - ultimate parent company is Baxter International, Inc.

Corporation Name: Hill-Rom Manufacturing, Inc.

Mailing Address: 1069 State Route 46E

City: Batesville State: IN Zip: 47006

Telephone: 614.757.8789 Email: licensure@cardinalhealth.com

Contact Person Name: LaToyia Martin

Date of SEC Registration: 3/21/1994 | SEC Registration Number: 0000010456 | Stock Exchange Symbol: BAX

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Hill-Rom Manufacturing, Inc.
Facility Name

LaToyia Martin
Print Name of Authorized Person Submitting Application

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

10/31/24
Date

Board Use Only	Date Received: 11/1/24	Amount: $1000-ck 1090391

Establishment Registration & Device Listing

Establishment:
HILL-ROM MANUFACTURING, INC.
Business Trade Name:
Advanced Respiratory, Inc

1020 COUNTY ROAD F W
SAINT PAUL, MN 55126
Registration Number: 2183816
FEI Number*: 2183816
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
BAXTER HEALTHCARE CORPORATION
One Baxter Parkway
Deerfield, IL US 60015
Owner/Operator Number: 1417572

Official Correspondent:
Julie Carolan
One Baxter Parkway
Deerfield, IL 60015
Phone: 224-9086010

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Corporate Officer List

1020 County Road W
St. Paul, Minnesota 55126

Officer Name	Title	Company	Business Address	Business Phone Number
Reazur Rasul	President and Director	Hill-Rom Manufacturing, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-6990
Karen L. Leets	Vice President and Treasurer	Hill-Rom Manufacturing, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-2000
James William Borzi	SVP, Chief Supply Chain Officer	Hill-Rom Manufacturing, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-2100
Ellen K. Bradford	SVP and Corporate Secretary	Hill-Rom Manufacturing, Inc.	One Baxter Parkway, Deerfield, IL 60015	224-948-3086

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State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

HILL-ROM COMPANY, INC.

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on December 22, 1981, and was in existence or authorized to transact business in the State of Indiana on January 06, 2025.

I further certify this Domestic For-Profit Corporation has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, January 06, 2025

Diego Morales

DIEGO MORALES
SECRETARY OF STATE

198112-634 / 20254161560

All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate

Expires on February 05, 2025.

Work Item 1479770200024
Original File Number 1479770200024

STATE OF MINNESOTA
OFFICE OF THE SECRETARY OF STATE
FILED
06/24/2024 11:59 PM

Steve Simon
Secretary of State

Office of the Minnesota Secretary of State

Foreign Corporation/Certificate of Authority to Transact Business in Minnesota

Minnesota Statutes, Chapter 303

This Certificate of Authority has been approved pursuant to *Minnesota Statutes*, Chapter 303. By filing this Certificate of Authority, the company certifies that it has complied with the organization laws in the jurisdiction of its organization and that it has not filed previously with this office and been revoked and understands that if a filing was on record and revocation occurred this certificate of authority is null and void.

CORPORATE NAME in HOME JURISDICTION:

Hill-Rom Manufacturing, Inc.

CORPORATE NAME in MINNESOTA:

Hill-Rom Manufacturing, Inc.

If an alternate name is used, the company certifies that its board of directors has adopted and approved the alternate name for use in Minnesota.

HOME JURISDICTION:

Indiana

REGISTERED OFFICE AND AGENT(S):

Name Address:

C T Corporation System Inc

1010 DALE ST N SAINT PAUL MN 55117 5603 USA

If you submit an attachment, it will be incorporated into this document. If the attachment conflicts with the information specifically set forth in this document, this document supersedes the data referenced in the attachment.

By typing my name, I, the undersigned, certify that I am signing this document as the person whose signature is required, or as agent of the person(s) whose signature would be required who has authorized me to sign this document on his/her behalf, or in both capacities. I further certify that I have completed all required fields, and that the information in this document is true and correct and in compliance with the applicable chapter of Minnesota Stotutes. I understond that by signing this document I am subject to the penolties of perjury as set forth in Section 609.48 as if I had signed this document under oath.

SIGNED BY: **Kimberly Olson**

MAILING ADDRESS: **None Provided**

EMAIL FOR OFFICIAL NOTICES: **None Provided**

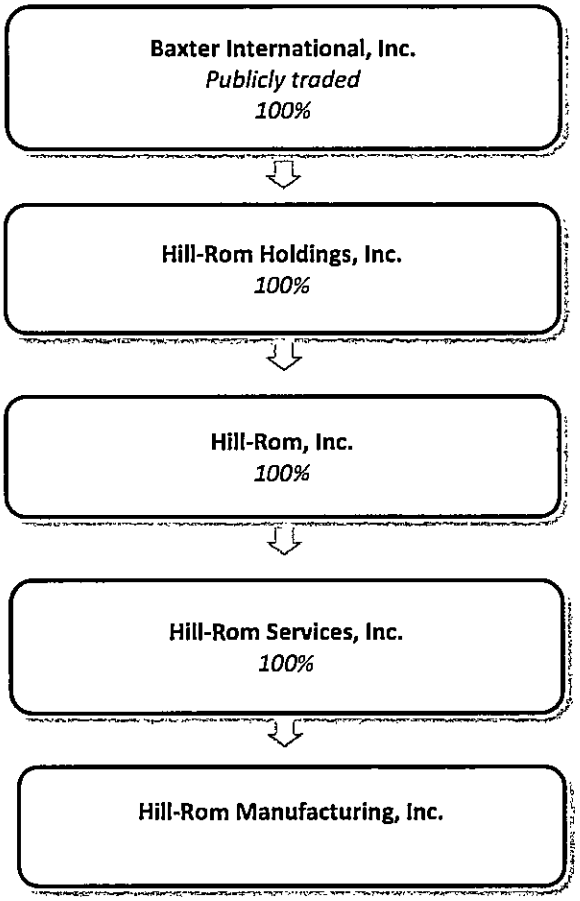
Does the Minnesota Board of Pharmacy license or register medical device or medical supply manufacturers, wholesale distributors, supplies or retailers?

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

1020 West County Road F
St. Paul, MN 55126

Hill-Rom Manufacturing, Inc.

Organizational Chart



State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

HILL-ROM MANUFACTURING, INC.

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on April 13, 1978, and was in existence or authorized to transact business in the State of Indiana on August 01, 2024.

I further certify this Domestic For-Profit Corporation has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, August 01, 2024

Diego Morales

DIEGO MORALES
SECRETARY OF STATE

197804-378 / 20243894014

All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate

Expires on August 31, 2024.

Office of the Minnesota Secretary of State
Certificate of Authority

I, Steve Simon, Secretary of State of Minnesota, do certify that: The following business entity has duly complied with the relevant provisions of Minnesota Statutes listed below, and is formed or authorized to do business in Minnesota on and after this date with all the powers, rights and privileges, and subject to the limitations, duties and restrictions, set forth in that chapter.

The business entity is now legally registered under the laws of Minnesota.

Name in Minnesota:	Hill-Rom Manufacturing, Inc.
Name in Home Jurisdiction:	Hill-Rom Manufacturing, Inc.
File Number:	1479770200024
Minnesota Statutes, Chapter:	303
Home Jurisdiction:	Indiana
This certificate has been issued on:	06/24/2024



Steve Simon
Secretary of State
State of Minnesota

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 08/27/2024

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

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

Holder Identifier :

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Chicago IL Office 200 East Randolph Chicago IL 60601 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Old Republic Insurance Company	24147
INSURER B:	Illinois Union Insurance Company	27960
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Baxter International Inc and All Affiliates, Divisions, and Subsidiaries thereof including Baxter Healthcare Corp and Hillrom Holdings, Inc.
One Baxter Parkway
Deerfield IL 60015-4633 USA

COVERAGES **CERTIFICATE NUMBER:** 570107836082 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR X Contractual Liability GEN'L AGGREGATE LIMIT APPLIES PER: POLICY X PRO-JECT LOC OTHER:			MWZY5782024	09/01/2024	09/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$2,000,000 $50,000 $25,000 $2,000,000 $4,000,000 Excluded
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY X HIRED AUTOS ONLY SCHEDULED AUTOS X NON-OWNED AUTOS ONLY			MWTB 20158 24	09/01/2024	09/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$5,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION			XEUG27981604009 SIR applies per policy terms & conditions	09/01/2024	09/01/2025	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N / N/A If yes, describe under DESCRIPTION OF OPERATIONS below			MWC11550217 All Other States	09/01/2024	09/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $2,000,000 $2,000,000 $2,000,000
A	Excess Workers Compensation			MWXS82924 Workers Comp Excess IL CE SIR applies per policy terms & conditions	09/01/2024	09/01/2025	EL Each Accident EL Disease - Policy EL Disease - Ea Emp	$1,500,000 $1,500,000 $1,500,000

Certificate No : 570107836082

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

For General liability, Products Liability and Automobile liability Additional insured status is provided to all parties Baxter is required by written contract to name as additional insured(s), including, where required by written contract, on a primary and non-contributory basis. Such status is limited to the operations of Baxter under said contract, subject to the liability and indemnity terms of the contract and subject to the terms and conditions of the policy.
For General liability, Products Liability, Automobile liability and Workers' Compensation where required by written contract, waiver of subrogation is provided. Such waiver is limited to the operations of Baxter under said contract, subject to the liability and indemnity terms of the contract and subject to the terms and conditions of the policy.

CERTIFICATE HOLDER

Baxter International, Inc. and All Affiliates, Divisions and Subsidiaries thereof including Baxter Healthcare Corp. and Hillrom Holdings, Inc.
One Baxter Parkway
Deerfield IL 60015-4633 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

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The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 10224186
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Baxter International Inc and All
POLICY NUMBER: See Certificate Number: 570107836082	
CARRIER: See Certificate Number: 570107836082 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
A	Products Liability			MWZY31692224 SIR applies per policy terms & conditions	09/01/2024	09/01/2025	Each Occurrence	$5,000,000
							Products - Comp/Op Agg	$5,000,000

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AGENCY CUSTOMER ID: 10224186
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Baxter International Inc and All
POLICY NUMBER: See Certificate Number: 570107836082	
CARRIER: See Certificate Number: 570107836082 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

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

Additional Description of Operations / Locations / Vehicles:

For General liability and Products Liability where required by written contract, aggregate limits apply on a per project basis.
Excess/Umbrella liability follows form over the General Liability, Automobile liability and Workers' Compensation policies.

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Hill-Rom Manufacturing, Inc.

Top Suppliers

1. **Flextronics Manufacturing**
   2 Changi South Lane
   Jit Logistics Centre
   Singapore, 486123

2. **Welch Allyn International Holdings, Inc.**
   Calle Emilio Flores 2471
   Otay Jardín, 22203
   Tijuana, B.C., Mexico

3. **AccuMED Corp.**
   155 Boyce Drive
   Mocksville, NC 27028

4. **Inventus Power, Inc.**
   1200 Internationale Parkway
   Woodridge, IL 60517

EXHIBIT A

BAXTER HEALTHCARE CORPORATION

ORDINARY COURSE OF BUSINESS
SIGNATURE AUTHORITY TABLE
(updated September 2017)

JOB CLASSIFICATION	FINANCIAL LIMITATION
Chief Executive Officer, Executive Vice President or any Senior Vice President	**No limitations**
Global Franchise Unit Head	**Up to $10 Million**
Vice President (including General Manager)	**Up to $5 Million**
Director	**Up to $1 Million**

BAXTER HEALTHCARE CORPORATION

DELEGATION OF AUTHORITY

As contemplated by the resolutions adopted by the Board of Directors of Baxter Healthcare Corporation, a Delaware corporation ("the Corporation"), effective September 15, 2017 ("Resolutions"), a copy of such Resolutions is attached hereto, the undersigned Ellen K. Bradford, Vice President and Secretary, an Authorized Employee of Baxter Healthcare Corporation, hereby delegates to Keegan Chamberlain, Director of Quality Management, and LaToyia Martin, Manager, Quality Compliance, employees of Cardinal Health 200 LLC, the authority to sign for all documents, applications, submissions and other related instruments required for the state pharmacy, wholesale distribution, and manufacturing licenses and legally required permits filed on behalf of Baxter Healthcare Corporation.

This delegation of authority shall be effective until December 31, 2024 and is subject to revocation by any officer of Baxter Healthcare Corporation at any time and shall occur automatically when Keegan Chamberlain or LaToyia Martin ceases to be an employee of Cardinal Health 200 LLC.

The undersigned further approves and ratifies any and all actions taken by Keegan Chamberlain and LaToyia Martin prior to this date, solely in connection with the execution of the above-referenced matters.

Effective: April 13, 2023

Baxter Healthcare Corporation

Ellen K. Bradford

Ellen K. Bradford
Vice President and Secretary

BAXTER HEALTHCARE CORPORATION

RESOLUTIONS FOR SIGNING AUTHORITY

September 15, 2017

RESOLVED, that the Corporation's elected officers and employees of the Corporation having the job classifications set forth in Exhibit A (each an "Authorized Signatory") are authorized and directed to sign any documents relating to matters within the Authorized Signatory's respective job responsibilities, commonly necessary and incidental to the Corporation's business and the execution of which is in the best interest of the Corporation;

FURTHER RESOLVED, that each Authorized Signatory shall have the authority to execute such documents that are within the financial limitations as set forth on Exhibit A, which may be updated from time to time without further resolution;

FURTHER RESOLVED, that any Authorized Signatory is authorized to delegate signing authority ("Delegation") to another individual with such limitations as the Authorized Signatory may establish from time to time, provided however, that any such Delegation shall be in writing in the form of Delegation provided by the office of the Secretary of the Corporation and shall be subject to any limits set forth therein by the Authorized Signatory;

FURTHER RESOLVED, that when signing authority is delegated, an original of any such Delegation shall be delivered to the Secretary of the Corporation to be retained as a part of the permanent records of the Corporation;

FURTHER RESOLVED, that the Secretary or an Assistant Secretary of the Corporation is authorized to attest to the signatures of the Authorized Signatories and affix the seal of the Corporation to such documents, however such documents shall be the binding obligation of the Corporation without the necessity of attestation or affixing of the corporate seal; and

FURTHER RESOLVED, that these resolutions supercede and replace resolutions adopted on November 7, 2008, and July 21, 2014 but any documents signed pursuant to the superceded resolutions remain valid until their expiration and any actions taken by an Authorized Signatory that would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of the foregoing resolutions are hereby authorized, ratified, confirmed and approved.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Hill-Rom Manufacturing, Inc MDEG License # (if applicable) N/A

Physical Address 1020 W County Road F

City St. Paul State MN Zip 55126

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

City Dublin State OH Zip 43017

Telephone _____ Website www.hillrom.com

Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First CHRISTIAN Middle ERIC Last KIELY

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

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

Mailing Address 1020 COUNTY ROAD F W

City SHOREVIEW State MN Zip 55126

Telephone [redacted] Email CHRISTIAN_KIELY@BAXTER.COM

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
STATE UNIVERSITY OF NEW YORK			1991 – 1995	
Address	**City**		**State**	**Zip**
1400 WASHINGTON AVE	ALBANY		NY	12222
Diploma/Degree obtained, if any				
BACHELOR OF ARTS				

School Name			From - To (MM/YY – MM/YY)	
DON BOSCO PREP			1987 – 1991	
Address	**City**		**State**	**Zip**
492 FRANKLIN TPKE	RAMSEY		NJ	07446
Diploma/Degree obtained, if any				
HIGH SCHOOL				

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2021 - PRESENT	[redacted]	HUGO	MN	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2008 – 2021	[redacted]	MISSION VIEJO	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name		From - To (MM/YY – MM/YY)	
BAXTER		8/2021 – PRESENT	
Business Address	**City**	**State**	**Zip**
1020 COUNTY ROAD F W	SHOREVIEW	MN	55126
Phone	**Title**	**Number of Employed Hours**	
6512341822	PLANT MANAGER	6760	
Description of Duties			
PLANT MANAGER, FULL FACILITY OVERSIGHT			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

This is in response to Question # N/A Provide all the following *where applicable*:

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/25/2024
Date

I, CHRISTIAN KIELY, **certify that as the MDEG Administrator for**

Hill-Rom Manufacturing, Inc.,

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

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

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

CHRISTIAN KIELY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/25/2024

Date

Board Use Only	Date Received:

List of employees

Christian Kiely, Plant Manager

Reazur Rasul, President and Director

Karen L. Leets, Vice President and Treasurer

James William Borzi, SVP, Chief Supply Chain Officer

Ellen K. Bradford SVP, and Corporate Secretary

Inline Viewer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 1-4448

Baxter

Baxter International Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	36-0781620
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
One Baxter Parkway, Deerfield, Illinois	60015
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code 224.948.2000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock, $1.00 par value	BAX (NYSE)	New York Stock Exchange
		Chicago Stock Exchange

INDIANA SECRETARY OF STATE
BUSINESS SERVICES DIVISION
CORPORATIONS CERTIFIED COPIES

INDIANA SECRETARY OF STATE
BUSINESS SERVICES DIVISION
302 West Washington Street, Room E018
Indianapolis, IN 46204

http://www.sos.in.gov

September 19, 2014

Company Requested: HILL-ROM MANUFACTURING, INC.
Control Number: 197804-378

Date	Transaction	# Pages
04/13/1978	Articles of Incorporation	45
11/23/1981	Certificate of Assumed Business Name	1
11/05/1998	Articles of Amendment	3
03/24/2000	Articles of Merger	8
03/23/2000	Articles of Merger	8
12/07/2001	Articles of Amendment	2
07/06/2004	Notice of Change of Registered Office or Registered Agent	1
12/28/2010	Articles of Amendment	6
06/03/2013	Notice of Change of Registered Office or Registered Agent	1
04/01/2014	Articles of Merger	5

State of Indiana
Office of the Secretary of State

I hereby certify that this is a true and complete copy of this 80 page document filed in this office.

Dated: September 19, 2014
Certification Number: 2014091962868

Connie Lawson

Connie Lawson
Secretary of State

The Indiana Secretary of State filing office certifies that this copy is on file in this office.

Form SSC-04

STATE OF INDIANA

OFFICE OF THE SECRETARY OF STATE

CERTIFICATE OF ADMISSION OF

AIR SHIELDS, INC.

A FOREIGN CORPORATION

I, LARRY A. CONRAD, *Secretary of State of Indiana, hereby certify that the Application for Admission to do business in the State of Indiana of the above corporation in the form prescribed by my office, prepared and signed in duplicate by the President or a Vice-President, and the Secretary or an Assistant Secretary, of the corporation, and verified under oath by the officers signing the same, has been presented to me at my office, accompanied by the fees prescribed by law; that I have found such Application conforms to law; that I have endorsed my approval upon each of the duplicate copies of such Application; that all fees have been paid as required by law; that one copy of such Application has been filed in my office, together with an authenticated copy of the Articles of Incorporation or Association of the corporation; and that one copy of such Application bearing the endorsement of my approval has been returned by me to the corporation, or its representatives; all as prescribed by the provisions of the Indiana General Corporation Act, as amended.*

I further certify that:

1. *The name of this corporation is* AIR SHIELDS, INC.
   a. *It is incorporated under the laws of the state of* DELAWARE,
   b. *The location of its principal office in such state is* 330 Jacksonville Rd. *Street,* Hatboro *City,* Pa. *State.*
2. *The name under which the corporation is to transact business in the State of Indiana, if different from above is*
3. *The character of business it is authorized to transact in Indiana, is as follows:*

   Retail and wholesale sale and service of medical instrumentation in the infant and adult market.

Certification Number: 2014091962868

The Indiana Secretary of State filing office certifies that this copy is on file in this office.

(b)

4. *The total number of shares of all kinds which this corporation is authorized to issue is* 150,000 *of which there is issued and outstanding* 49,364

5. *The proportion of its capital stock represented by business to be transacted and tangible property to be employed in this state is* 108 Indiana Shares

6. *The amount of the fee paid for admission is $* 36.00

7. *The address of the corporation in this state is* 1011 Merchants Bank Building, Indianapolis (*Street*, *City*) Marion (*County*) *Indiana.*

8. *The name of its resident agent in Indiana for service of legal process is* C T Corporation System, *whose post office address is* 1011 Merchants Bank Building *Street or Building, City of* Indianapolis, *County of* Marion, *Indiana.*

Wherefore, I hereby issue to such Corporation this Certificate of Admission, in duplicate, and further certify that it has been admitted, and shall have authority, to transact the character of business set forth above in the State of Indiana, subject to the terms and conditions prescribed by the Indiana General Corporation Act, as amended.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the State of Indiana, at the City of Indianapolis, this 13th *day of* April, 78

Secretary of State

By *Deputy*

Certification Number: 2014091962868

0361

The Indiana Secretary of State filing office certifies that this copy is on file in this office.

Use White Paper—Size 8½ x 11 Inches—for Inserts

Filing Requirements—Present 2 Originally Executed Copies to Secretary of State.

Recording Requirements—None.

Other Requirements — a duly authenticated copy of the Articles of Incorporation with all amendments thereto, as certified by the proper officer in the state wherein the Corporation is domiciled, must be submitted with and accompany the Application.

Corporate Form No. 112 (July 1977)—Page One

APPLICATION FOR ADMISSION

Prescribed by the Secretary of State of Indiana

APPROVED AND FILED
APR 13 1978
SECRETARY OF STATE OF INDIANA

APPLICATION FOR ADMISSION OF

AIR SHIELDS, INC.,

A FOREIGN CORPORATION, TO DO BUSINESS IN THE STATE OF INDIANA

The undersigned officers of the above DELAWARE (State of domicile) corporation (hereinafter referred to as the "Corporation"), which exists pursuant to the provisions of Title VIII of General Corporation Law (statute pursuant to which the corporation exists), as amended, desiring to effectuate the admittance of the Corporation to do business in the State of Indiana, certify the following facts:

ARTICLE I
NAME

The name of the Corporation is:

AIR SHIELDS, INC.

ARTICLE II
PRINCIPAL OFFICE

The location of its principal office or place of business outside the State of Indiana is 330 Jacksonville Rd. Hatboro, Pa. 19040;

and the location of its proposed principal office or place of business in Indiana is

(cf. Article XII). 1011 Merchants Bank Building, Indianapolis, Ind. 46204

Certification Number: 2014091962868

The Indiana Secretary of State filing office certifies that this copy is on file in this office.

ARTICLE III

ADMISSION IN OTHER STATES

The Corporation has been admitted or is qualified to do business in the following states:

Arizona	North Carolina	Michigan
Oregon	Minnesota	
Alabama	Virginia	
California	Illinois	
Missouri	Maryland	
Texas	Florida	
Iowa	Georgia	
New York	Kentucky	
Pennsylvania	Ohio	
Massachusetts	West Virginia	

ARTICLE IV

CHARACTER OF BUSINESS

The character of business which the Corporation intends to carry on in Indiana is as follows:

Retail and Wholesale sale and service of medical instrumentation in the infant and adult market.

Certification Number: 2014091962868

0363

The Indiana Secretary of State filing office certifies that this copy is on file in this office.

ARTICLE V
AUTHORIZED SHARES

The Corporation is authorized to issue and has issued the following number of shares, respectively:

.....shares of.....without par value, of which.....
shares are presently issued and outstanding;

150,000 shares of Common with a par value of $ 1.00 per share,
of which 49,364 shares are presently issued and outstanding.

ARTICLE VI
STATEMENT OF TOTAL BUSINESS

Section 1. Fiscal Year. The fiscal year of the Corporation is from December 1 to November 30, both inclusive.

Section 2. Last Fiscal Year. The total amount of business transacted by the Corporation during its last complete fiscal year was $ 16,000,000

Section 3. Current Fiscal Year. The total amount of business to be transacted by the Corporation during its current fiscal year is estimated at approximately $ 19,000,000

Section 4. Next Fiscal Year. The total amount of business to be transacted by the Corporation during its next succeeding fiscal year is estimated at approximately $ 21,000,000

ARTICLE VII
STATEMENT OF INDIANA BUSINESS

The amount of business to be transacted by the Corporation at or from places of business in Indiana during the next succeeding fiscal years is estimated at approximately $ 60,000

Certification Number: 2014091962868

The Indiana Secretary of State filing office certifies that this copy is on file in this office.

ARTICLE VIII
STATEMENT OF TOTAL TANGIBLE PROPERTY

Section 1. Last Fiscal Year. The total amount of tangible property employed by the Corporation during its last complete fiscal year was approximately $4,284,000

Section 2. Current Fiscal Year. The total amount of tangible property to be employed by the Corporation during its current fiscal year is estimated at approximately $6,100,000

Section 3. Next Fiscal Year. The total amount of tangible property to be employed by the Corporation during its next succeeding fiscal year is estimated at approximately $6,375,000

ARTICLE IX
STATEMENT OF INDIANA TANGIBLE PROPERTY

The amount of tangible property to be employed by the Corporation in the State of Indiana during its next succeeding fiscal year is estimated at approximately $None

ARTICLE X
CORPORATE OFFICERS

The names and post-office addresses of the officers of the Corporation are as follows:

Name	Office	Post-Office Address (Number, Street, and City)	State (and Zip Code)
A. DeFrancesco ✓	President	S. Forge Mountain Dr. Valley Forge, Pa.	19481
E. Ray ✓	Vice Pres.	1222 Prospect Hill Rd., Villanova, Pa.	19085
N. Martin	Vice Pres.	1505 N. Fiedler Rd. Ambler, Pa.	19096
J. Schwartz	Asst. Sec.	519 Moreno Rd., Wynnewood, Pa.	19096
J. Tuite	Sec.& Treas.	412 Hilltop Rd. Paoli, Pa.	19301

Certification Number: 2014091962868

The Indiana Secretary of State filing office certifies that this copy is on file in this office.

ARTICLE XI
BOARD OF DIRECTORS

The names and post-office addresses of the Board of Directors of the Corporation are as follows:

Name	Post-Office Address (Number, Street, and City)	State (and Zip Code)
A. DeFrancesco	S. Forge Mountain Rd.	Valley Forge, Pa. 19481
H. Cullumbine	541 W. Moreland Ave.	Phila. Pa. 19118
E. Ray	1222 Prospect Hill Rd.	Villanova, Pa. 19085
E. Garfield	450 Dreshertown Rd.	Ft. Washington, Pa. 19034
W. Ogletree	Saw Mill Rd.	Newtown Square, Pa. 19073

ARTICLE XII
RESIDENT AGENT

The Resident Agent of the Corporation on whom service of legal process may be had in Indiana is

C.T. Corporation System

(Name)

and his address is the same as the address of the principal office or place of business of the Corporation in Indiana, as given in Article II.

(Note: The Act requires that all corporations designate an individual or corporation resident in Indiana as Resident Agent; the Secretary of State may not be appointed as Resident Agent.)

Certification Number: 2014091962868

The Indiana Secretary of State filing office certifies that this copy is on file in this office.

ARTICLE XIII
"INDIANA SHARES" FORMULA

Section 1. Calculation of Shares Represented in Indiana. The following calculation establishes the number of shares of the Corporation that will be represented in Indiana during the next succeeding fiscal year:

Clause (a)	Insert figure from Article VII	$ 60,000
Clause (b)	Insert figure from Article IX	$ ---
Clause (c)	Add Clauses (a) and (b)	$ 60,000
Clause (d)	Insert figure from Article VI, Section 4	$ 21,000,000
Clause (e)	Insert figure from Article VIII, Section 3	$ 6,375,000
Clause (f)	Add Clauses (d) and (e)	$ 27,375,000
Clause (g)	Divide Clause (c) by Clause (f)	$ .2%
Clause (h)	Set forth the number of authorized shares of all classes presently issued and outstanding from Article V	$ 49,364
Clause (i)	Multiply Clause (h) by Clause (g). (Number of shares of the Corporation that will be represented in Indiana during the next succeeding fiscal year.)	$ 108
Clause (j)	Credit claimed as result of merger with Indiana or previously qualified foreign corporation (see Article XIV) — may not exceed figure from Clause (i)	$

*Note—Special Instructions:
The purpose of Article XIII is to compute "Indiana Shares," as defined in IC 23-3-2-1 (f) et sec., and thus determine the amount of fee due. It is imperative that this Section be fully completed.

Filing Fee Schedule

First 1,000 "Indiana Shares" or less	(minimum fee) $30.00*
1,001 through 200,00 "Indiana Shares"	2¢ per share*
200,001 through 1,000,000 "Indiana Shares"	1¢ per shares*
Additional shares over 1,000,000 "Indiana Shares"	0.2¢ per share*

*Plus $6.00 Certificate of Admission fee

Certification Number: 2014091962868

The Indiana Secretary of State filing office certifies that this copy is on file in this office.

ARTICLES XIV
"INDIANA SHARES" CREDIT

Pursuant to *IC 23-3-2-2(e) (as amended by Indiana Acts 1977, P.L. 76)*, foreign corporations which are the survivors of mergers or consolidations with Indiana corporations, or foreign corporations qualified to transact business in Indiana at the time of such merger or consolidation, may claim a credit for the aggregate of all shares of stock authorized the merging Indiana corporation(s) and all "Indiana shares" paid by the merging foreign corporation(s) at the time of such merger or consolidation, provided that this Application for Admission is filed with the Secretary of State within thirty (30) calendar days of the filing of the Articles of Merger or Consolidation with the Secretary of State. This procedure does not operate to increase the presently qualifying corporation's "Indiana shares", per se, for future calculation in filing annual reports, but merely allows a credit for the shares previously paid by Indiana and foreign corporation parties to a merger into or consolidation with such corporation.

Section 1. Date of filing Articles of Merger or Consolidation with the Secretary of State: _____

Section 2. Indiana or qualified foreign corporation parties to merger or consolidation:

Corporate Title	State of Domicile	Authorized Shares or "Indiana shares" paid
N/A	N/A	N/A

Section 3. Total "Indiana Shares" Credit claimed (aggregate of all authorized shares and "Indiana shares" from Section 2.) ..... _____ *

*NOTE: In transposing to Article XIII, Clause (j), this figure may not be greater than the figure reflected in Clause (i).

Certification Number: 2014091962868

0368

4J

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: HSG-S Corp.

Physical Address: 3701 Litsey Rd. Suite 101

City: Fort Worth State: TX Zip: 76177

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: (817) 416-9770 Website: _____

Name of Designated Representative (DR): Thomas Schulz

Licensing Company Email: Licensure@henryschein.com DR Email: Thomas.Schulz@henryschein.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others: 3PL

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

This is an initial application and business has not begun. Below is a potential customer that HSG-S Corp could 3PL for:

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: DuKal Corporation
Address: 2 Fleetwood Ct City: Ronkonkoma State: NY Zip: 11779
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): N/A
Corporation Name: Henry Schein, Inc.
Mailing Address: 135 Duryea Rd.
City: Melville State: NY Zip: 11747
Telephone: 631-843-5500 Email: Licensure@henryschein.com
Contact Person Name: Regulatory Affairs Department, Riley Fruge

Date of SEC Registration: 2/25/2025 | SEC Registration Number: 0-27078 | Stock Exchange Symbol: HSIC

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

HSG-S Corp.

Facility Name

Yvonne Smith

Print Name of Authorized Person Submitting Application

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

25th June '25

Date

Board Use Only	Date Received: 7/2/25	Amount: $1000 ck 0082053921

HSG-S Corp.
F.E.I.N 27-3531273
Corporate Executive Officers:

Marc C. Gordon, President – 0% ownership
Marc.Gordon@henryschein.com
Work address: 3701 Litsey Rd. Suite 101
Fort Worth, TX 76177
631-845-2955 (Work)

Ronald N. South, Senior Vice President, and Chief Financial Officer – 0% ownership
Ronald.South@henryschein.com
Work address: 3701 Litsey Rd. Suite 101
Fort Worth, TX 76177
631-845-2802 x2222802 (Work)

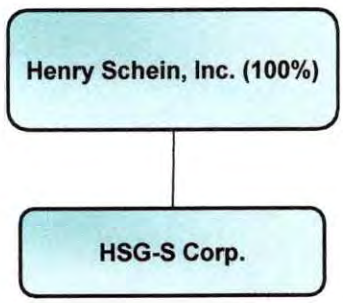
Michael S. Ettinger, Executive Vice President – 0% ownership
Michael.Ettinger@henryschein.com
Work address: 3701 Litsey Rd. Suite 101
Fort Worth, TX 76177
631-843-5993 (Work)

Jennifer Ferrero, Secretary– 0% ownership
Jennifer.Ferrero@henryschein.com
Work address: 3701 Litsey Rd. Suite 101
Fort Worth, TX 76177
631-843-5674 (Work)

Yvonne M. Smith, Vice President – 0% ownership
Yvonne.Smith@henryschein.com
Work address: 3701 Litsey Rd. Suite 101
Fort Worth, TX 76177
912.925.8525 x5401 (Work)

Incorporated Delaware 04/06/2010

HSG-S Corp
Ownership Structure



Revised 01/2025

Delaware

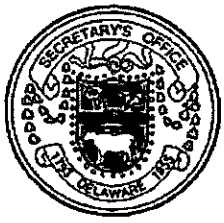
The First State

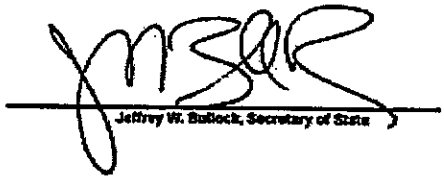
I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HSG-S CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTEENTH DAY OF JANUARY, A.D. 2025.

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HSG-S CORP." WAS INCORPORATED ON THE SIXTH DAY OF APRIL, A.D. 2010.

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





4808115 8300

SR# 20250151246

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

Authentication: 202715771

Date: 01-16-25

TEXAS Health and Human Services | Texas Department of State Health Services

Contact your licensing board or program | Internet Policy
Return to the Main Menu | Contact Us

License Details

"License" means a license, certificate, registration, permit, or other form of authorization, including a renewal of the authorization, that: a person must obtain to practice or engage in a particular business, occupation, or profession; or a facility must obtain before a particular business, occupation, or profession is practiced or engaged in within the facility. A "License Rank" is the level of license; a "License Modifier" provides additional information on the scope of the license.

A license may have one or two statuses. The first status is normally "Current" which means the license is in good standing. If the first status is "Expired" or "Null and Void", or if either status shows "Inactive", the licensee may not practice in the profession and/or operate as a licensed business.

For more information regarding this license, including any disciplinary information displayed below, please contact the appropriate board or program office. A list of DSHS licensing board and programs may be found at: http://www.dshs.state.tx.us/Licensee-Registrant-Permittee.aspx or click the link at the bottom of this page.

Press "Previous Record" to display the previous license.

Press "Next Record" to display the next license.

Press "Search Results" to return to the Search Results list.

Press "New Search Criteria" to do another search of this type.

Press "New Search" to start a new search.

License Number: 1004112 ***Current Date: 06/02/2025 04:33 PM***

Name:	HSG S CORP
License Type:	Prescription Drug Distributor
License Status:	Current
Expiry Date:	03/26/2027
Effective Rank Date:	05/30/2025
Modifier(s):	Other Operation Prescription Non Prescript Third Party Logistics Provider

Addresses

Mailing Address	Address	**HSG S CORP** **FORT WORTH , TX** **TARRANT** **76177** **US**
Physical Loc	Address	**HSG S CORP** **3701 LITSEY RD STE 101** **FORT WORTH , TX** **TARRANT** **76177** **US**

Food & Drug Owner

Licensee's Role:	Food & Drug License
Related Party Role:	Food & Drug Owner

Related Party Name	License	Address
HSG S CORP	Owner # Status: Current Expiration Date:	FORT WORTH , TX TARRANT 76177 US

Previous Record Next Record Search Results New Search Criteria New Search Print

TEXAS Health and Human Services | Texas Department of State Health Services

Contact your licensing board or program | Internet Policy
Return to the Main Menu | Contact Us

License Details

"License" means a license, certificate, registration, permit, or other form of authorization, including a renewal of the authorization, that: a person must obtain to practice or engage in a particular business, occupation, or profession; or a facility must obtain before a particular business, occupation, or profession is practiced or engaged in within the facility. A "License Rank" is the level of license; a "License Modifier" provides additional information on the scope of the license.

A license may have one or two statuses. The first status is normally "Current" which means the license is in good standing. If the first status is "Expired" or "Null and Void", or if either status shows "Inactive", the licensee may not practice in the profession and/or operate as a licensed business.

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Press "Previous Record" to display the previous license.

Press "Next Record" to display the next license.

Press "Search Results" to return to the Search Results list.

Press "New Search Criteria" to do another search of this type.

Press "New Search" to start a new search.

License Number: 1002280 ***Current Date: 06/02/2025 04:34 PM***

Name:	HSG S CORP
License Type:	Multiple Products with Non-Prescription Drugs
License Status:	Current
Expiry Date:	03/26/2027
Effective Rank Date:	05/30/2025
Modifier(s):	Food Devices

Addresses

Physical Loc	Address	**HSG S CORP** **3701 LITSEY RD STE 101** **FORT WORTH , TX** **TARRANT** **76177** **US**
Mailing Address	Address	**HSG S CORP** **FORT WORTH , TX** **TARRANT** **76177** **US**

Food & Drug Owner

Licensee's Role:	Food & Drug License
Related Party Role:	Food & Drug Owner

Related Party Name	License	Address
HSG S CORP	Owner # Status: Current Expiration Date:	FORT WORTH , TX TARRANT 76177 US

Previous Record Next Record Search Results New Search Criteria New Search Print

DSHS Certifications, Licenses and Permits | Disclaimer

Last Updated Mar 27, 2013

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 01/27/2025

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

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

PRODUCER
Aon Risk Services Northeast, Inc.
New York NY Office
One Liberty Plaza
165 Broadway, Suite 3201
New York NY 10006 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Liberty Insurance Corporation	42404
INSURER B:	Liberty Mutual Fire Ins Co	23035
INSURER C:	ProAssurance Specialty Insurance Company	17400
INSURER D:	Berkshire Hathaway Specialty Ins Company	22276
INSURER E:	QBE Specialty Insurance Company	11515
INSURER F:		

INSURED
Henry Schein, Inc.,
Subsidiaries & Affiliates
135 Duryea Road
Melville NY 11747 USA

COVERAGES **CERTIFICATE NUMBER:** 570110601626 **REVISION NUMBER:**

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

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY			TB2621093363034	06/01/2024	06/01/2025	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	$5,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$5,000,000
	POLICY PRO-JECT X LOC						PRODUCTS - COMP/OP AGG	Excluded
	OTHER:							
B	AUTOMOBILE LIABILITY			AS2-621-093363-044	06/01/2024	06/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
A	X UMBRELLA LIAB X OCCUR			TH7621093363074	06/01/2024	06/01/2025	EACH OCCURRENCE	$5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$5,000,000
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			WA762D093363014 AOS	06/01/2024	06/01/2025	X PER STATUTE OTH-ER	
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER (Mandatory in NH) Y/N: N	N/A		WC7621093363024 WI	06/01/2024	06/01/2025	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000
C	Products Liability			N24NY380027 Claims Made	06/01/2024	06/01/2025	Each Occurrence	$10,000,000
							Aggregate	$10,000,000

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

Evidence of Insurance.

CERTIFICATE HOLDER

Henry Schein, Inc.
and its Subsidiary and Affiliated Companies
135 Duryea Road
Melville NY 11747 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast Inc.

Holder Identifier : EOC

Certificate No : 570110601626

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AGENCY CUSTOMER ID: 570000025511

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER: See Certificate Number: 570110601626	
CARRIER: See Certificate Number: 570110601626 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

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

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
E	E&O - Miscellaneous Professional-Primary			130003732 Cyber Liab/Tech& E&O SIR applies per policy terms & conditions	12/01/2024	12/01/2025	Limit of Liability	$10,000,000
D	Fiduciary Liability - Prima			47EPC31399304 SIR applies per policy terms & conditions	11/01/2024	11/01/2025	Aggregate Limit	$10,000,000

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AGENCY CUSTOMER ID: 570000025511

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER	
See Certificate Number: 570110601626	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570110601626	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

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

Named Insureds

Ace Southern Surgical Solutions
Ace Surgical Supply Company, Inc.
AEP MPE Holdings, LLC
All Star Orthodontics
BIOHORIZONS IMPLANT SYSTEMS, INC.
Camlog
CB Healthcare Consulting GmbH
DenMat Holdings, LLC
Dental Instrument Sales & Service, LLC
Dental Practice Transitions
Dentrix Dental Systems
eAssist Inc.
eAssist Publishing LLC
Edge Endo
Exan Enterprises
Firefly Supply LLC
G.I.V. Inc.
General Injectibles & Vaccines, Inc.
Hand Piece Parts & Repair, Inc.
Hayes Handpiece Franchises, Inc.
HealthFirst
Henry Schein, Inc
Henry Schein and Schvadent
Henry Schein Dental, Inc.
Henry Schein Global Sourcing, Inc.
Henry Schein Medical
Henry Schein One, LLC
Henry Schein Practice Solutions
Henry Schein Services GmbH
Henry Schein, Supply
HF Acquisition Co. LLC
HSG-S Corp
Impromed, LLC.
Insource, Inc.
Lighthouse 360, Inc.
Midway Dental Supply LLC
NAR Medical Depot LLC
NAR Training LLC
North American Rescue LLC and TQM, LLC
ORTHO2 LLC
Ortho Organizers, Inc.
Ortho Technology, Inc.
Precision One
Prism Medical Products
RXWORKS, INC.
Sesame Communications
Southern Anesthesia & Surgical Inc.
Shield HealthCare
TDSC, Inc.
The Custom Milling Center, Inc.
US Endodontics
Vulcan Custom Dental
Zahn Dental Company, Inc.
Zahn/Darby Lab

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 015228717

Application/License No. _____

HSG-S CORP., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
3701 Litsey Road Suite 101 Fort Worth, TX 76177, as
(Address of Applicant/Principal)
PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY, a
(Surety Company)
corporation organized under the laws of the state of MA
(State of Incorporation)
and authorized to transact a general surety business in the State of
Nevada, whose address for purposes of service is
175 Berkeley Street Boston, MA 02116 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 1, 2025.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of July, 2025.

APPLICANT/PRINCIPAL
HSG-S CORP.

COMPANY

Authorized Representative

SURETY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sandra Diaz, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Anne Potter

Witness Aklima Noorhassan

Countersigned by:

Nevada Resident Agent Frances A Rodriguez
Non-Resident License No. 3349643

Posted February 20, 2020

Liberty Mutual. SURETY

POWER OF ATTORNEY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8213584-015009

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aklima Noorhassan; Anne Potter; Beverly A. Woolford; Debra A. Deming; Frances Rodriguez; Francesca Kazmierczak; Jennifer L. Jakaitis; Pablo Garcia Horcajo; Peter Healy; Sandra Diaz; Susan A. Welsh; Valorie Spates; Vilma Gonzalez

all of the city of New York state of NY each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 2nd day of April, 2025.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 2nd day of April, 2025 before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 1st day of July, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/24

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2024

Assets		Liabilities	
Cash and Bank Deposits	$4,608,826,756.00	Unearned Premiums	$9,890,896,878.00
*Bonds – U.S Government	$4,281,375,446.74	Reserve for Claims and Claims Expense	$29,467,071,865.00
*Other Bonds	$21,566,489,527.26	Funds Held Under Reinsurance Treaties	$341,948,172.00
*Stocks	$15,589,644,012.00	Reserve for Dividends to Policyholders	$954,025.00
Real Estate	$86,497,925.00	Additional Statutory Reserve	$150,547,865.00
Agents' Balances or Uncollected Premiums	$7,512,975,129.00	Reserve for Commissions, Taxes and Other Liabilities	$5,049,906,410.00
Accrued Interest and Rents	$225,249,712.00	**Total**	**$47,104,416,171.00**
Other Admitted Assets	$19,367,663,200.00	Special Surplus Funds	$174,153,086.00
Total Admitted Assets	**$74,539,483,661.00**	Capital Stock	$10,000,075.00
		Paid in Surplus	$13,209,595,772.00
		Unassigned Surplus	$13,415,980,561.00
		Surplus to Policyholders	$27,435,067,490.00
		Total Liabilities and Surplus	**$74,539,483,661.00**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2024, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2025.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG HSG-S Corp MDEG License # (if applicable) _____

Physical Address 3701 Litsey Rd. Suite 101

City Fort Worth State TX Zip 76117

Mailing Address (if different from physical address) SAME

City _____ State _____ Zip _____

Telephone 817-416-9770 Website N/A

Licensing Company Email licensure@henryschein.com

Section 2: Personal Information

First Thomas Middle Richard Last Schulz

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

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

Mailing Address [redacted]

City Paradise State TX Zip [redacted]

Telephone (817) 416-9770 x4370 Email Thomas.Schulz@henryschein.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Birdville Highschool		2001-2005	
Address	**City**	**State**	**Zip**
9100 Mid Cities Blvd	North Richland Hills	TX	76180
Diploma/Degree obtained, if any			
Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/23 - Present	[redacted]	Paradise	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	
08/20- 09/23		North Richland Hills	TX	
From - To (MM/YY – MM/YY)		City	State	
01/15 - 08/20		Fort Worth	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Henry Schein, Inc.			01/2006 - Present	
Business Address		**City**	**State**	**Zip**
3701 Litsey Rd.		Fort Worth	TX	76177
Phone	**Title**		**Number of Employed Hours**	
817-416-9770	Supervisor, Receiving		~40,560	

Description of Duties

Outbound distribution supervisor overseeing and directing all aspects of the warehouse's outbound operations. Such as order fulfillment, packing, shipping, and loading. Responsible for ensuring efficient and accurate processes, managing warehouse staff, and maintaining a safe workplace.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

I, Thomas Schulz, **certify that as the MDEG Administrator for**

HSG-S Corp,

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

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

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

Thomas Schulz
Print Name (First, Last)

Thomas Schulz
Original Signature (electronic, copies or stamps not accepted)

6-20-25
Date

Board Use Only	Date Received: 7/2/25

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler HSG-S Corp.

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 3701 Litsey Rd. Suite 101

City Fort Worth State TX Zip 76177

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 817-416-9770 Website N/A

Licensing Company Email Licensure@henryschein.com

Section 2: Personal Information

First Thomas Middle Richard Last Schulz

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

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

Mailing Address [redacted]

City Paradise State TX Zip [redacted]

Telephone (817) 416-9770 x4370 Email Thomas.Schulz@henryschein.com

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

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

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

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

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From - To (MM/YY – MM/YY)		City	State	
08/20- 09/23		North Richland Hills	TX	
From - To (MM/YY – MM/YY)		City	State	
01/15 - 08/20		Fort Worth	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Henry Schein, Inc.			01/2006 - Present	
Business Address		**City**	**State**	**Zip**
3701 Litsey Rd.		Fort Worth	TX	76177
Phone	**Title**		**Number of Employed Hours**	
817-416-9770	Supervisor, Receiving		~40,560	

Description of Duties

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Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
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Description of Duties

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Phone	**Title**		**Number of Employed Hours**	

Description of Duties

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Description of Duties

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

Business Name			From - To (MM/YY – MM/YY)	
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Description of Duties				

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Phone	Title		Number of Employed Hours	
Description of Duties				

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

I, Thomas Schulz, **certify that as the designated representative for**

HSG-S Corp.,

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

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

Thomas Schulz
Print Name (First, Last)

Thomas Schulz
Original Signature (electronic, copies or stamps not accepted)

6-20-25
Date

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

Thomas Schulz
Print Name (First, Last)

Thomas Schulz
Original Signature (electronic, copies or stamps not accepted)

6-20-25
Date

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

State of Texas, ss. County of Denton

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

Thomas Schulz
Original Signature

6-20-25
Date

Subscribed and Sworn to before me this 20th day of June

Notary Public Signature

TIMOTHY NITTLER
MY COMMISSION EXPIRES
12/11/2028
NOTARY ID: 135200761

(Seal)

HSG-S Corp.

3701 Litsey Rd. Suite 101
Fort Worth, TX 76177

List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.

HSG-S Corp is currently conducting interviews to fill positions.

Employee	Title
Thomas Schulz	Supervisor, Receiving
Dennis McKee	Sr Manager, Operations
Arnie Roberts	Sr Director, Distribution Center

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 28, 2024

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 0-27078

HENRY SCHEIN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**11-3136595**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

135 Duryea Road
Melville, New York
(Address of principal executive offices)
11747
(Zip Code)
(631) 843-5500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.01 per share	HSIC	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
YES: ☒ NO: ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
YES: ☐ NO: ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
YES: ☒ NO: ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
YES: ☒ NO: ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer: ☒ Accelerated filer: ☐ Non-accelerated filer: ☐ Smaller reporting company: ☐
Emerging growth company: ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).
YES: ☐ NO: ☒

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant, computed by reference to the closing sales price as quoted on the Nasdaq Global Select Market on June 29, 2024, was approximately $8,092,479,000.

As of February 18, 2025, there were 124,176,781 shares of registrant's Common Stock, par value $.01 per share, outstanding.

Documents Incorporated by Reference:

Portions of the Registrant's definitive proxy statement to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year (December 28, 2024) are incorporated by reference in Part III hereof.

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0403

PART I

ITEM 1. Business

General

Henry Schein, Inc. is a solutions company for health care professionals powered by a network of people and technology. We believe we are the world's largest provider of health care products and services primarily to office-based dental and medical practitioners, as well as alternate sites of care. Our philosophy is grounded in our commitment to help customers operate a more efficient and successful business so the practitioner can provide better clinical care.

With 93 years of experience distributing health care products, we have built a vast base of small, mid-sized and large customers in the dental and medical markets, serving more than one million customers worldwide across dental practices, laboratories, physician practices, and ambulatory surgery centers, as well as government, institutional health care clinics and other alternate care clinics.

We are headquartered in Melville, New York and employ approximately 25,000 people. Approximately 49% of our workforce is based in the United States and 51% outside of the United States. Our operations or affiliates are located in 33 countries and territories. Our broad global footprint has evolved over time through organic growth as well as through the contribution from our strategic acquisitions.

We stock a comprehensive selection of more than 300,000 branded products and Henry Schein corporate brand products through our main distribution centers. Our infrastructure, including over 5.4 million square feet of space in 36 strategically located distribution centers and 0.5 million square feet of space in 15 manufacturing facilities around the world, enables us to historically provide rapid and accurate order fulfillment, better serve our customers and increase our operating efficiency. This infrastructure, together with broad product and service offerings at competitive prices, and a strong commitment to customer service, enables us to be a single source of supply for our customers' needs, which we believe is a competitive advantage.

During the fourth quarter of our fiscal year ended December 28, 2024, we revised our reportable segments to align with how the Chairman and Chief Executive Officer manages the business, assesses performance and allocates resources. Our revised reportable segments consist of: (i) Global Distribution and Value-Added Services; (ii) Global Specialty Products; and (iii) Global Technology.

Global Distribution and Value-Added Services includes distribution to the global dental and medical markets of national brand and corporate brand merchandise, as well as equipment and related technical services. This segment also includes value-added services such as financial services, continuing education services, consulting and other services. This segment also markets and sells under our own corporate brand, a portfolio of cost-effective, high-quality consumable merchandise. Global Specialty Products includes manufacturing, marketing and sales of dental implant and biomaterial products; and endodontic, orthodontic and orthopedic products and other health care-related products and services. Global Technology includes development and distribution of practice management software, e-services, and other products, which are distributed to health care providers.

Recent Developments

See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments" herein for a discussion related to recent Company developments.

Industry

The distribution and value-added services industry, as it relates to office-based health care practitioners, is fragmented and diverse. The industry ranges from sole practitioners working out of relatively small offices to mid-sized and large group practices ranging in size from a few practitioners to several hundred practices owned or operated by dental support organizations ("DSOs"), medical group purchasing organizations ("GPOs"), health maintenance organizations ("HMOs"), hospital systems or integrated delivery networks ("IDNs").

Due in part to the limited capacity of office-based health care practitioners to store and manage large quantities of supplies in their offices, the distribution of health care supplies and small equipment to office-based health care practitioners has been characterized by frequent, small quantity orders, and a need for rapid, reliable and substantially complete order fulfillment. The purchasing decisions within an office-based health care practice are typically made by the practitioner, hygienist or office manager. Supplies and small equipment are generally purchased from more than one distributor, with one generally serving as the primary supplier.

The distribution and value-added services industry should benefit from favorable long-term macro trends that should help stimulate patient traffic and demand for products and services. This includes an aging population, increased health care awareness and the importance of preventive care, an increasing understanding of the connection between good oral health and overall health, improved access to care globally, the proliferation of medical technology and testing, new pharmacology treatments and expanded third-party insurance coverage, partially offset by the effects of unemployment on insurance coverage and technological improvements, including the advancement of software and services, prosthetic solutions and telemedicine. In addition, the non-acute market continues to benefit from the shift of procedures and diagnostic testing from acute care settings to alternate-care sites, particularly physicians' offices and ambulatory surgery centers.

We believe that consolidation within the industry will continue to result in a number of distributors, particularly those with limited financial, operating and marketing resources, seeking to combine with larger companies that can provide growth opportunities. This consolidation also may continue to result in distributors seeking to acquire companies that can enhance their current product and service offerings or provide opportunities to serve a broader customer base.

In addition, customer consolidation will likely lead to multiple locations under common management and the movement of more procedures from the hospital setting to the physician or alternate care setting, as the health care industry is increasingly focused on efficiency and cost containment. This trend has benefited distributors capable of providing a broad array of products and services at low prices. It also has accelerated the growth of HMOs, group practices, other managed care accounts and collective buying groups such as DSOs and GPOs, which, in addition to their emphasis on obtaining products at competitive prices, tend to favor distributors capable of providing specialized management information support. We believe that the trend towards cost containment has the potential to favorably affect demand for technology solutions, including software, which can enhance the efficiency and facilitation of practice management.

Competition

The distribution and manufacture of health care supplies and equipment is highly competitive. Many of the health care products we sell are available to our customers from a number of suppliers. In addition, our competitors could obtain exclusive rights from manufacturers to market particular products. Manufacturers also could seek to sell directly to end-users, and thereby eliminate or reduce our role and that of other distributors. In certain parts of the dental end market, such as those related to dental specialty products, and medical end market manufacturers already sell directly to end customers.

In North America, we compete with other distributors, as well as several manufacturers, of dental and medical products, primarily on the basis of price, breadth of product line, e-commerce capabilities, customer service and value-added products and services. In the dental distribution market, our primary competitors in the U.S. are the Patterson Dental division of Patterson Companies, Inc. and Benco Dental Supply Company. In addition, we compete against a number of other distributors that operate on a national, regional and local level. Our primary competitors in the U.S. medical distribution market, which accounts for the large majority of our global medical sales, are McKesson Corporation and Medline Industries, Inc., which are national distributors. We also compete with a number of regional and local medical distributors, as well as a number of manufacturers that sell directly to physicians and patients in their homes.

Outside of the U.S., we believe we are the only global distributor of supplies and equipment to dental practices and our competitors are primarily local and regional companies. We also face significant competition internationally, where we compete on the basis of price and customer service against several large competitors, including the GACD Group, Proclinic SA, Lifco AB, Nuent Group AB, Planmeca Oy and Billericay Dental Supply Co. Ltd., as well as a large number of other dental and medical product distributors and manufacturers in international countries and territories we serve.

Within Global Specialty Products, our primary competitors include Straumann, Envista, Zimvie, and Dentsply Sirona.

With regard to our dental software, we compete against numerous companies, including the Eaglesoft division of Patterson Companies, Inc., Carestream Dental LLC, Centaur Software Development Co Pty Ltd. (d.b.a. dental4windows, dental4web), Open Dental Software, Inc., PlanetDDS LLC, Good Methods Global Inc. (d.b.a. CareStack), Curve Dental, LLC., the NextGen division of Quality Systems, Inc., eClinicalWorks and Epic Systems Corporation. In other software end markets, including revenue cycle management, patient relationship management and patient demand generation, we compete with companies such as Vyne Medical, Weave Communications, Inc., and Solutionreach, Inc. Many of these competitors connect to our software platforms through our API program.

Manufacturing and Raw Materials

We manufacture certain of our products for our specialty businesses (oral surgery solutions including dental implants, endodontics, and orthopedics) at our 15 company manufacturing sites. We also outsource certain manufacturing to third parties. We purchase our raw materials from various third-party suppliers. No single supplier is material; however, raw materials may be sourced from a single supplier or a limited number of suppliers for reasons of quality assurance, regulatory requirements, cost, and availability.

We believe that we have a readily available supply of raw materials and components sourced from various suppliers, for our significant products.

We may experience shortages of raw materials or purchased components. In recent periods, we have experienced increased costs and shortages of purchased components, which had a negative impact on our profit margins and on our sales for certain product categories, due to our inability to fully satisfy demand.

Competitive Strengths

We have 93 years of experience in distributing products to health care practitioners resulting in strong awareness of the Henry Schein® brand. Our competitive strengths include:

A focus on meeting our customers' unique needs. We are committed to providing customized solutions to our customers that are driven by our understanding of the end markets we serve and that reflect the technology-driven products and services best suited for their practice needs. We are committed to continuing to enhance these offerings through organic investment in our products and our teams, as well as through the acquisition of new products and services that may help us better serve our customers.

Direct sales and marketing expertise. Our sales and marketing efforts are designed to establish and solidify customer relationships through personal or virtual visits by field sales representatives, frequent direct marketing and telesales contact, emphasizing our broad product lines, including exclusive distribution agreements, competitive prices and ease of order placement, particularly through our e-commerce platforms. The key elements of our direct sales and marketing efforts are:

- *Field sales consultants.* Our field sales consultants, including equipment sales specialists, covering major North American, European and other international markets. These consultants complement our direct marketing and telesales efforts and enable us to better market, service and support the sale of more sophisticated products and equipment.

- *Marketing.* We market to existing and prospective office-based health care providers through a combination of owned, earned and paid digital channels, tradeshows, as well as through catalogs, flyers, direct mail and other promotional materials. Our strategies include an emphasis on educational content through webinars and content marketing initiatives. We continue to enhance our marketing technology to improve our targeting capability and the relevance of messaging and offers.

- *Telesales.* We support our direct marketing effort with inbound and outbound telesales representatives, who facilitate order processing, generate new sales through direct and frequent contact with customers and stay abreast of market developments and the hundreds of new products, services and technologies introduced each year to educate practice personnel.

- *Electronic commerce solutions.* We provide our customers and sales teams with innovative and competitive e-commerce solutions. We continue to invest in our e-commerce platform to offer enhanced content management so customers can more easily find the products they need and to enable an engaging purchase experience, supported by excellent customer service.

- *Social media.* Our operating entities and employees engage our customers and supplier partners through various social media platforms, which are an important element of our communications and marketing efforts. We continue to expand our social media presence to raise awareness about issues, engage customers beyond a sale and deliver services and solutions to specialized audiences.

Cost-effective purchasing. We believe that cost-effective purchasing is a key element to maintaining and enhancing our position as a competitively priced provider of health care products. We continuously evaluate our purchase requirements and suppliers' offerings and prices in order to obtain products at the lowest possible cost. In 2024, our top 10 Global Distribution and Value-Added Services suppliers and our single largest supplier accounted for approximately 25% and 4%, respectively, of our aggregate purchases.

Efficient distribution. We distribute our products from our 36 strategically located distribution centers. We strive to maintain optimal inventory levels in order to satisfy customer demand for prompt delivery and complete order fulfillment. These inventory levels are managed on a daily basis with the aid of our management information systems. Once an order is entered, it is electronically transmitted to the distribution center nearest the customer's location for order fulfillment.

Broad product and service offerings at competitive prices. We offer a broad range of products and services to our customers, at competitive prices, in the following categories:

Global Distribution and Value-Added Services

- *Consumable merchandise and equipment.* We distribute consumable products, small equipment, laboratory products, large equipment, equipment repair services, branded and generic pharmaceuticals, vaccines, dental specialty products, diagnostic tests, infection-control products and vitamins. We stock a comprehensive selection of more than 300,000 branded products and Henry Schein corporate brand products through our main distribution centers. We also market and sell our own corporate brand portfolio of cost-effective, high-quality consumable merchandise products.

- *Home health business.* We distribute homecare medical products, including incontinence, urology, ostomy, enteral nutrition, advanced wound, and diabetes supplies, as well as continuous glucose monitoring devices. These products are delivered directly to patients in their homes, providing convenience and accessibility while supporting patient care and adherence to treatment plans.

- *Value-added products and services.* We offer a broad range of value-added solutions, including continuing education programs for practitioners, and consulting services. Our suite of technology-driven tools and expert advisory services helps health care professionals enhance practice efficiency and improve patient outcomes.

- *Repair services.* We have 129 equipment sales and service centers worldwide that provide a variety of repair, installation and technical services for our health care customers. Our technicians provide installation and repair services for dental handpieces, dental and medical small equipment, table-top sterilizers and large dental equipment.

- *Financial services.* We offer our customers solutions in operating their practices more efficiently by providing access to a number of financial services and products provided by third party suppliers (including non-recourse financing for equipment, technology and software products, non-recourse practice financing for leasehold improvements, business debt consolidation and commercial real estate, non-recourse patient financing and credit card processing) at rates that we believe are generally lower than what our customers would be able to secure independently. We also provide staffing services, dental practice valuation and brokerage services.

Global Specialty Products

- *Dental implants and digital solutions.* We develop, manufacture, market and distribute a broad portfolio of dental implants, prosthetic components, instruments and digital workflow solutions for implant-based tooth restorations. With research and development and manufacturing facilities in the United States, Switzerland, Germany, Brazil and France, we serve customers with various global and regional implant brands across a wide range of price segments. Supported by our specialized sales force, we market our products and solutions in approximately 90 countries, directly to dental practices and surgical specialists via our sales subsidiaries and our network of international third-party and Henry Schein distribution partners.

- *Biomaterials.* We market and distribute a broad portfolio of biomaterials for dental tissue regeneration. The product portfolio primarily consists of a broad range of privately branded allograft, xenograft, and synthetic biomaterials. Our dedicated biomaterial specialists support our direct implant sales force and Henry Schein oral surgery-focused distribution channels.

- *Orthodontics.* We develop, manufacture, and distribute a comprehensive range of orthodontic products, including brackets, braces, aligners, and accessories. In collaboration with leading clinicians, our research and development teams drive innovation to enhance patient care. With manufacturing facilities in the

4K

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: HSG-S Corp.

Physical Address: 1 Brasseler Blvd., Suite 300

City: Savannah State: GA Zip: 31419

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Name of Designated Representative (DR): Brendan Mcelhatton

Licensing Company Email: Licensure@henryschein.com DR Email: Brendan.Mcelhatton@henryschein.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: 3PL

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

This is an initial application and business has not begun. Below is a potential customer that HSG-S Corp could 3PL for:

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Edge Endo, LLC
Address: 5600 Wyoming Blvd. NE Ste 100 City: Albuquerque State: NM Zip: 87109
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): N/A
Corporation Name: Henry Schein, Inc.
Mailing Address: 135 Duryea Rd.
City: Melville State: NY Zip: 11747
Telephone: 631-843-5500 Email: Licensure@henryschien.com
Contact Person Name: Regulatory Affairs Department, Riley Fruge

Date of SEC Registration: 2/25/2025 | SEC Registration Number: 0-27078 | Stock Exchange Symbol: HSIC

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any)
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

HSG-S Corp.

Facility Name

Yvonne Smith

Print Name of Authorized Person Submitting Application

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

16th June 25

Date

Board Use Only	Date Received: 6/03/25	Amount: $1000 CK 0081999072

HSG-S Corp.
F.E.I.N 27-3531273
Incorporated Delaware 11/25/2024
Corporate Executive Officers:

Marc C. Gordon, President – 0% ownership
Marc.Gordon@henryschein.com
Work address: 1 Brasseler Blvd. Suite 300
Savannah GA 31419
631-845-2955 (Work)

Ronald N. South, Senior Vice President, and Chief Financial Officer – 0% ownership
Ronald.South@henryschein.com
Work address: 1 Brasseler Blvd. Suite 300
Savannah GA 31419
631-845-2802 x2222802 (Work)

Michael S. Ettinger, Executive Vice President – 0% ownership
Michael.Ettinger@henryschein.com
Work address: 1 Brasseler Blvd. Suite 300
Savannah GA 31419
631-843-5993 (Work)

Jennifer Ferrero, Secretary– 0% ownership
Jennifer.Ferrero@henryschein.com
Work address: 1 Brasseler Blvd. Suite 300
Savannah GA 31419
631-843-5674 (Work)

Yvonne M. Smith, Vice President – 0% ownership
Yvonne.Smith@henryschein.com
Work address: 1 Brasseler Blvd. Suite 300
Savannah GA 31419
912.925.8525 x5401 (Work)

Delaware

The First State

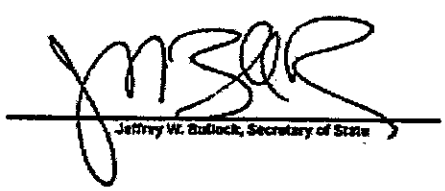
I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HSG-S CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTEENTH DAY OF JANUARY, A.D. 2025.

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HSG-S CORP." WAS INCORPORATED ON THE SIXTH DAY OF APRIL, A.D. 2010.

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





4808115 8300

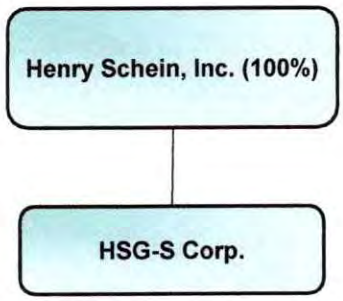
SR# 20250151246

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

Authentication: 202715771

Date: 01-16-25

HSG-S Corp
Ownership Structure



Revised 01/2025

Licensee Information

Name: HSG-S Corp

Owner:

DBA:

Address: 1 Brasseler Blvd Ste 300
Savannah GA 31419

Primary Source License Information

Profession:	Pharmacy	**License No:**	PHTPL000047	**License Status:**	Active
License Type:	Third Party Distributor	**Obtained By Method:**	Application	**License Subtype:**	
Issue Date:	5/7/2025	**Expiration Date:**	6/30/2027	**Last Renewal Date:**	

Discipline Information
- Public Board Orders -

If a public board order exists, it may be listed below.
Public Board Order means that there is a public document concerning the licensee.
The existence of a public Board order does not necessarily mean the licensee is currently under any type of disciplinary action.

Please understand that the absence of a scanned order linked to this record does not necessarily mean that no public actions exist.

No scanned public board order documents exist.

Associated Licenses

No data available

You may close this window to return to your search results

Data current as of: June 18, 2025 11:53:23
This website is to be used as a primary source verification for licenses issued by the Boards of Dentistry and Pharmacy. Paper verifications are available for a fee. Please contact the Boards of Dentistry and Pharmacy at 404-651-8000.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/27/2025

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE		NAIC #
Henry Schein, Inc., Subsidiaries & Affiliates 135 Duryea Road Melville NY 11747 USA	INSURER A:	Liberty Insurance Corporation	42404
	INSURER B:	Liberty Mutual Fire Ins Co	23035
	INSURER C:	ProAssurance Specialty Insurance Company	17400
	INSURER D:	Berkshire Hathaway Specialty Ins Company	22276
	INSURER E:	QBE Specialty Insurance Company	11515
	INSURER F:		

COVERAGES **CERTIFICATE NUMBER:** 570110601626 **REVISION NUMBER:**

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

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [X] LOC OTHER:			TB2621093363034	06/01/2024	06/01/2025	EACH OCCURRENCE	$1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	$5,000
							PERSONAL & ADV INJURY	$1,000,000
							GENERAL AGGREGATE	$5,000,000
							PRODUCTS - COMP/OP AGG	Excluded
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			AS2-621-093363-044	06/01/2024	06/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$2,000,000
							BODILY INJURY (Per person)	
							BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION			TH7621093363074	06/01/2024	06/01/2025	EACH OCCURRENCE	$5,000,000
							AGGREGATE	$5,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY	Y/N		WA762D093363014	06/01/2024	06/01/2025	X PER STATUTE OTH-ER	
				AOS				
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER (Mandatory in NH)	N	N/A	WC7621093363024	06/01/2024	06/01/2025	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			WI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000
C	Products Liability			N24NY380027 Claims Made	06/01/2024	06/01/2025	Each Occurrence Aggregate	$10,000,000 $10,000,000

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

Evidence of Insurance.

CERTIFICATE HOLDER

Henry Schein, Inc.
and its Subsidiary and Affiliated Companies
135 Duryea Road
Melville NY 11747 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast Inc.

Holder Identifier: EOC

Certificate No: 570110601626

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AGENCY CUSTOMER ID: 570000025511

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER: See Certificate Number: 570110601626	
CARRIER: See Certificate Number: 570110601626 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
E	E&O - Miscellaneous Professional-Primary			130003732 Cyber Liab/Tech& E&O SIR applies per policy terms & conditions	12/01/2024	12/01/2025	Limit of Liability	$10,000,000
D	Fiduciary Liability - Prima			47EPC31399304 SIR applies per policy terms & conditions	11/01/2024	11/01/2025	Aggregate Limit	$10,000,000

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AGENCY CUSTOMER ID: 570000025511

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER	
See Certificate Number: 570110601626	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570110601626	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

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

Named Insureds

Ace Southern Surgical Solutions
Ace Surgical Supply Company, Inc.
AEP MPE Holdings, LLC
All Star Orthodontics
BIOHORIZONS IMPLANT SYSTEMS, INC.
Camlog
CB Healthcare Consulting GmbH
DenMat Holdings, LLC
Dental Instrument Sales & Service, LLC
Dental Practice Transitions
Dentrix Dental Systems
eAssist Inc.
eAssist Publishing LLC
Edge Endo
Exan Enterprises
Firefly Supply LLC
G.I.V. Inc.
General Injectibles & Vaccines, Inc.
Hand Piece Parts & Repair, Inc.
Hayes Handpiece Franchises, Inc.
HealthFirst
Henry Schein, Inc
Henry Schein and Schvadent
Henry Schein Dental, Inc.
Henry Schein Global Sourcing, Inc.
Henry Schein Medical
Henry Schein One, LLC
Henry Schein Practice Solutions
Henry Schein Services GmbH
Henry Schein, Supply
HF Acquisition Co. LLC
HSG-S Corp
Impromed, LLC.
Insource, Inc.
Lighthouse 360, Inc.
Midway Dental Supply LLC
NAR Medical Depot LLC
NAR Training LLC
North American Rescue LLC and TQM, LLC
ORTHO2 LLC
Ortho Organizers, Inc.
Ortho Technology, Inc.
Precision One
Prism Medical Products
RXWORKS, INC.
Sesame Communications
Southern Anesthesia & Surgical Inc.
Shield HealthCare
TDSC, Inc.
The Custom Milling Center, Inc.
US Endodontics
Vulcan Custom Dental
Zahn Dental Company, Inc.
Zahn/Darby Lab

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 015223991

Application/License No. _____

HSG-S CORP., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
1 Brasseler Blvd. Suite 300 Savannah, GA 31419, as
(Address of Applicant/Principal)
PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY, a
(Surety Company)
corporation organized under the laws of the state of MA
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
175 Berkeley Street Boston, MA 02116 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 4, 2025.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 4th day of February, 2025.

APPLICANT/PRINCIPAL
HSG-S CORP.

COMPANY

Authorized Representative

SURETY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sandra Diaz, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

SIGNED and SEALED in the presence of:

Witness Francesca Kazmierczak

Witness

Witness Aklima Noorhassan

Countersigned by:

Nevada Resident Agent Frances A Rodriguez
NV Non-Resident License # 3349643

Posted February 20, 2020

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8210937- 016009

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Debra A. Deming, Sandra Diaz, Vilma Gonzalez, Peter Healy, Pablo Garcia Horcajo, Jennifer L. Jakaitis, Francesca Kazmierczak, Aklima Noorhassan, Anne Potter, Frances Rodriguez, Valorie Spates, Susan A. Welsh, Beverly A. Woolford

all of the city of New York state of NY each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 6th day of November, 2023.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 6th day of November, 2023 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 4th day of February, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2023

Assets		Liabilities	
Cash and Bank Deposits	$1,850,245,073.00	Unearned Premiums	$10,298,963,305.00
*Bonds – U.S Government	$3,859,565,383.00	Reserve for Claims and Claims Expense	$28,848,537,243.00
*Other Bonds	$21,048,805,773.00	Funds Held Under Reinsurance Treaties	$360,714,151.00
*Stocks	$19,937,271,802.00	Reserve for Dividends to Policyholders	$1,310,198.00
Real Estate	$122,228,711.00	Additional Statutory Reserve	$296,126,000.00
Agents' Balances or Uncollected Premiums	$8,208,660,427.00	Reserve for Commissions, Taxes and Other Liabilities	$7,622,413,466.63
Accrued Interest and Rents	$186,906,667.00	**Total**	**$47,428,064,363.63**
Other Admitted Assets	$15,677,869,683.63	Special Surplus Funds	$209,508,757.00
Total Admitted Assets	**$70,891,553,519.63**	Capital Stock	$10,000,075.00
		Paid in Surplus	$13,834,867,488.00
		Unassigned Surplus	$9,409,112,836.00
		Surplus to Policyholders	$23,463,489,156.00
		Total Liabilities and Surplus	**$70,891,553,519.63**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2023, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2024.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/ Wholesaler Information

Name of MDEG HSG-S Corp MDEG License # (if applicable) N/A

Physical Address 1 Brasseler Blvd Suite 300

City Savannah State GA Zip 31419

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 631-843-5500 Website N/A

Licensing Company Email Licensure@henryschein.com

Section 2: Personal Information

First Brendan Middle _____ Last McElhatton

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

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

Mailing Addres[redacted]

City Savannah State GA Zip [redacted]

Telephor[redacted] Email brednan.mcelhatton@henryschein.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Farmingdale State College		01/2011-08/2013	
Address	**City**	**State**	**Zip**
2350 Broadhollow Road, Farmingdale, NY 11735	Farmingdale	NY	11735
Diploma/Degree obtained, if any			
Bachelors Degree			
School Name		From - To (MM/YY – MM/YY)	
Suffolk County Community College		08/2007-12/2010	
Address	**City**	**State**	**Zip**
533 College RD	Selden	NY	11784
Diploma/Degree obtained, if any			
Associates Degree			
School Name		From - To (MM/YY – MM/YY)	
Half Hollow Hills High School West		09/2003-06/2007	
Address	**City**	**State**	**Zip**
375 Wolf Hill Rd	Dix Hills	NY	11746
Diploma/Degree obtained, if any			
Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2025-Present	[redacted]	Savannah	GA	[redacted]
05/2022-05/2025	[redacted]	Savannah	GA	
05/2018-05/2022	[redacted]	Dix Hills	NY	

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

Business Name			From - To (MM/YY – MM/YY)
Henry Schein Inc.			11/2019- Present
Business Address	**City**	**State**	**Zip**
135 Duryea Road	Melville	NY	11747
Phone	**Title**	**Number of Employed Hours**	
631-843-5500	Sr. QA Specialist	11,400 hrs	

Description of Duties

Maintaining the day to day responsibilities of the Quality management System. Maintaining the Document Control System. Processing product complaints. Processing State licensure applications.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

N/A

06-03-2025

Provide explanation below:

_____ _____

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

I, Brendan McElhatton, **certify that as the MDEG Administrator for**

HSG-S,

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

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

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

Brendan McElhatton
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06-03-2025
Date

Board Use Only	Date Received: 6/03/25

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler HSG-S Corp.

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 1 Brasseler Blvd

City Savannah State GA Zip 31419

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 631-843-5500 Website N/A

Licensing Company Email Licensure@henryschein.com

Section 2: Personal Information

First Brendan Middle _____ Last Mcelhatton

Alias(es, nicknames, name changes, etc.) [redacted]

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

Mailing Address _____

City Savannah State GA Zip [redacted]

Telephone [redacted] Email brendan.mcelhatton@henryschein.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
Farmingdale State College			01/2011-08/2013	
Address		City	State	Zip
2350 Broadhollow Road, Farmingdale, NY 11735		Farmingdale	NY	11735
Diploma/Degree obtained, if any				
Bachelors Degree				
School Name			From - To (MM/YY – MM/YY)	
Suffolk County community College			08/2007-12/2010	
Address		City	State	Zip
533 College Rd,		Selden	NY	11784
Diploma/Degree obtained, if any				
Associates Degree				
School Name			From - To (MM/YY – MM/YY)	
Half Hollow Hills High School West			09/2003-06/2007	
Address		City	State	Zip
375 Wolf Hill Rd		Dix Hills	NY	11746
Diploma/Degree obtained, if any				
Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2025- Present	[redacted]	Savannah	GA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
05/2022-05/2025		Savannah	GA	
From - To (MM/YY – MM/YY)		City	State	
05/2018-05/2022		Dix Hills	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Henry Schein, INC.			11/2020-Present	
Business Address		**City**	**State**	**Zip**
135 Duryea Road		Melville	NY	11747
Phone	**Title**		**Number of Employed Hours**	
631-843-5500	Sr. QA Specialist		11,400 hrs	
Description of Duties				
Maintaining the day to day responsibilities of the Quality management System. Maintaining the Document Control System. Processing product complaints. Processing State licensure applications.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

N/A

06-03-2025

Provide explanation below:

_____ _____

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

I, Brendan McElhatton, **certify that as the designated representative for**

HSG-S Corp.,

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

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

Brendan McElhatton

Print Name (First, Last)

Brendan McElhatton

Original Signature (electronic, copies or stamps not accepted)

06-03-2025

Date

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

Brendan Mcelhatton

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06-03-2025

Date

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

State of Georgia, ss. County of Chatham

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

Original Signature

06-03-2025

Date

Subscribed and Sworn to before me this 3rd day of June, 2025

Pamela Marie Kennedy

Notary Public Signature

OFFICIAL SEAL
PAMELA MARIE KENNEDY
NOTARY PUBLIC-GEORGIA
CHATHAM COUNTY
My Comm. Expires Feb. 19, 2028

(Seal)

HSG-S Corp.

1 Brasseler Blvd. Suite 300
Savannah, GA 31419

List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.

HSG-S Corp is currently conducting interviews to fill positions.

Employee	Title
Brendan Mcelhatton	Sr Quality Assurance Specialist
Heather Zellers	Manager, Warehouse
Gary Walden	Director, Operations

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 28, 2024

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 0-27078

HENRY SCHEIN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**11-3136595**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

135 Duryea Road
Melville, New York
(Address of principal executive offices)
11747
(Zip Code)
(631) 843-5500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.01 per share	HSIC	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
YES: ☒ NO: ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
YES: ☐ NO: ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
YES: ☒ NO: ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
YES: ☒ NO: ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer: ☒ Accelerated filer: ☐ Non-accelerated filer: ☐ Smaller reporting company: ☐
Emerging growth company: ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).
YES: ☐ NO: ☒

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant, computed by reference to the closing sales price as quoted on the Nasdaq Global Select Market on June 29, 2024, was approximately $8,092,479,000.

As of February 18, 2025, there were 124,176,781 shares of registrant's Common Stock, par value $.01 per share, outstanding.

Documents Incorporated by Reference:

Portions of the Registrant's definitive proxy statement to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year (December 28, 2024) are incorporated by reference in Part III hereof.

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PART I

ITEM 1. Business

General

Henry Schein, Inc. is a solutions company for health care professionals powered by a network of people and technology. We believe we are the world's largest provider of health care products and services primarily to office-based dental and medical practitioners, as well as alternate sites of care. Our philosophy is grounded in our commitment to help customers operate a more efficient and successful business so the practitioner can provide better clinical care.

With 93 years of experience distributing health care products, we have built a vast base of small, mid-sized and large customers in the dental and medical markets, serving more than one million customers worldwide across dental practices, laboratories, physician practices, and ambulatory surgery centers, as well as government, institutional health care clinics and other alternate care clinics.

We are headquartered in Melville, New York and employ approximately 25,000 people. Approximately 49% of our workforce is based in the United States and 51% outside of the United States. Our operations or affiliates are located in 33 countries and territories. Our broad global footprint has evolved over time through organic growth as well as through the contribution from our strategic acquisitions.

We stock a comprehensive selection of more than 300,000 branded products and Henry Schein corporate brand products through our main distribution centers. Our infrastructure, including over 5.4 million square feet of space in 36 strategically located distribution centers and 0.5 million square feet of space in 15 manufacturing facilities around the world, enables us to historically provide rapid and accurate order fulfillment, better serve our customers and increase our operating efficiency. This infrastructure, together with broad product and service offerings at competitive prices, and a strong commitment to customer service, enables us to be a single source of supply for our customers' needs, which we believe is a competitive advantage.

During the fourth quarter of our fiscal year ended December 28, 2024, we revised our reportable segments to align with how the Chairman and Chief Executive Officer manages the business, assesses performance and allocates resources. Our revised reportable segments consist of: (i) Global Distribution and Value-Added Services; (ii) Global Specialty Products; and (iii) Global Technology.

Global Distribution and Value-Added Services includes distribution to the global dental and medical markets of national brand and corporate brand merchandise, as well as equipment and related technical services. This segment also includes value-added services such as financial services, continuing education services, consulting and other services. This segment also markets and sells under our own corporate brand, a portfolio of cost-effective, high-quality consumable merchandise. Global Specialty Products includes manufacturing, marketing and sales of dental implant and biomaterial products; and endodontic, orthodontic and orthopedic products and other health care-related products and services. Global Technology includes development and distribution of practice management software, e-services, and other products, which are distributed to health care providers.

Recent Developments

See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments" herein for a discussion related to recent Company developments.

Industry

The distribution and value-added services industry, as it relates to office-based health care practitioners, is fragmented and diverse. The industry ranges from sole practitioners working out of relatively small offices to mid-sized and large group practices ranging in size from a few practitioners to several hundred practices owned or operated by dental support organizations ("DSOs"), medical group purchasing organizations ("GPOs"), health maintenance organizations ("HMOs"), hospital systems or integrated delivery networks ("IDNs").

Due in part to the limited capacity of office-based health care practitioners to store and manage large quantities of supplies in their offices, the distribution of health care supplies and small equipment to office-based health care practitioners has been characterized by frequent, small quantity orders, and a need for rapid, reliable and substantially complete order fulfillment. The purchasing decisions within an office-based health care practice are typically made by the practitioner, hygienist or office manager. Supplies and small equipment are generally purchased from more than one distributor, with one generally serving as the primary supplier.

The distribution and value-added services industry should benefit from favorable long-term macro trends that should help stimulate patient traffic and demand for products and services. This includes an aging population, increased health care awareness and the importance of preventive care, an increasing understanding of the connection between good oral health and overall health, improved access to care globally, the proliferation of medical technology and testing, new pharmacology treatments and expanded third-party insurance coverage, partially offset by the effects of unemployment on insurance coverage and technological improvements, including the advancement of software and services, prosthetic solutions and telemedicine. In addition, the non-acute market continues to benefit from the shift of procedures and diagnostic testing from acute care settings to alternate-care sites, particularly physicians' offices and ambulatory surgery centers.

We believe that consolidation within the industry will continue to result in a number of distributors, particularly those with limited financial, operating and marketing resources, seeking to combine with larger companies that can provide growth opportunities. This consolidation also may continue to result in distributors seeking to acquire companies that can enhance their current product and service offerings or provide opportunities to serve a broader customer base.

In addition, customer consolidation will likely lead to multiple locations under common management and the movement of more procedures from the hospital setting to the physician or alternate care setting, as the health care industry is increasingly focused on efficiency and cost containment. This trend has benefited distributors capable of providing a broad array of products and services at low prices. It also has accelerated the growth of HMOs, group practices, other managed care accounts and collective buying groups such as DSOs and GPOs, which, in addition to their emphasis on obtaining products at competitive prices, tend to favor distributors capable of providing specialized management information support. We believe that the trend towards cost containment has the potential to favorably affect demand for technology solutions, including software, which can enhance the efficiency and facilitation of practice management.

Competition

The distribution and manufacture of health care supplies and equipment is highly competitive. Many of the health care products we sell are available to our customers from a number of suppliers. In addition, our competitors could obtain exclusive rights from manufacturers to market particular products. Manufacturers also could seek to sell directly to end-users, and thereby eliminate or reduce our role and that of other distributors. In certain parts of the dental end market, such as those related to dental specialty products, and medical end market manufacturers already sell directly to end customers.

In North America, we compete with other distributors, as well as several manufacturers, of dental and medical products, primarily on the basis of price, breadth of product line, e-commerce capabilities, customer service and value-added products and services. In the dental distribution market, our primary competitors in the U.S. are the Patterson Dental division of Patterson Companies, Inc. and Benco Dental Supply Company. In addition, we compete against a number of other distributors that operate on a national, regional and local level. Our primary competitors in the U.S. medical distribution market, which accounts for the large majority of our global medical sales, are McKesson Corporation and Medline Industries, Inc., which are national distributors. We also compete with a number of regional and local medical distributors, as well as a number of manufacturers that sell directly to physicians and patients in their homes.

Outside of the U.S., we believe we are the only global distributor of supplies and equipment to dental practices and our competitors are primarily local and regional companies. We also face significant competition internationally, where we compete on the basis of price and customer service against several large competitors, including the GACD Group, Proclinic SA, Lifco AB, Nuent Group AB, Planmeca Oy and Billericay Dental Supply Co. Ltd., as well as a large number of other dental and medical product distributors and manufacturers in international countries and territories we serve.

Within Global Specialty Products, our primary competitors include Straumann, Envista, Zimvie, and Dentsply Sirona.

With regard to our dental software, we compete against numerous companies, including the Eaglesoft division of Patterson Companies, Inc., Carestream Dental LLC, Centaur Software Development Co Pty Ltd. (d.b.a. dental4windows, dental4web), Open Dental Software, Inc., PlanetDDS LLC, Good Methods Global Inc. (d.b.a. CareStack), Curve Dental, LLC., the NextGen division of Quality Systems, Inc., eClinicalWorks and Epic Systems Corporation. In other software end markets, including revenue cycle management, patient relationship management and patient demand generation, we compete with companies such as Vyne Medical, Weave Communications, Inc., and Solutionreach, Inc. Many of these competitors connect to our software platforms through our API program.

Manufacturing and Raw Materials

We manufacture certain of our products for our specialty businesses (oral surgery solutions including dental implants, endodontics, and orthopedics) at our 15 company manufacturing sites. We also outsource certain manufacturing to third parties. We purchase our raw materials from various third-party suppliers. No single supplier is material; however, raw materials may be sourced from a single supplier or a limited number of suppliers for reasons of quality assurance, regulatory requirements, cost, and availability.

We believe that we have a readily available supply of raw materials and components sourced from various suppliers, for our significant products.

We may experience shortages of raw materials or purchased components. In recent periods, we have experienced increased costs and shortages of purchased components, which had a negative impact on our profit margins and on our sales for certain product categories, due to our inability to fully satisfy demand.

Competitive Strengths

We have 93 years of experience in distributing products to health care practitioners resulting in strong awareness of the Henry Schein® brand. Our competitive strengths include:

A focus on meeting our customers' unique needs. We are committed to providing customized solutions to our customers that are driven by our understanding of the end markets we serve and that reflect the technology-driven products and services best suited for their practice needs. We are committed to continuing to enhance these offerings through organic investment in our products and our teams, as well as through the acquisition of new products and services that may help us better serve our customers.

Direct sales and marketing expertise. Our sales and marketing efforts are designed to establish and solidify customer relationships through personal or virtual visits by field sales representatives, frequent direct marketing and telesales contact, emphasizing our broad product lines, including exclusive distribution agreements, competitive prices and ease of order placement, particularly through our e-commerce platforms. The key elements of our direct sales and marketing efforts are:

- *Field sales consultants.* Our field sales consultants, including equipment sales specialists, covering major North American, European and other international markets. These consultants complement our direct marketing and telesales efforts and enable us to better market, service and support the sale of more sophisticated products and equipment.

- *Marketing.* We market to existing and prospective office-based health care providers through a combination of owned, earned and paid digital channels, tradeshows, as well as through catalogs, flyers, direct mail and other promotional materials. Our strategies include an emphasis on educational content through webinars and content marketing initiatives. We continue to enhance our marketing technology to improve our targeting capability and the relevance of messaging and offers.

- *Telesales.* We support our direct marketing effort with inbound and outbound telesales representatives, who facilitate order processing, generate new sales through direct and frequent contact with customers and stay abreast of market developments and the hundreds of new products, services and technologies introduced each year to educate practice personnel.

- *Electronic commerce solutions.* We provide our customers and sales teams with innovative and competitive e-commerce solutions. We continue to invest in our e-commerce platform to offer enhanced content management so customers can more easily find the products they need and to enable an engaging purchase experience, supported by excellent customer service.

- *Social media.* Our operating entities and employees engage our customers and supplier partners through various social media platforms, which are an important element of our communications and marketing efforts. We continue to expand our social media presence to raise awareness about issues, engage customers beyond a sale and deliver services and solutions to specialized audiences.

Cost-effective purchasing. We believe that cost-effective purchasing is a key element to maintaining and enhancing our position as a competitively priced provider of health care products. We continuously evaluate our purchase requirements and suppliers' offerings and prices in order to obtain products at the lowest possible cost. In 2024, our top 10 Global Distribution and Value-Added Services suppliers and our single largest supplier accounted for approximately 25% and 4%, respectively, of our aggregate purchases.

Efficient distribution. We distribute our products from our 36 strategically located distribution centers. We strive to maintain optimal inventory levels in order to satisfy customer demand for prompt delivery and complete order fulfillment. These inventory levels are managed on a daily basis with the aid of our management information systems. Once an order is entered, it is electronically transmitted to the distribution center nearest the customer's location for order fulfillment.

Broad product and service offerings at competitive prices. We offer a broad range of products and services to our customers, at competitive prices, in the following categories:

Global Distribution and Value-Added Services

- *Consumable merchandise and equipment.* We distribute consumable products, small equipment, laboratory products, large equipment, equipment repair services, branded and generic pharmaceuticals, vaccines, dental specialty products, diagnostic tests, infection-control products and vitamins. We stock a comprehensive selection of more than 300,000 branded products and Henry Schein corporate brand products through our main distribution centers. We also market and sell our own corporate brand portfolio of cost-effective, high-quality consumable merchandise products.

- *Home health business.* We distribute homecare medical products, including incontinence, urology, ostomy, enteral nutrition, advanced wound, and diabetes supplies, as well as continuous glucose monitoring devices. These products are delivered directly to patients in their homes, providing convenience and accessibility while supporting patient care and adherence to treatment plans.

- *Value-added products and services.* We offer a broad range of value-added solutions, including continuing education programs for practitioners, and consulting services. Our suite of technology-driven tools and expert advisory services helps health care professionals enhance practice efficiency and improve patient outcomes.

- *Repair services.* We have 129 equipment sales and service centers worldwide that provide a variety of repair, installation and technical services for our health care customers. Our technicians provide installation and repair services for dental handpieces, dental and medical small equipment, table-top sterilizers and large dental equipment.

- *Financial services.* We offer our customers solutions in operating their practices more efficiently by providing access to a number of financial services and products provided by third party suppliers (including non-recourse financing for equipment, technology and software products, non-recourse practice financing for leasehold improvements, business debt consolidation and commercial real estate, non-recourse patient financing and credit card processing) at rates that we believe are generally lower than what our customers would be able to secure independently. We also provide staffing services, dental practice valuation and brokerage services.

Global Specialty Products

- *Dental implants and digital solutions.* We develop, manufacture, market and distribute a broad portfolio of dental implants, prosthetic components, instruments and digital workflow solutions for implant-based tooth restorations. With research and development and manufacturing facilities in the United States, Switzerland, Germany, Brazil and France, we serve customers with various global and regional implant brands across a wide range of price segments. Supported by our specialized sales force, we market our products and solutions in approximately 90 countries, directly to dental practices and surgical specialists via our sales subsidiaries and our network of international third-party and Henry Schein distribution partners.

- *Biomaterials.* We market and distribute a broad portfolio of biomaterials for dental tissue regeneration. The product portfolio primarily consists of a broad range of privately branded allograft, xenograft, and synthetic biomaterials. Our dedicated biomaterial specialists support our direct implant sales force and Henry Schein oral surgery-focused distribution channels.

- *Orthodontics.* We develop, manufacture, and distribute a comprehensive range of orthodontic products, including brackets, braces, aligners, and accessories. In collaboration with leading clinicians, our research and development teams drive innovation to enhance patient care. With manufacturing facilities in the

4L

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: LENZ Therapeutics, Inc

Physical Address: 201 Lomas Santa Fe Drive, Suite 300

City: Solana Beach State: CA Zip: 92075

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 888-928-5369 Website: www.lenz-tx.com

Name of Designated Representative (DR): Melissa Rosness

Licensing Company Email: contact@lenz-tx.com DR Email: melissa@lenz-tx.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Ophthalmic	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Rommelag

Address: Holopack Verpackungstechnik GmbHBah City: Sulzbach-Laufen,Germany State: _____ Zip: 74429

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): N/A

Corporation Name: LENZ Therapeutics, Inc

Mailing Address: 201 Lomas Santa Fe Drive, Suite 300

City: Solana Beach State: CA Zip: 92075

Telephone: 888-928-5369 Email: contact@lenz-tx.com

Contact Person Name: Melissa Rosness

Date of SEC Registration: 10/28/2020 | SEC Registration Number: 7677148 | Stock Exchange Symbol: LENZ

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

LENZ Therapeutics, Inc

Facility Name

Evert Schimmelpennink

Print Name of Authorized Person Submitting Application

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

24 April 2025

Date

Board Use Only	Date Received: 7/14/25	Amount: $1000 CK 661718

LENZ THERAPEUTICS

201 Lomas Santa Fe Drive, Suite 300
Solana Beach, CA 92075

To Whom It May Concern:

LENZ Therapeutics is a pre-commercial biopharmaceutical company focused on the development and commercialization of the first and only aceclidine-based eye drop (LNZ100) in the treatment of Presbyopia. LENZ Therapeutics submitted a New Drug Application (NDA) to the U.S. FDA in August 2024. The U.S. Food and Drug Administration (FDA) accepted this application and assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 8, 2025 for LNZ100.

Once approved, the product will be shown within the FDA National Drug Code Directory. With that, LENZ Therapeutics is seeking official state licensure in preparation of FDA approval.

Lenz Officer and Owner List

Officers:

Eef (Evert) Schimmelpennink - President and Chief Executive Officer

Shawn Olsson - Chief Commercial Officer

Daniel Ritchey Chevallard - Chief Financial Officer

Marc Odrich – Chief Medical Officer

Owners:

Lenz Therapeutics, Inc. is a publicly traded entity.

Delaware

The First State

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

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

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

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7677148 8300

SR# 20252187349

Authentication: 203662077

Date: 05-12-25

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

LENZ Ownership Flowchart



CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 8485

ISSUE DATE 9/6/2024

LENZ THERAPEUTICS INC
201 LOMAS SANTA FE DR SUITE 300
SOLANA BEACH, CA 92075

The above is licensed with the State Board of Pharmacy as a Corporation

ROSNESS MELISSA MARIE — EXEMPTEE IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL 9/1/2025

RECEIPT NUMBER 00767115

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

Name	Employee Type
Ahmad Chaudhri	Regular Employee
Aimee Jenkins	Regular Employee
Alanna Arno	Regular Employee
Alisyn Facemire	Regular Employee
Amanda Daghaly	Regular Employee
Andre Watts	Regular Employee
Anita Gulmiri	Regular Employee
Apple Decena	Regular Employee
Arjun Parti	Regular Employee
Barry Eiden	Regular Employee
Breianna Bowen	Regular Employee
Carly Caracozza	Regular Employee
Chisom Chukwumerije	Regular Employee
Dan Chevallard	Regular Employee
David Choromanski	Regular Employee
David Lampariello	Regular Employee
David Murphy	Regular Employee
Domenick Porfidia	Regular Employee
Eric Bonfadini	Regular Employee
Ethan Mengle	Regular Employee
Evert Schimmelpennink	Regular Employee
Gerald Horn	Regular Employee
Germaine Nagel	Regular Employee
Gloria Lam	Regular Employee
Grant McNamara	Regular Employee
Hina Robertson	Regular Employee
Hsin-Tze Lu	Regular Employee
Ian Whipple	Regular Employee
Jaime Elledge	Regular Employee
James Sluck	Regular Employee
Jeff Ebeier	Regular Employee
Jerry Hatter	Regular Employee
Jon Wilfong	Regular Employee
Joseph Bryant	Regular Employee
Joshua Cox	Regular Employee
Jullian Cerasuolo	Regular Employee
Kashif Qadeer	Regular Employee
Katarina Simonovic	Regular Employee
Katie Coffey	Regular Employee
Kenneth Kolbeck	Regular Employee
Kerry Robbers	Regular Employee
Kristin Gambelin	Regular Employee
Kruti Nakrani	Regular Employee
Mansi Parikh	Regular Employee
Marc Odrich	Regular Employee
Marianna Rabinovich	Regular Employee
Mario Magdaleno	Regular Employee
Marjan Akhlaghi	Regular Employee
Melissa Molomby	Regular Employee
Melissa Rosness	Regular Employee
Melody Burcar	Regular Employee
Mina Ghazizadeh	Regular Employee
Natasha Balani	Regular Employee
Robert Burrus	Regular Employee
Sam Wilson	Regular Employee
Shawn Olsson	Regular Employee
Stephen Aiken	Regular Employee
Ted Wheeler	Regular Employee
Thalia Gotsis	Regular Employee
Todd Allen	Regular Employee
Tyler Snell	Regular Employee
Zena Khan	Regular Employee

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-40532

LENZ THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**84-4867570**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

201 Lomas Santa Fe Dr., Suite 300
Solana Beach, California 92075
(Address of principal executive offices, including zip code)

(858) 925-7000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	**LENZ**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates, based upon the closing price of the common stock on June 28, 2024, as reported by The Nasdaq Stock Market LLC, was $362.6 million. Shares of common stock held by each executive officer and director and by each other person who is deemed to be an affiliate of the registrant have been excluded from such computation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 12, 2025, 27,542,874 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, commercial activities and costs, research and development costs, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates to the satisfaction of the Food and Drug Administration ("FDA"), and other positive results;
- the timing, scope and likelihood of regulatory approval for LNZ100;
- our ability to obtain and maintain regulatory approval of LNZ100;
- our plans relating to commercializing LNZ100, if approved, including the anticipated timing and geographic areas of focus and sales strategy;
- our plans relating to the development of LNZ100;
- the size of the market opportunity for LNZ100, including our estimates of the size of the affected population and potential adoption rate;
- our competitive position and the success of competing therapies that are or may become available;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of LNZ100;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our plans relating to the further development and manufacturing of LNZ100 and any future product candidates;
- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the rate and degree of market acceptance and clinical utility of LNZ100 and any other product candidates we may develop;
- the impact of existing laws and regulations and regulatory developments in the United States and other jurisdictions;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering LNZ100, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct any additional clinical trials of LNZ100 or any future product candidates, and for the manufacture of our product candidates for any such trials;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- costs related to the Merger (as defined in Part II, Item 8, Note 1, "Organization and Liquidity," in our notes to consolidated financial statements in this Annual Report on Form 10-K);

- our expectation that our existing cash, cash equivalents, and marketable securities will be sufficient to fund the Company to positive operating cash flow subsequent to commercial launch, if LNZ100 is approved;
- our expectations regarding the period during which we will remain an emerging growth company under the Jumpstart Our Business Startups Act (the "JOBS Act"); and
- our anticipated use of our existing resources, the proceeds from the Merger and the concurrent March 2024 PIPE Financing (as defined in Part II, Item 8, Note 3, "Merger and Related Transactions," in our notes to consolidated financial statements in this Annual Report on Form 10-K), and the July 2024 PIPE Financing (as defined in Part II, Item 8, Note 8, "Stockholders' Equity," in our notes to consolidated financial statements in this Annual Report on Form 10-K).

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we undertake no obligation to update or revise any forward-looking statements contained herein to reflect events or circumstances after the date of this Annual Report, whether as a result of any new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Part I

Item 1. Business

Overview

We are a pre-commercial biopharmaceutical company focused on the development and commercialization of innovative therapies to improve vision. Our initial focus is the treatment of presbyopia, the inevitable loss of near vision that impacts the daily lives of nearly all people over 45. In the United States, the estimated addressable population who suffer from this condition, known as presbyopes, is 128 million, almost four times the number of individuals suffering from dry eye disease and three times the number of individuals suffering from childhood myopia, macular degeneration, diabetic retinopathy and glaucoma combined. We believe that a once-daily pharmacological eye drop that can effectively and safely improve near vision throughout the full workday, without the need for reading glasses, could be a highly attractive commercial product with an estimated U.S. market opportunity in excess of $3 billion. It is our goal to develop and commercialize such a product, and we have assembled an executive team with extensive clinical and commercial experience to execute this goal and become the category leader.

Our lead product candidate LNZ100 is a preservative-free, single-use, once-daily eye drop containing aceclidine. We believe our product candidate is differentiated based on rapid onset, degree and duration of near vision improvement, its ability to be used across the full age range of presbyopes, from their mid-40s to well into their mid-70s, as well as a broad refractive range. Aceclidine's pupil-selective mechanism of action was demonstrated in our clinical trials where near vision improved while avoiding blurry distance vision. Our product candidate was well-tolerated in clinical trials, and its active ingredient aceclidine has a favorable tolerability profile that have been well-established empirically. LNZ100 has patent protection until 2039 in the United States, at a minimum, due to a robust intellectual property portfolio underpinned by issued patents.

In the safety and efficacy trials of our Phase 3 study ("CLARITY 1 and 2"), LNZ100 achieved the primary endpoints and key secondary endpoints, with statistically significant three-lines or greater improvement in Best Corrected Distance Visual Acuity ("BCDVA") at near, without losing one or more lines in distance visual acuity. In the vehicle-controlled CLARITY 2 trial, the day 1 results showed (all $p<0.0001$):

- **Rapid onset:** 71% achieved three-lines or greater improvement at 30 minutes.
- **Primary endpoint:** 71% achieved three-lines or greater improvement at 3 hours.
- **Long duration:** 40% achieved three-lines or greater improvement at 10 hours.

Near vision improvement was reproducible and consistent across both CLARITY 1 and 2 throughout the four-week study periods. LNZ100 was well-tolerated with no serious treatment-related adverse events observed in the over 30,000 treatment days, including the six-week safety study period in CLARITY 1 and 2, and the six-month period in the CLARITY 3 Phase 3 long-term safety trial (collectively, the "CLARITY study").

Our other product candidate LNZ101, a preservative-free eye drop containing aceclidine and brimonidine, showed similar results, including achieving primary and secondary endpoints in both CLARITY 1 and 2, but did not show superiority to LNZ100. Based on these results, we selected LNZ100 as our lead product candidate, for which we submitted a New Drug Application ("NDA") to Food and Drug Administration ("FDA") in August 2024. In October 2024, the FDA assigned a Prescription Drug User Fee Act ("PDUFA") target action date of August 8, 2025, which, if approved, will be immediately followed by a commercial launch in the United States, with the product anticipated to be available in the market in the fourth quarter of 2025. We believe that LNZ100 could be the first and only aceclidine-based product approved by the FDA and would then be eligible for five years of new chemical entity ("NCE") exclusivity in the United States.

It is estimated that there are 1.8 billion presbyopes globally and 128 million presbyopes in the United States. As people age, the crystalline lens in their eyes gradually hardens, resulting in a loss of lens elasticity that reduces the ability of the lens to increase its curvature and refractive power to focus incoming light for near vision onto the retina, known as accommodation. Although the progression of presbyopia is gradual, presbyopes often experience an abrupt change in their daily life as the symptoms become more pronounced starting in their mid-40s, when reading glasses or other corrective aids are suddenly necessary to read text or conduct close-up work. Presbyopia is typically self-diagnosed and self-managed with over-the-counter reading glasses, or managed, after evaluation by an eye care professional ("ECP"), with prescription reading or bifocal glasses or multifocal contact lenses. Currently, the only approved and marketed pharmaceutical treatment for presbyopia is marketed by AbbVie under the brand name Vuity.

Based on data collected in a third-party study commissioned by us in early 2023 that is further described in the section "*Market Opportunity,*" we found that presbyopes have high willingness to use a daily prescription eye drop that improves their near vision throughout the full workday. We expect that there will be a wide range of presbyopes that will be interested in using the eye drops at least four times a week. The large initial demand seen for Vuity during its launch in late 2021 and early 2022 corroborates the market demand for a pharmaceutical option for the treatment of presbyopia. However, despite a promising initial launch, Vuity's user uptake has been limited by reportedly lower-than-expected efficacy and duration of effect across users. Additionally, Vuity use is associated with some side effects, including rare incidences of retinal tears and detachments, induced by the stimulation of the ciliary muscle. These limitations on efficacy and safety subsequently resulted in lower than anticipated prescription refill rates and a label amendment reflecting the risk of retinal tears and detachment specifically associated with Vuity. We believe that our once-daily eye drop, if approved, could become the leading brand for presbyopes, by improving near vision throughout the full workday.

LNZ100 is formulated with aceclidine, a miotic, and is designed to achieve optimal pupil diameter without impacting distance vision, a key limitation of other miotics. Miotics are compounds that cause pupil constriction, or miosis, creating a pinhole effect that enables better focus of incoming light from near objects onto the retina. Research has shown that a pupil diameter below two millimeters (2 mm) is optimal for presbyopia treatment and results in clinically meaningful improvement in near vision. Unlike other miotics such as pilocarpine and carbachol, aceclidine's mechanism of action is pupil-selective, meaning it can activate the iris sphincter muscle and cause miosis of the pupil to a diameter below 2 mm without overstimulating the ciliary muscles that can cause a myopic shift and impair distance vision. As a result, aceclidine does not require any remaining accommodation to improve near vision, broadening its benefits to older presbyopes whose lens has lost this capacity. Therefore, we expect that users may be able to benefit from treatment even as they age from mid-40s to well into their mid-70s and across a broad range of refractive errors, as demonstrated in clinical testing to date.

While aceclidine is new to the United States, it has a long-established history outside of the United States, having been approved in Europe since the 1970s for the treatment of glaucoma and marketed by Merck under the brand Glaucostat, at higher concentrations than in LNZ100 and up to four times a day. Given the known favorable tolerability profile of aceclidine, LNZ100's sole active ingredient, its decades-long use, and unique mechanism of action, we believe LNZ100 has the potential to treat the broadest population of presbyopes and become the category leader.

Given our goal to develop and commercialize the leading, once-daily eye drop for presbyopia that can effectively and safely improve near vision throughout the full workday, we continue to build a robust commercial strategy in the United States and plan to be launch-ready upon potential FDA approval. We retain the flexibility to not only seek commercialization of our product candidates, but to also remain opportunistic in developing, in-licensing or partnering other products or product candidates to further leverage our commercial infrastructure to drive growth and operating leverage.

To execute our vision, we have assembled a team with extensive experience in building successful life science and consumer product companies. Our team has helped launch and commercialize over a dozen ophthalmic products and therapies, including Acuvue, Alphagan P, Combigan, Dailies AquaComfort Plus, Durysta, Latisse, Lumigan, Pred Forte, Refresh, Restasis, Truetear, and Vuity, as well as major consumer-focused brands such as Red Bull, Dermalogica, Botox, Herbalife and Ray-Ban. Members of our management team have held senior positions at Alcon, Allergan, Alvotech, Avanir, Bausch + Lomb, Coca-Cola, Dermalogica, Herbalife, Hospira, Johnson & Johnson, Pfenex, Pfizer, Red Bull, STAAR, VISX, Prometheus Laboratories, Regulus Therapeutics and others. We have also engaged a strong team of medical advisors across the ophthalmology and optometry fields. Our team is further supported by a strong group of investors that share our commitment to helping the millions of people experiencing symptoms of presbyopia in the United States and globally.

LENZ Strategy

We are a pre-commercial biopharmaceutical company focused on the development and commercialization of innovative therapies to improve vision. Our goal is to develop and commercialize the leading, once-daily eye drop for presbyopia that can effectively and safely improve near vision throughout the full workday. We intend to achieve this goal by pursuing the following key strategic objectives:

- **Capitalize on the unique characteristics of aceclidine through LNZ100.** A key part of our strategy was the selection and development of aceclidine as a miotic agent for the treatment of presbyopia. As the only known pupil-selective miotic, aceclidine has a unique mechanism of action that we believe should allow for development as a category leading eye drop for presbyopia. We have since demonstrated our ability to enable rapid onset, degree and duration of near vision improvement with minimal risk of impact to distance vision in multiple clinical

trials. Furthermore, we believe that aceclidine can address both a wider age range of presbyopes from mid-40s to well into their mid-70s, as well as broader refractive range, relative to currently available eye drops.

- **Pursue approval and commercialization of LNZ100.** Based on our positive Phase 3 results, we selected LNZ100 as our lead product candidate. We submitted an NDA for LNZ100 in August 2024 and in October 2024, the FDA assigned a Prescription Drug User Fee Act ("PDUFA") target action date of August 8, 2025. Commercial launch is planned to immediately follow the potential approval in the United States, with the product anticipated to be available in the market in the fourth quarter of 2025. We believe that LNZ100 could be the first and only aceclidine-based product approved by the FDA and would then be eligible for five years of NCE exclusivity in the United States. If approved by FDA, our objective is to best create loyalty and value based on an "all eyes, all day" brand mission.

- **Pursue our focused commercial strategy across U.S. ECPs and presbyopes.** We are focused on targeting and partnering with the estimated 15,000 ECPs who prescribed over 85% of the pharmaceutical presbyopia prescriptions in the United States in 2022 to enable efficient commercialization and rapid adoption of our product. We are currently educating ECPs on the importance of pupil-selective miotics that have a clinical profile that reduces pupil diameter below 2 mm without overstimulating the ciliary muscles with our EYEAMSELECTIVE campaign. If approved, we plan to communicate the efficacy profile of the approved product and highlight the value proposition of an alternative treatment option for presbyopia for ECPs. In parallel, our commercial team will deploy a cost-effective, highly targeted and digitally-focused consumer strategy to identify, target, and build loyalty among presbyopes in the United States. We expect to commercialize through the self-pay healthcare market (without third-party reimbursement), which is strategically advantageous in the United States and enables immediate patient access and volume-based pricing strategies.

- **Continue to build an experienced commercial team with the capabilities of a leading consumer-focused company.** We have built a leadership team with extensive experience across successful life science and consumer product companies who have launched and commercialized over a dozen ophthalmic products and therapies and well-known consumer-focused brands. Our leadership team is complemented by a team of leading medical advisors across the ophthalmology and optometry fields. To ensure immediate commercialization upon the potential approval of LNZ100, we are timing the expansion of our existing commercial capabilities and the establishment of a sales organization of 100 to 150 individuals to coincide with the expected timing of any such approval.

- **Continue to strengthen our intellectual property portfolio.** We have developed and continue to expand a strong portfolio of intellectual property for the treatment of presbyopia with aceclidine-based eye drops. We have patent protection until 2039, at a minimum, in the United States due to a robust intellectual property portfolio underpinned by issued patents. If LNZ100 is approved, we believe that it could be the first FDA-approved aceclidine-based product and would then be eligible for five years of NCE exclusivity in the United States. We plan to actively seek to obtain, where appropriate, the broadest intellectual property protection possible by filing for additional patents or other applicable intellectual property protection covering new or enhanced proprietary technology, including new methods of use, formulations, and dosing regimens. We also rely on regulatory frameworks, trademarks, trade secrets, know-how, and continuing technological innovation and may consider in-licensing opportunities to develop and maintain our proprietary position.

- **Opportunistically evaluate strategic and commercial opportunities.** We are focused on commercializing in the United States on our own. In addition, we have entered into a license and collaboration agreement (the "CORXEL License") with CORXEL Pharmaceuticals (formerly known as Ji Xing Pharmaceuticals Hong Kong Limited) ("CORXEL") to develop product candidates in Greater China and are developing regulatory strategies and intend to opportunistically seek partnerships for Europe, Canada, and other markets. For more details, see the subsection entitled "License and Collaboration Agreement with CORXEL." We believe our presbyopia program, if approved and successful, can serve as a cornerstone for building a suite of ophthalmology biopharmaceuticals. As a result, we may acquire other products or product candidates that we believe can make a substantial impact on vision and yield high user satisfaction. We may seek to maximize the commercial infrastructure and relationships with ECPs that we are currently building for our presbyopia program, to potentially offer a broad portfolio of ophthalmology biopharmaceuticals to our users to drive growth and operating leverage.

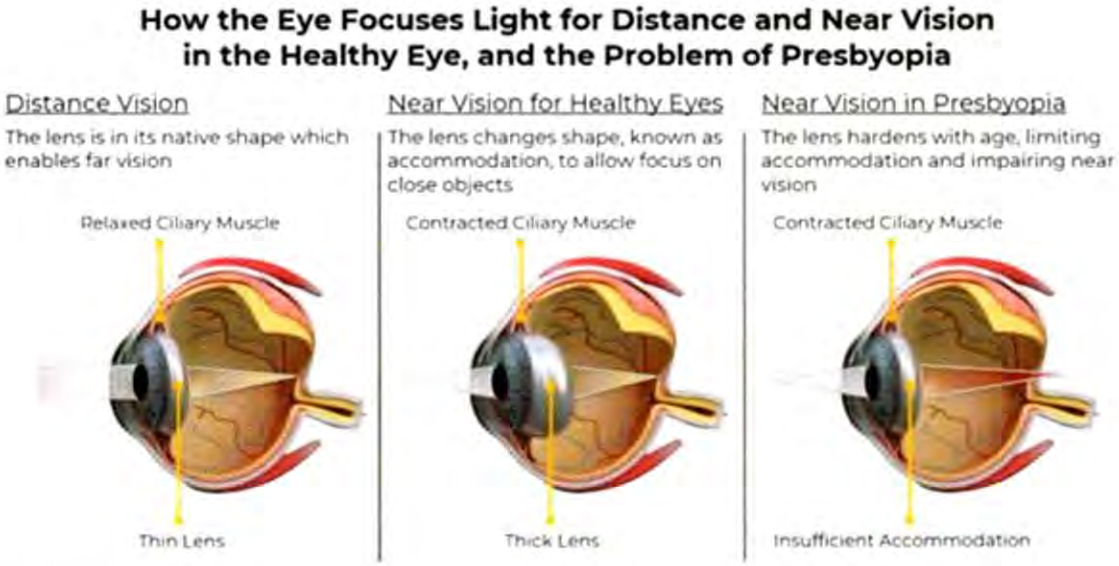
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Presbyopia

Background

Presbyopia is the inevitable loss of near vision associated with aging. It impacts the daily lives of nearly all people over 45. As people age, the crystalline lens in their eyes gradually hardens and becomes less able to change shape. This loss of elasticity of the lens reduces the ability of the lens to focus incoming light from near objects onto the retina. Adults over age 50 lose on average 1.5 lines of near vision every six years. Although the progression of presbyopia is gradual, presbyopes often experience an abrupt change in their daily life as the symptoms become more pronounced starting in their mid-40s, when reading glasses or other corrective aids are suddenly necessary to read text or conduct close-up work. Presbyopia is typically self-diagnosed and self-managed with over-the-counter reading glasses, or managed, after evaluation by an ECP, with prescription reading or bifocal glasses or multifocal contact lenses. Currently, the only approved and marketed pharmaceutical treatment for presbyopia is marketed by AbbVie under the brand name Vuity.

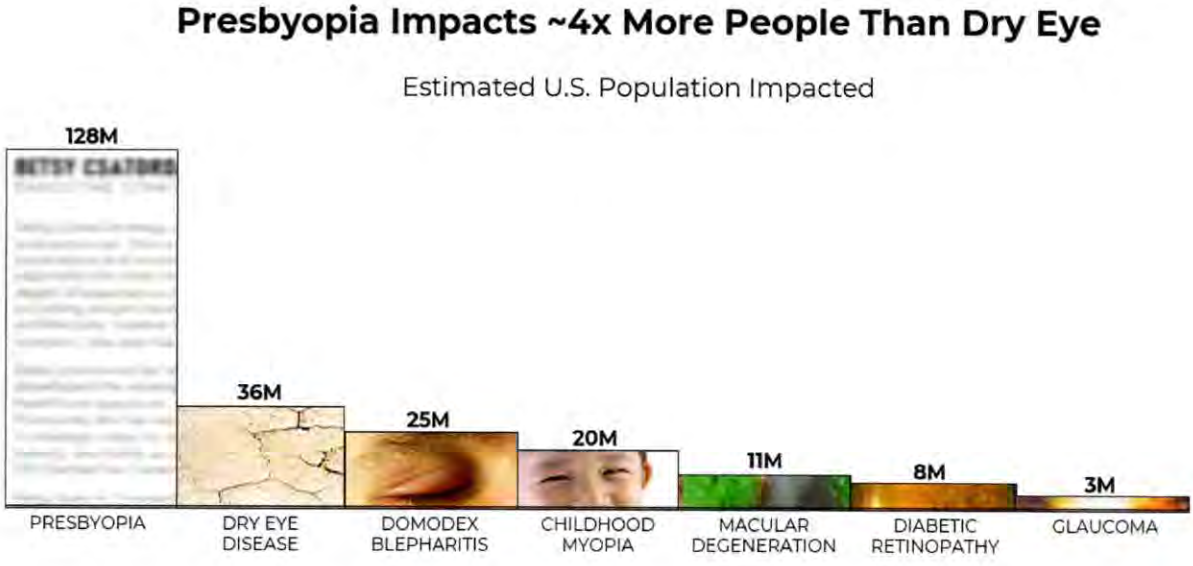
As illustrated in the figure below, contraction of the ciliary muscle allows the flexible lens in a healthy eye (center panel) to increase its curvature and refractive power and focus incoming light for near vision onto the retina in a process known as accommodation. As the lens hardens with age, the presbyopic lens (right panel) loses its flexibility and ability to accommodate and, despite contraction of the ciliary muscles, the incoming light for near vision no longer focuses on the surface of the retina, resulting in blurry near vision.



Market Opportunity

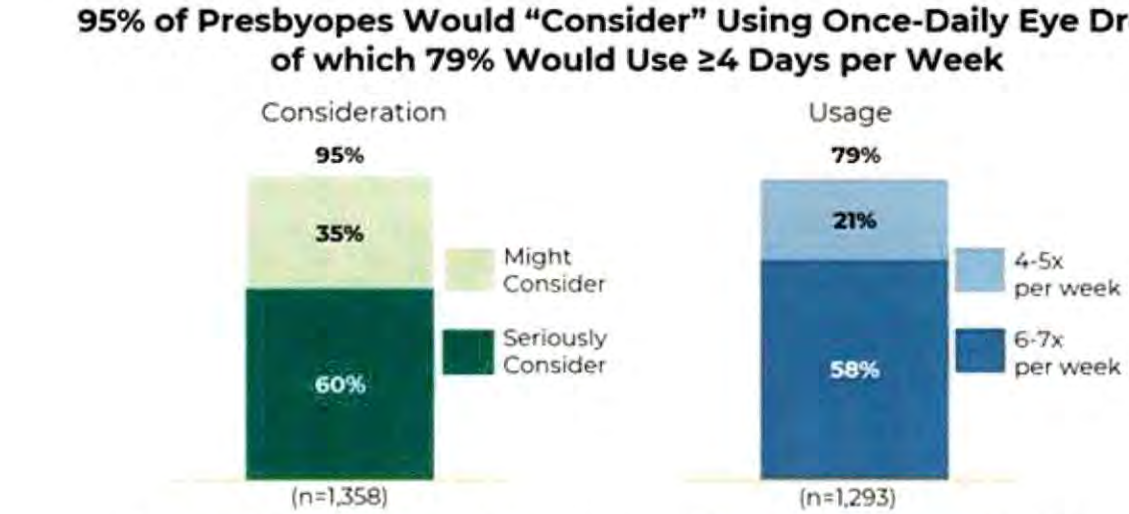
Presbyopia impacts an estimated 1.8 billion people globally and 128 million people in the United States, which makes it the most prevalent ophthalmology indication, outside latent refractive errors. On an addressable population basis, presbyopia is almost four times greater than dry eye disease and three times greater than childhood myopia, macular degeneration, diabetic retinopathy and glaucoma combined. Furthermore, the market opportunity for presbyopia is growing due to the

aging of the general population. As people continue working and stay active longer, they will require effective treatment for presbyopia for near vision acuity in their daily lives.



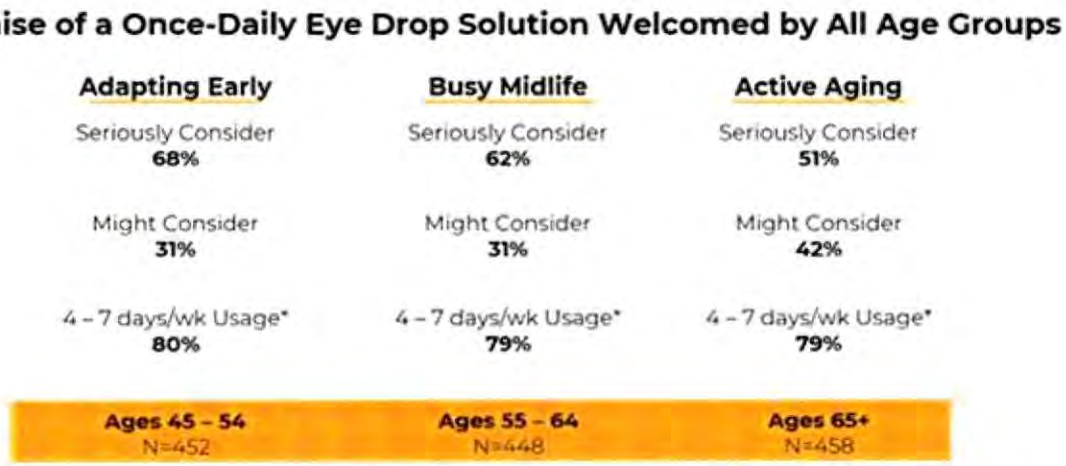
Presbyopia is a consumer-driven and cash pay market that requires intense focus on the needs and desires of presbyopes. We believe that the likely demand for a pharmaceutical option is driven by multiple factors, most notably presbyopes seeking to have a functional visual benefit in their day-to-day life, as well as those that want the cosmetic benefit of not requiring reading glasses. From a functional and cosmetic perspective, we see many similarities to the market dynamics between contact lenses and glasses. The contact lens market has grown to approximately $17 billion globally and approximately $6 billion in the United States in 2022. Contact lens users tend to have strong brand loyalty and the market has shown they are willing to spend out of pocket as an alternative to glasses for a variety of factors, including convenience, a more natural field of vision, enabling an active lifestyle and the ability to look younger. Similarly, over 10 million individuals have elected to complete laser vision correction, such as LASIK, which demonstrates a willingness to undergo elective surgical procedures to improve vision. Additionally, global sales of Botox injections for non-therapeutic applications, such as for cosmetic purposes, were $2.6 billion in 2022, demonstrating a high willingness to pay out of pocket for differentiated pharmaceutical brands. Currently, as people begin to develop presbyopia, they often have to stop using contact lenses, which seldom allow for simultaneous effective distance and near vision correction. A prescription eye drop that can be used in combination with distance correcting lenses can allow patients to stay in their contact lenses longer.

We expect that there will be a wide range of presbyopes that will be interested in using the eye drops at least four times a week as well as a smaller group that will use them on a more episodic basis. In early 2023, we commissioned a third-party consultant to conduct a market research study of at least 1,000 presbyopes in the United States, ranging from ages 45 to 74, through an online survey. The third-party consultant contacted and screened individuals who self-identified to be open to online surveys to ensure the participants satisfied the pre-specified age and near vision acuity requirements and that the group of respondents were balanced in gender and household income. Of the individuals screened, 1,358 individuals were qualified and completed the survey, and approximately 95% indicated they would "consider" using a once-daily prescription eye drop for up to 10 hours of near vision improvement, including 60% who indicated they would "seriously consider" using such eye drop. Of the respondents who also indicated that they would either "seriously consider" or "might consider" such eye drops, 79% indicated they would use such eye drops at least four times a week, including 58% who indicated they would use such eye drop six to seven times a week.



Results based on a third-party market research study of U.S. presbyopes commissioned by LENZ

Furthermore, presbyopes indicated potential demand across multiple age cohorts across the following stages, including those adapting early (ages 45 to 54), busy midlife (ages 55 to 64) and active aging (ages 65+). 68% of respondents ages 45 to 54 (n=452) would "seriously consider" and another 31% "might consider" such eye drop, of which 80% (of those who would consider such eye drops) would use such eye drop at least four times a week. For respondents ages 55 to 64 (n=448), 62% would "seriously consider" and another 31% "might consider" such eye drop, of which 79% would use such eye drop at least four times a week, and for respondents ages 65 to 74 (n=458), 51% would "seriously consider" and another 42% "might consider" such eye drop, of which 79% would use such eye drop at least four times a week. This market survey aligns with our patient reported outcomes from our CLARITY Phase 3 study, where 75% of the 223 participants surveyed on the 28th day of receiving LNZ100 indicated interest in continuing to use the eye drops after the study, of which 81% would use the drops at least four times a week.



Results based on a third-party market research study of U.S. presbyopes commissioned by LENZ (n=1,358 Presbyopes)
* percent of those who "would seriously" or "might" consider (n=1,293)

There is high demand for prescription eye drop-based treatments. In 2022 alone, more than 120,000 unique users paid out-of-pocket for a prescription for Vuity, the first miotic-based eye drop approved by the FDA in late 2021. Furthermore, the market opportunity for presbyopia is growing due to the aging of the general population and as people continue working and stay active longer they will require effective treatment for presbyopia for near vision acuity in their daily lives. Assuming a 6% adoption rate of the addressable presbyope patient population in the United States, we estimate there are eight million potential users in the United States for LNZ100, if approved and marketed, well below our estimate of the number of users of other out-of-pocket products such as LASIK. Using existing market price for Vuity of $79 per prescription and assuming a 42% refill rate (or five refills in a twelve-month period), we estimate a U.S. market opportunity in excess of $3 billion.



Approaches to Manage or Treat Presbyopia and Their Limitations

Currently, the primary options available for the management of presbyopia are limited to reading glasses or multi-focal glasses and contact lenses. The only currently FDA-approved and marketed pharmaceutical treatment for presbyopia is marketed by AbbVie under the brand name Vuity.

Glasses and Contact Lenses

Over-the-counter or prescription reading glasses ("readers"), prescription bifocal glasses and lenses ("bifocals"), graduated glasses ("transitions"), and multifocal contact lenses are commonly used to correct for presbyopia by focusing near objects on the retina. The additional refractive power that these types of corrective lenses offer can also be combined with other vision corrections in the same prescription lenses. However, users often report dissatisfaction with the inconvenience caused by having to wear and carry glasses or insert and remove contact lenses. There are also undesirable cultural connotations associated with the use of glasses, especially reading glasses, as they can be associated with aging. Additionally, these products require a trade-off between near vision and distance vision, either removing the readers, or looking at different areas of the bifocals.

Eye Drops

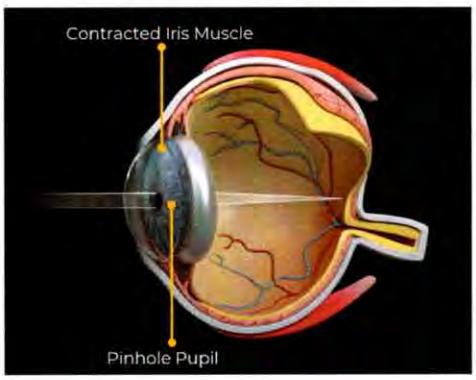
Eye drops can be an attractive method of treatment for presbyopia, especially when they only need to be administered once daily and effectively improve near vision throughout the full workday. Such an option can obviate the need to carry and wear reading glasses.

Miotics are pharmacological agents that are being developed and commercialized for the treatment of presbyopia. Miotic agents treat presbyopia by creating a pinhole effect to increase the depth of focus and thus improve the ability to see up-close. The pinhole effect is based on an optical effect whereby the depth of focus is inversely correlated with the size of the opening that light travels through. When light passes through a small pinhole or pupil, the rays that hit the outer areas of the eye and would need the most refraction to be focused on one point of the retina are blocked, leaving only the center rays which require minimal refraction to land on the retina to form a clear image. In presbyopes who have minimal accommodation or refraction ability left in their lens, this pinhole effect improves their ability to clearly see objects that are up-close. Because some miotics are historically known to negatively impact distance vision caused by a potential myopic shift associated with stimulation of the ciliary muscle, the FDA has indicated that the clinical endpoint for the approval of eye drops for the treatment of presbyopia is showing three-lines or greater (15 letters) of improvement in near visual acuity as a result of the reduction of the pupil diameter without losing one or more line (5 letters) in distance visual acuity.

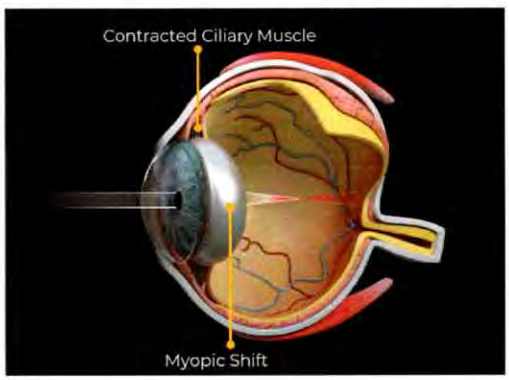
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Ideal presbyopia eye drop creates a pinhole pupil while avoiding a myopic shift that impacts distance vision

Create a pinhole pupil



While avoiding a myopic shift

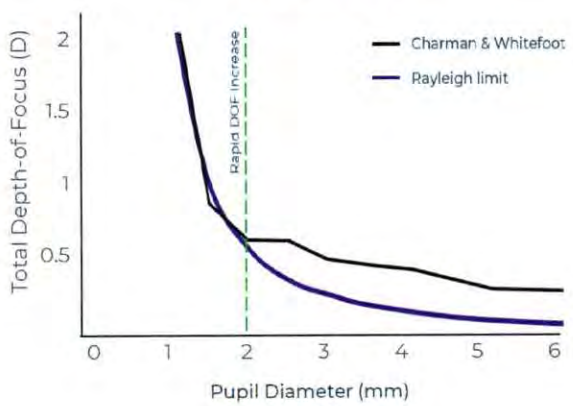


FDA requires 3 lines of near vision improvement while not losing 1 or more lines of distance vision

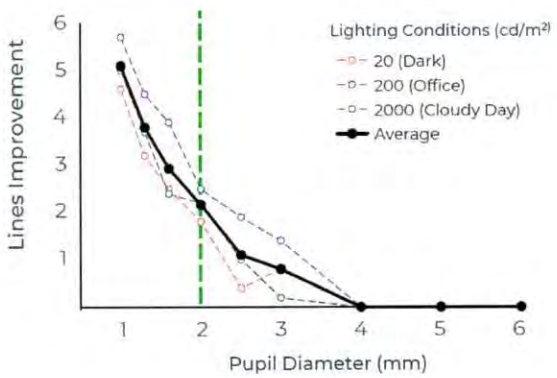
Independent, peer-reviewed, academic studies conducted by third parties and summarized by W. Neil Charman in a published editorial[1] have shown that pupil diameter is highly correlated with the depth of focus and that reducing pupil diameters below 2 mm is correlated with a dramatic increase in depth of focus (left graphic below). Similarly, in another independent, peer-reviewed, academic study[2] of near vision improvement conducted by a third party across a variety of lighting conditions, pupil diameters below 2 mm were correlated with two- to five-lines or greater improvement in near visual acuity (right graphic below).

Pupil diameter correlates to depth of focus and near vision improvement

Total Depth-of-Focus



Near Vision Improvement



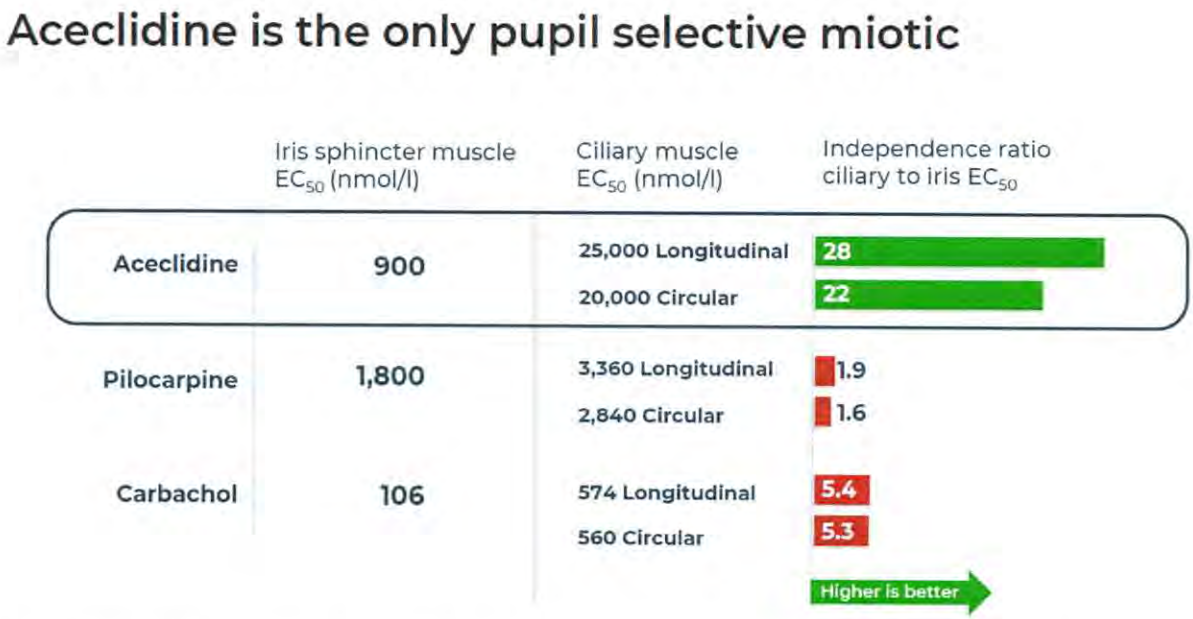
[1] Charman, W.N. (2019), Pinholes and presbyopia: solution or sideshow?. Ophthalmic Physiol Opt, 39: 1-10; Ciuffreda, K.J., Rosenfield, M., Mordi, J., Chen, HW. (2000). Accommodation, age and presbyopia. In: Franzén, O., Richter, H., Stark, L. (eds) Accommodation and Vergence Mechanisms in the Visual System. Birkhäuser, Basel.

[2] Xu, R, Gil, D, Dibas, M, Hare, W, and Bradley, A, The Effect of Light Level and Small Pupils on Presbyopic Reading Performance. Investigative Ophthalmology & Visual Science October 2016, Vol.57, 5656-5664.

Comparison of Miotics

LNZ100 is designed and formulated with aceclidine, a unique miotic, to achieve the below 2 mm pupil diameter without impacting distance vision, a key limitation seen by other miotics. Unlike other miotics such as pilocarpine and carbachol, aceclidine's mechanism of action is pupil-selective, meaning it can activate the iris sphincter muscle and cause miosis without overstimulating the ciliary muscles that can cause a myopic shift and impair distance vision. Due to its pupil-selectivity and its ability to reduce the pupil diameter below 2 mm, aceclidine does not require any remaining accommodation to improve near vision, broadening its benefit to older presbyopes whose lens has lost this capacity.

The potency of a miotic towards the iris sphincter muscle or ciliary muscles can be expressed by EC50, the drug concentration required to produce 50% of its maximal effect, and its degree of pupil-selectivity can be expressed by the independence ratio, the ratio of the EC50 for the ciliary muscles to EC50 for the iris sphincter muscle. Based on a third-party, independent, peer-reviewed, academic study[3] of the selectivity of certain miotics on human intraocular muscles, the independence ratio of aceclidine between the longitudinal ciliary muscle and the iris sphincter muscle can be calculated to be 28, and between the circular ciliary muscle and iris sphincter muscle to be 22, compared to 1.9 and 1.6, respectively, for pilocarpine and 5.4 and 5.3, respectively, for carbachol. The 11 to 17 times higher independence ratio of aceclidine compared to pilocarpine reflects its pupil-selectivity.



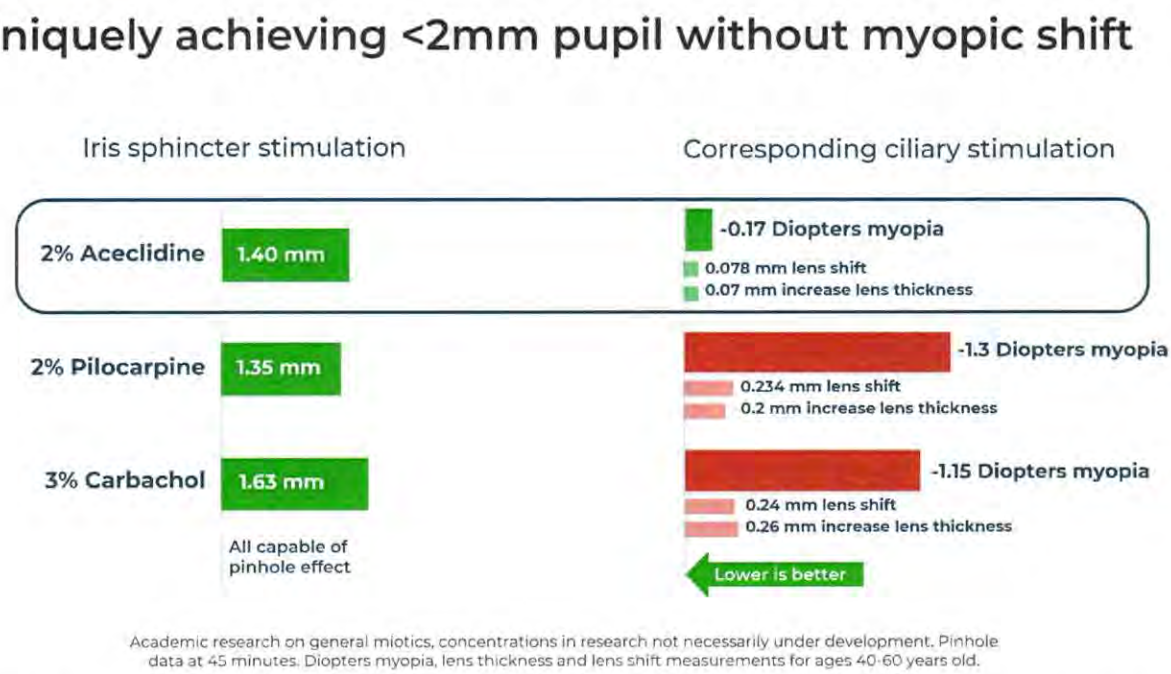
In addition to the independence ratio, another independent, peer-reviewed, academic in vivo study[4] looked at the correlation of pupil diameter and visual distortion caused by the myopic shift of various miotics, including aceclidine at a concentration different from LNZ100, which contains 1.75% aceclidine. The distortion is expressed in diopters ("D"), a measurement of focusing strength and distance used widely by ECPs to measure vision. Less change in diopter strength equates to lower disruption to distance vision. The results show that, among 40- to 60-year-old patients, treatment with 2% aceclidine results in reducing the pupil diameter below 2 mm with a negligible myopic shift as compared to 2% pilocarpine and 3% carbachol which drive respectively a -1.3D and -1.15D of myopic shift, respectively. A 1.0D myopic shift changes 20/20 vision to 20/50 distance vision, which can be measured as a decrease of four lines of vision in an eye exam. 20/20 visual acuity means that a person can see at 20 feet what should normally be seen at that distance. 20/50 visual acuity means that a person needs to be at 20 feet to see what a normal person can see at 50 feet. A minimum of 20/40 vision is required to complete a driver's test, so the >1.0D myopic shift caused by pilocarpine and carbachol is enough to make an otherwise able driver now unfit to drive.

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[3] H Ishikawa, L DeSantis, PN Patil, Selectivity of muscarinic agonists including (+/-)-aceclidine and antimuscarinics on the human intraocular muscles, J Ocul Pharmacol Ther. 1998 Aug;14(4):363-73

[4] J. François; F. Goes, Ultrasonographic Study of the Effect of Different Miotics on the Eye Components, Ophthalmologica (1977) 175 (6): 328–338.

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Academic research on general miotics, concentrations in research not necessarily under development. Pinhole data at 45 minutes. Diopters myopia, lens thickness and lens shift measurements for ages 40-60 years old.

When using non-pupil selective miotics, a trade-off is required between improvement in near vision and reduction in distance vision. Because aceclidine is a pupil-selective miotic and can reduce pupil diameter below 2 mm without overstimulating the ciliary muscles, no such compromise is needed.

In addition, contraction of the ciliary muscle by drugs such as carbachol and pilocarpine pulls on a critical area of the eye where these muscle fibers connect to the retina. This constant tugging or pulling by the stimulated ciliary muscle can lead to retinal traction, vitreous detachments, secondary retinal pathology, and in severe cases, retinal detachments. Besides being described in peer-reviewed literature on chronic pilocarpine use for glaucoma, retinal detachments have also been reported by Vuity users. In August 2022, Vuity's label was amended by the FDA to include a warning related to cases of retinal tears and detachments being reported with Vuity specifically, as opposed to miotics in general. In addition, the revised label advises having ECPs examine the retina of all patients prior to initiation of therapy. Despite the potential severity, concerns related to the risk of retinal tears and detachments ranked third behind low efficacy and low duration of efficacy among reasons why survey participants discontinued treatment with Vuity. Given that aceclidine has minimal effect on the ciliary muscle, we believe that the risk of side effects caused by activating the ciliary muscle are also reduced.

To date, the only approved and marketed pharmaceutical treatment for presbyopia is an eye drop using pilocarpine as the active ingredient that is marketed by AbbVie under the brand Vuity. Despite an initial strong commercial launch with over 120,000 unique user prescriptions filled in 2022, the refill rate has lagged, primarily due to lower-than-expected efficacy and duration. Based on our commissioned survey of 40 ECPs, a majority reported that the barrier to Vuity adoption was that the product either did not work or did not work long enough. An additional survey of 18 optometrists indicated that 66% of their patients did not see duration past four hours despite one of the Vuity clinical trial results showing some effectiveness to the sixth hour. While this aligns with the primary endpoint of at three hours in both Phase 3 trials, the functional benefit was not sufficient enough to support patient needs. The ECPs and their patients identified the low effectiveness and short duration of effectiveness as the key factors for discontinuing use. To resolve the duration issue, AbbVie tested a twice-a-day dosing of the same formulation following initial approval of Vuity and achieved FDA approval for this updated dosing frequency in March 2023. The updated Vuity label now recommends that a second dose may be administered three to six hours after the first dose. Nonetheless, we believe users are looking for a once-daily solution that can last the full workday, which is further supported by the lack of increased Vuity uptake thus far following FDA approval of this label amendment.

Furthermore, Vuity was primarily tested in younger presbyopes ranging from ages 40 to 55 with the average age of 50 in each of its Phase 3 GEMINI trials. Therefore, we expect that older users may experience even less effect as they have little or no remaining accommodation to be activated to improve near vision, and Vuity has not been shown to reduce pupil diameter below 2 mm.

N/K - for Publicly Traded

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0832694

Application/License No. _____

Lenz Therapeutics, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 445 Marine View Ave, Suite 320, Del Mar, CA 92014 (Address of Applicant/Principal), as PRINCIPAL, and Harco National Insurance Company (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 4200 Six Forks Road, Suite 1400, Raleigh, NC 27609 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 4/13/2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 13th day of April, 2023.

APPLICANT/PRINCIPAL

_____
Authorized Representative

SURETY COMPANY

_____
Surety Company's Representative

Patricia White, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Bond # 0832694

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY,** a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY,** a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

PAUL JEFFREY HERING, PATRICIA WHITE, MARTA COLLETT, DANIELLE ENRIQUEZ, SANDRA CORONA, SHANNON ALVAREZ, KATHLEEN VANDERSLICE, TIMOTHY MCCLELLAN

San Diego, CA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY,** as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED,** that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2022

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1984 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2022, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY;** that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

SHIRELLE A. OUTLEY NOTARY PUBLIC No. 50079910 My Comm. Exp. 04-04-2023 NEW JERSEY

IN TESTIMONY WHEREOF, I heve hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, April 13, 2023

A00874

Irene Martins, Assistant Secretary

4M

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Arrowhead Pharmaceuticals, Inc.

Physical Address: 177 E Colorado Blvd Suite 700

City: Pasadena State: CA Zip: 91105

Mailing Address (if different from physical address): 177 E Colorado Blvd Suite 700

City: Pasadena State: CA Zip: 91105

Telephone: (626) 304-3400 Website: https://arrowheadpharma.com

Name of Designated Representative (DR): Jesse Ho

Licensing Company Email: statelicensing@arrowheadpharma.com DR Email: jho@arrowheadpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies		☒ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): N/A Publicly traded

Corporation Name: Arrowhead Pharmaceuticals, Inc.

Mailing Address: 177 E Colorado Blvd Suite 700

City: Pasadena State: CA Zip: 91105

Telephone: (626) 304-3400 Email: statelicensing@arrowheadpharma.com

Contact Person Name: Jesse Ho

Date of SEC Registration: 02-13-2001 | SEC Registration Number: 0000879407 | Stock Exchange Symbol: ARWR

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form at:** http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Arrowhead Pharmaceuticals, Inc.
Facility Name

Patrick O'Brien
Print Name of Authorized Person Submitting Application

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

March 13, 2025
Date

Board Use Only	Date Received: 7/22/25	Amount: $1000-CK 3454

arrowhead pharmaceuticals

Description of Operations

Arrowhead Pharmaceuticals is a VirtualManufacturer. Arrowhead Pharmaceuticals' products are manufactured by a Contract Manufacturer and will be distributed to Specialty Pharmacies by their Third-Party Logistics Provider, Integrated Commercialization Solutions, LLC , who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

Ajinomoto Althea, Inc.
11040 Roselle Street
San Diego, CA 92121
FDA Establishment Number: 3004575449

Contact Person: Jennifer Vavala
Contact Email: Jennifer.Vavala@US.AjiBio-Pharma.com

Ajinomoto manufactures Arrowhead Pharmaceuticals' finished product. At no time does Ajinomoto own the product, contract with Arrowhead Pharmaceuticals' customers, invoice, nor sell a Arrowhead Pharmaceuticals product. Arrowhead Pharmaceuticals' products are not Controlled Substances.

Labeler Code:
84141

Third Party Logistic information:
For distribution into the commercial supply channels, Integrated Commercialization Solutions, LLC acts as Arrowhead Pharmaceuticals' Third Party Logistics (3PL) provider to manage the storage and distribution of Arrowhead Pharmaceuticals' product throughout the United States. Integrated Commercialization Solutions, LLC's address is:

Integrated Commercialization Solutions, LLC
420 International Boulevard, Suite 500, Brooks, KY 40109

Amanda Bauer – (888) 285-7481

Arrowhead Pharmaceuticals has 144 employees working on site during normal business hours.

Arrowhead Pharmaceuticals' hours of operation are 9:00 am – 5:00pm Monday through Friday.

Arrowhead Pharmaceuticals' facility square footage is 48,868.

From: Sheldon Mullins
To: Emily Talbert
Subject: FW: Labeler Code Request Approved
Date: Thursday, May 23, 2024 1:14:00 PM

---

fyi

From: Jesse Ho <jho@arrowheadpharma.com>
Sent: Friday, March 1, 2024 10:50 AM
To: Sheldon Mullins <smullins@arrowheadpharma.com>
Subject: RE: Labeler Code Request Approved

Re-submitted to confirm the labeler code as per the process. I'll let you know when I have confirmed receipt of the submission being accepted.

Kind regards,
Jesse

From: Jesse Ho
Sent: Friday, March 1, 2024 10:34 AM
To: Sheldon Mullins <smullins@arrowheadpharma.com>
Subject: FW: Labeler Code Request Approved

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Friday, March 1, 2024 10:33 AM
To: Jesse Ho <jho@arrowheadpharma.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 28-FEB-2024
Labeler DUNS: 607735859
Labeler Name: Arrowhead Pharmaceuticals, Inc.
Labeler Code Assigned: 84141

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other**

Company Information

Arrowhead Pharmaceuticals, Inc.
177 E Colorado Blvd Suite 700
Pasadena, CA 91105
Phone: (626) 304-3400
Website: https://arrowheadpharma.com
E-mail: statelicensing@arrowheadpharma.com

FEIN: 46-0408024
State of Formation: Delaware
Date Incorporated: 02/13/2001
File Number: 3354811

Ownership Information

Arrowhead Pharmaceuticals, Inc.is a Publicly Traded company on the NASDAQ stock exchange under the symbol ARWR.

Officers

Christopher R Anzalone, President & Chief Executive Officer
Business Address: 177 E. Colorado Blvd, Suite 700, Pasadena, CA 91105
Business Phone: (626) 304-3400
Email: canzalone@arrowheadpharma.com

Patrick C O'Brien, Chief Operating Officer & General Counsel
Business Address: 177 E. Colorado Blvd, Suite 700, Pasadena, CA 91105
Business Phone: (626) 304-3400
Email: pobrien@arrowheadpharma.com

Kenneth A Myszkowski, Chief Financial Officer
Business Address: 177 E. Colorado Blvd, Suite 700, Pasadena, CA 91105
Business Phone: (626) 304-3400
Email: kmyszkowski@arrowheadpharma.com

Delaware

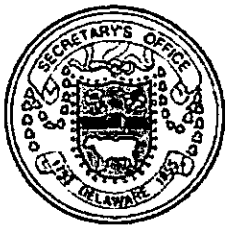
The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ARROWHEAD PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF JANUARY, A.D. 2025.

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ARROWHEAD PHARMACEUTICALS, INC." WAS INCORPORATED ON THE THIRTEENTH DAY OF FEBRUARY, A.D. 2001.

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





3354811 8300

SR# 20250064033

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

Authentication: 202658916

Date: 01-09-25

[redacted] [redacted]

RE: Licensure Requirements- Manufacturers/Virtual Manufacturers

[redacted]

Tue 6/25/2024 7:05 PM

To [redacted]

[External]

Good Afternoon,

I was requested to respond to your question. Please refer to **Business and Professions Code sec on 4160(h)** which states a drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Sec on 11615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of it own manufacture is exempt from this sec on and sec on 4161.

Therefore, if you are a virtual manufacturer/manufacturer, licensure as a wholesaler or nonresident wholesaler with the California State Board of Pharmacy is not required if you only distribute dangerous drugs and dangerous devices that XXXXXXX has the NDA or manufactures.

However, if XXXXX also distributes dangerous or dangerous devices, which they **are not listed** with the FDA or the California Dept of Public Health, State Food and Drug Branch (CDPH, SFDB), as the manufacturer or does not hold the NDA, then a wholesaler license (if located in CA) or nonresident wholesaler license (outside of CA and within the United States or a territory of the U.S.) is required.

I hope this answers your question. Otherwise, my contact information is below if you have any additional questions.

Sincerely,

[redacted]

Supervising Inspector
California State Board of Pharmacy
(661) [redacted] | FAX (661) 286-1567 | [redacted]

[redacted]blank

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended September 30, 2024

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 001-38042

ARROWHEAD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	46-0408024
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

(626) 304-3400
177 E. Colorado Blvd, Suite 700
Pasadena, California 91105
(Address and telephone number of principal executive offices)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	ARWR	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by a check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐						

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

The aggregate market value of issuer's voting and non-voting outstanding common stock held by non-affiliates was approximately $3.0 billion based upon the closing stock price of issuer's common stock on March 31, 2024. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of November 20, 2024, 124,434,442 shares of the issuer's Common Stock were issued and outstanding.

Legal First Name	Legal Last Name	Union Local Description
Aaron	Schnipper	Pasadena, CA
Aaron	Tan	Pasadena, CA
Alexandra	Roeser	Pasadena, CA
Allister	Baldwin	Pasadena, CA
Amabel	Legaspi	Pasadena, CA
Amy	Rocha	Pasadena, CA
Ana	Vitomirov	Pasadena, CA
Anais	Gutierrez	Pasadena, CA
Andre	Trigueros Cespedes	Pasadena, CA
Andreea	Oancea	Pasadena, CA
Andrew	Davis	Pasadena, CA
Angela	Legarda	Pasadena, CA
Angele	Williams	Pasadena, CA
Anjli	Warner	Pasadena, CA
Anna	Duong	Pasadena, CA
Armine	Balian	Pasadena, CA
Atham	Ali	Pasadena, CA
Audrey	Ripley	Pasadena, CA
Bandol	Naguiat	Pasadena, CA
Britt	Overholt	Pasadena, CA
Bruce	Given	Pasadena, CA
Carly	Chaput	Pasadena, CA
Caroline	LaPlaca Davis	Pasadena, CA
Catherine	Houston	Pasadena, CA
Cecilia	Vitali	Pasadena, CA
Chika	Okonkwo	Pasadena, CA
Ching Hua	Wu	Pasadena, CA
Chituru	Aso	Pasadena, CA
Christine	Mumolo	Pasadena, CA
Christophe	El Khally	Pasadena, CA
Christopher	Anzalone	Pasadena, CA
Claudia	Coral	Pasadena, CA
Courtney	Grosslight	Pasadena, CA
Courtney	Lillich	Pasadena, CA
Danielle	Rimboi	Pasadena, CA
Darnell	Fuller	Pasadena, CA
David	Swift	Pasadena, CA
David	Hernandez	Pasadena, CA
Dharshika	Chindris	Pasadena, CA
Diana	Borges	Pasadena, CA
Do	Kim	Pasadena, CA
Dominick	Summa	Pasadena, CA
Donggyu	Lee	Pasadena, CA
Elena	Moore	Pasadena, CA

EMPLOYEE LIST

Eleonora	Goldberg	Pasadena, CA
Elise	Sullivan	Pasadena, CA
Elliott	Blufer	Pasadena, CA
Eric	Garcia-Medel	Pasadena, CA
Erick	Leung	Pasadena, CA
Erin	Vaystub	Pasadena, CA
Grigoriy	Shekhtman	Pasadena, CA
Gwendolyn	Sale	Pasadena, CA
Hannah	Freed	Pasadena, CA
Hivaniben	Patel	Pasadena, CA
Ivana	Cheng	Pasadena, CA
Ivette	Lucero	Pasadena, CA
Jack	Shi	Pasadena, CA
Jae-Ryung	Kim	Pasadena, CA
James	Hamilton	Pasadena, CA
James	Ousey	Pasadena, CA
Jane	Davidson	Pasadena, CA
Jane	Culbertson	Pasadena, CA
Janna	Jagoe	Pasadena, CA
Jennifer	Cooke	Pasadena, CA
Jennifer	Kammerer	Pasadena, CA
Jennifer	Merkel	Pasadena, CA
Jennifer	Boesen	Pasadena, CA
Jennifer	Hellawell	Pasadena, CA
Jesse	Ho	Pasadena, CA
Jingwen	Liu	Pasadena, CA
Jobby	Abraham	Pasadena, CA
John	Montgomery	Pasadena, CA
John	An	Pasadena, CA
Jong Woo	Lee	Pasadena, CA
Kasim	Manekia	Pasadena, CA
Katherine	Kramer	Pasadena, CA
Kelly	Fidler	Pasadena, CA
Kenneth	Myszkowski	Pasadena, CA
Kevin	Torre	Pasadena, CA
Kostadin	Basamakov	Pasadena, CA
Kristina	Roxas	Pasadena, CA
LaShana	Pamplin	Pasadena, CA
Liam	Reay	Pasadena, CA
Lindsey	Sever	Pasadena, CA
Lori	Ha	Pasadena, CA
Mahshid	Mohammadi	Pasadena, CA
Marcos	Calderon	Pasadena, CA
Margaret	Yuen	Pasadena, CA
Maria Lourdes	Berdan	Pasadena, CA

Maria Susana	Hernandez Hernandez	Pasadena, CA
Mariya	Gulyan	Pasadena, CA
Marlan	Delgado	Pasadena, CA
Matthew	Pulisic	Pasadena, CA
Meredith	Halleen	Pasadena, CA
Merlyne	Mesidor	Pasadena, CA
Michael	Probst	Pasadena, CA
Michele	Morris	Pasadena, CA
Michelle	Tran	Pasadena, CA
Nadejda	Meshkova	Pasadena, CA
Nathalie	Kertesz	Pasadena, CA
Nicholas	Gould	Pasadena, CA
Norman	Phillips	Pasadena, CA
Patrick	O'Brien	Pasadena, CA
Pepito	Santiago	Pasadena, CA
Phedellee	Reyes	Pasadena, CA
Pitchayarasm	Kunghae	Pasadena, CA
Priya	Patel	Pasadena, CA
Qi	Li	Pasadena, CA
Rachel	Halsey	Pasadena, CA
Ran	Fu	Pasadena, CA
Randall	Steiner	Pasadena, CA
Renee	Lewis	Pasadena, CA
Richard	Verzosa	Pasadena, CA
Robert	Byun	Pasadena, CA
Rolando	Maldonado	Pasadena, CA
Rong	Zhou	Pasadena, CA
Ruth	Hummel	Pasadena, CA
Ryan	Shih	Pasadena, CA
Samuel	Meng	Pasadena, CA
Scott	Boger	Pasadena, CA
Shadi	Van Trease	Pasadena, CA
Shuhua	He	Pasadena, CA
Stacey	Melquist	Pasadena, CA
Stacey	Hayes	Pasadena, CA
Stephen	Balawajder	Pasadena, CA
Susan	Rubyan	Pasadena, CA
Sylvia	Rivera	Pasadena, CA
Thamilarasi	Vijayaraj	Pasadena, CA
Thomas	Schluep	Pasadena, CA
Tonyo	Vanov	Pasadena, CA
Tracie	Oliver	Pasadena, CA
Trueby	Bodiford	Pasadena, CA
Tzu-hsin	Lin	Pasadena, CA
Usha	Srinivasan	Pasadena, CA

Veronica	Hashemi	Pasadena, CA
Vincent	Anzalone	Pasadena, CA
Wagdi	Assar	Pasadena, CA
Wenhao	Dong	Pasadena, CA
Yiyao	Hu	Pasadena, CA
Yue	Fei	Pasadena, CA
Yuhan	Dai	Pasadena, CA
Yvonne	Nguyen	Pasadena, CA
Zeyu	Li	Pasadena, CA

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement to be filed for Arrowhead Pharmaceuticals, Inc.'s 2025 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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SIGNATURE

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and we intend that such forward-looking statements be subject to the safe harbors created thereby. For this purpose, any statements contained in this Annual Report on Form 10-K except for historical information may be deemed to be forward-looking statements. Without limiting the generality of the foregoing, words such as "may," "might," "will," "expect," "believe," "anticipate," "goal," "endeavor," "strive," "intend," "plan," "project," "could," "estimate," "target," "might," "forecast," or "continue" or the negative of these words or other variations thereof or comparable terminology are intended to identify forward-looking statements. In addition, any statements that refer to projections of our future financial performance, trends in our business, or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements include, but are not limited to, statements about the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; our expectations regarding regulatory approval for and commercial launch of plozasiran our expectations regarding the potential benefits of the partnership, licensing and/or collaboration arrangements and other strategic arrangements and transactions we have entered into or may enter into in the future; our beliefs and expectations regarding the amount and timing of future milestone, royalty or other payments that could be due to or from third parties under existing agreements; and our estimates regarding future revenues, research and development expenses, capital requirements and payments to third parties.

The forward-looking statements included herein are based on current expectations of our management based on available information and involve a number of risks and uncertainties, all of which are difficult or impossible to predict accurately, and many of which are beyond our control. As such, our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. Forward-looking statements are not guarantees of future performance and our actual results of operations, financial condition and cash flows may differ materially. Factors that may cause or contribute to such differences include, but are not limited to, those discussed in more detail in "Item 1. Business" and "Item 1A. Risk Factors" of Part I and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of Part II of this Annual Report on Form 10-K. Readers should carefully review these risks, as well as the additional risks described in other documents we file from time to time with the Securities and Exchange Commission (the "SEC"). In light of the significant risks and uncertainties inherent in the forward-looking information included herein, the inclusion of such information should not be regarded as a representation by us or any other person that such results will be achieved, and readers are cautioned not to place undue reliance on such forward-looking information. Statements made herein are as of the date of the filing of this Annual Report on Form 10-K with the SEC and should not be relied upon as of any subsequent date. Except as may be required by law, we disclaim any intent to revise the forward-looking statements contained herein to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

PART I

Unless otherwise noted, (1) the term "Arrowhead" refers to Arrowhead Pharmaceuticals, Inc., a Delaware corporation and its Subsidiaries, (2) the terms "Company," "we," "us," and "our," refer to the ongoing business operations of Arrowhead and its Subsidiaries, whether conducted through Arrowhead or a subsidiary of Arrowhead, (3) the term "Subsidiaries" refers to Arrowhead Madison Inc. ("Arrowhead Madison"), Arrowhead Australia Pty Ltd ("Arrowhead Australia"), and Visirna Therapeutics Inc. ("Visirna") (4) the term "common stock" refers to Arrowhead's common stock, (5) the term "preferred stock" refers to Arrowhead's preferred stock and (6) the term "stockholder(s)" refers to the holders of Arrowhead common stock.

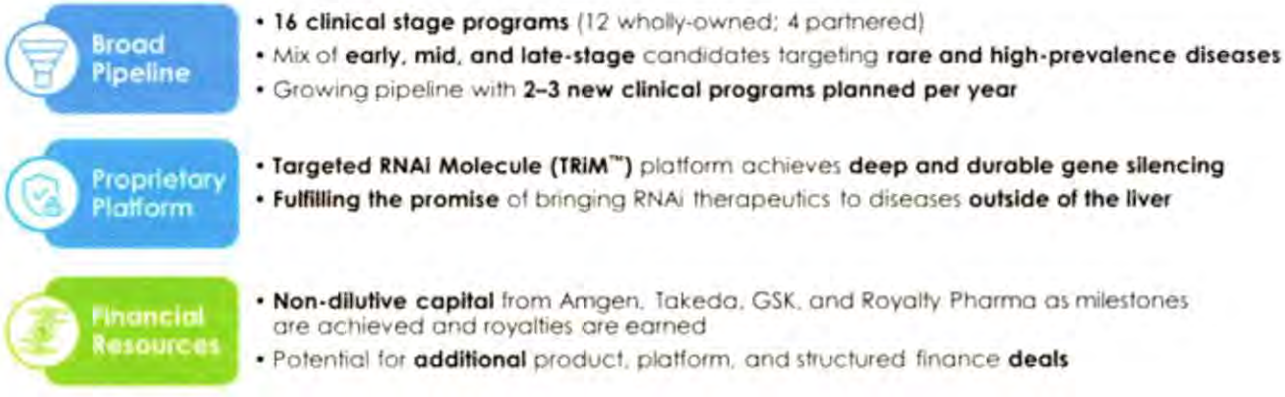
ITEM 1. BUSINESS

A. Overview

The Company develops medicines that treat intractable diseases by silencing the genes that cause them. Using a broad portfolio of RNA chemistries and efficient modes of delivery, the Company's therapies trigger the RNA interference mechanism to induce rapid, deep and durable knockdown of target genes.

The Company's most advanced candidate, plozasiran, has completed a Phase 3 study in patients with familial chylomicronemia syndrome (FCS) and expects to have its first commercial launch in 2025, provided the United States Food and Drug Administration (the "FDA") accepts the New Drug Application ("NDA") for filing and after a successful review and subsequent approval. The Company's pipeline of 16 clinical stage investigational medicines range in development stage from Phase 1 to Phase 3. In addition, the Company has a robust discovery stage pipeline which is capable of generating multiple new clinical candidates each year.

The Company endeavors to serve unmet medical needs and change lives leveraging the versatility of its proprietary RNAi-based technology. The Company is acutely aware of the urgent need to develop solutions for the many diseases that have genetic targets that are otherwise undruggable by small molecules or biologics. To that end, the Company embraced its bold goal and strives to have 20 individual drugs, either partnered or wholly owned, in clinical trials or on the market in 2025.

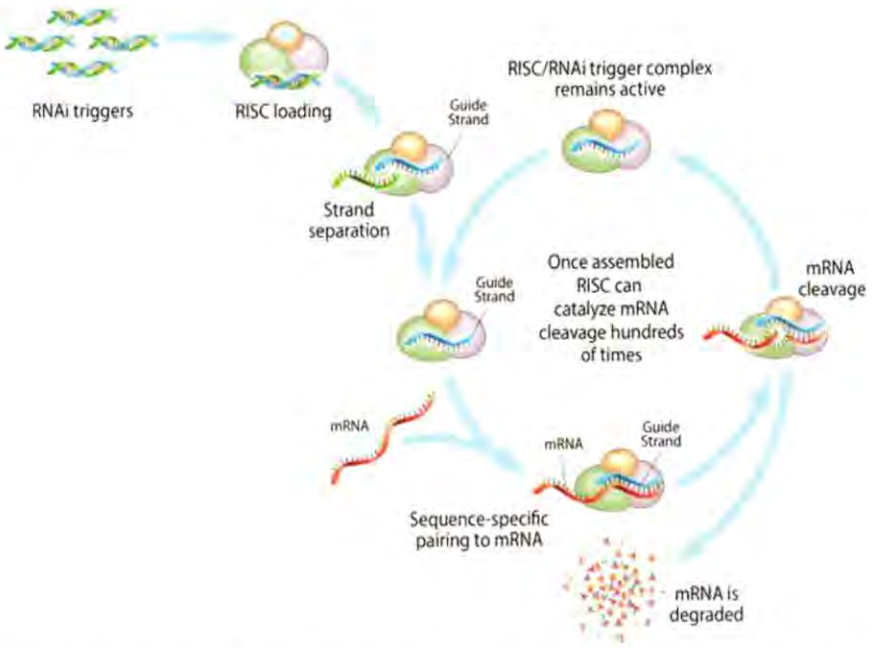


RNA Interference and the Benefits of RNAi Therapeutics

RNA interference ("RNAi") is a mechanism present in living cells that inhibits the expression of a specific gene, thereby affecting the production of a specific protein. RNAi-based therapeutics may leverage this natural pathway of gene silencing to target and shut down specific disease-causing genes.

Small molecule and antibody drugs have proven effective at inhibiting certain cell surface, intracellular, and extracellular targets. However, other drug targets have proven difficult to inhibit with traditional drug-based and biologic therapeutics. Developing effective drugs for these targets would have the potential to address large underserved markets for the treatment of many diseases. Using the ability to specifically silence any gene, RNAi therapeutics may be able to address previously "undruggable" targets, unlocking the market potential of such targets.

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This figure depicts the mechanism by which gene silencing occurs. Double stranded RNAi triggers are introduced into a cell and are loaded into the RNA-induced silencing complex ("RISC"). The strands are then separated, leaving an active RISC/RNAi trigger complex. This complex can then pair with and degrade the complementary messenger RNAs ("mRNA") and stop the production of the target proteins. RNAi is a catalytic process, so each RNAi trigger can degrade mRNA hundreds of times, which results in a relatively long duration of effect for RNAi therapeutics.

Key Benefits of RNAi as a Therapeutic Modality:

- Silences the expression of disease associated genes;
- Potential to address any target in the transcriptome including previously "undruggable" targets;
- Rapid lead identification;
- High specificity;
- Opportunity to use multiple RNA sequences in one drug product for synergistic silencing of related targets; and
- RNAi therapeutics are uniquely suited for personalized medicine through target and cell specific delivery and gene knockdown.

Targeted RNAi Molecule (TRiM™) Platform

The Company's Targeted RNAi Molecule (TRiM™) platform utilizes ligand-mediated delivery and is designed to enable tissue-specific targeting while being structurally simple. Targeting has been core to the Company's development philosophy and the TRiM™ platform builds on more than a decade of work on actively targeted drug delivery vehicles. The Company's scientists have discovered ways to progressively "TRiM" away extraneous features and chemistries and retain optimal pharmacologic activity.

The TRiM™ platform is comprised of a highly potent RNA trigger identified using the Company's proprietary trigger selection rules and algorithms with the following components optimized, as needed, for each drug candidate: a high affinity targeting ligand; various linker chemistries; structures that enhance pharmacokinetics; and highly potent RNAi triggers with sequence specific stabilization chemistries.

Therapeutics developed with the TRiM™ platform offer several advantages: simplified manufacturing and reduced costs; multiple routes of administration; and potential for improved safety because there are less metabolites from smaller molecules, thereby reducing the risk of intracellular buildup. The Company also believes that for RNAi to reach its true potential, it must target organs outside the liver. The Company is leading this expansion with the TRiM™ platform, which has shown the potential to reach multiple tissues, including liver, lung, central nervous system (CNS), muscle, and adipose tissue.



TRiM™ – *Targeting the gene, to Silence the disease*

- ***Activity*** characterized by depth & duration of effect
  - Ability to unlock previously undruggable targets
- ***Specificity*** to maximize activity and innate stability with the potential for reduced off-target effects
- ***Versatility*** in formulation & ligand design offers multiple routes of administration, and access to multiple tissues
  - Facilitates rapid drug development and speed to patients
- ***Simplicity*** in design translates to relatively lower costs, and production at scale

RNA Chemistries

The structure and chemistries of the oligonucleotide molecules used to trigger the RNAi mechanism can be tailored for optimal activity. The Company's broad portfolio of RNA trigger structures and chemistries, including some proprietary structures, enable the Company to optimize each drug candidate on a target-by-target basis and utilize the combination of structure and chemical modifications that yield the most potent RNAi trigger.

As a component of the TRiM™ platform, the Company's design philosophy for RNA chemical modifications is to start with a structurally simple molecule and add only selective modification and stabilization chemistries as necessary to achieve the desired level of target knockdown and duration of effect. The conceptual framework for the stabilization strategy starts with a more sophisticated RNAi trigger screening and selection process that identifies potent sequences rapidly in locations that others may miss.

B. Pipeline

The Company is focused on developing innovative drugs for diseases with a genetic basis, typically characterized by the overproduction of one or more proteins that are involved with disease. The depth and versatility of the Company's RNAi technologies enables the Company to potentially address conditions in virtually any therapeutic area and pursue disease targets that are not otherwise addressable by small molecules and biologics. The Company is focused on bringing the promise of RNAi to address diseases outside of the liver, and its pipeline now includes disease targets in the liver, lung, central nervous system (CNS), muscle and adipose tissue.



Plozasiran (ARO-APOC3)

Plozasiran (formerly ARO-APOC3) is designed to reduce production of Apolipoprotein C-III (apoC-III), a component of triglyceride rich lipoproteins (TRLs) including Very Low Density Lipoprotein (VLDL) and chylomicrons, a key regulator of triglyceride metabolism. The Company believes that knocking down the hepatic production of apoC-III may result in reduced VLDL synthesis and assembly, enhanced breakdown of TRLs, and better clearance of VLDL and chylomicron remnants. The Company is currently investigating plozasiran in one Phase 2 clinical trial and four Phase 3 clinical trials. In the Phase 3 PALISADE trial in patients with familial chylomicronemia syndrome (FCS), plozasiran has met its primary endpoint of triglyceride reduction as well as all of its key (alpha controlled) secondary endpoints. The Company is currently in the process of seeking regulatory approval for plozasiran for the treatment of FCS.

Hypertriglyceridemia: Elevated triglyceride levels are an independent risk factor for cardiovascular disease. Severely elevated triglycerides in patients with severe hypertriglyceridemia (SHTG) or familial chylomicronemia syndrome (FCS), a rare genetic disorder, can result in potentially fatal acute pancreatitis.

Study Name: Study of ARO-APOC3 in Adults With Dyslipidemia
A Phase 2 Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of ARO-APOC3 in Adults With Dyslipidemia
ClinicalTrials.gov Identifier: NCT05413135

Study Name: Study of ARO-APOC3 in Adults With FCS (PALISADE)
A Phase 3 Study to Evaluate the Efficacy and Safety of ARO-APOC3 in Adults With Familial Chylomicronemia Syndrome
ClinicalTrials.gov Identifier: NCT05089084

Study Name: Study of Plozasiran (ARO-APOC3) in Adults With Severe Hypertriglyceridemia (SHASTA-3)
Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Plozasiran in Adults With Severe Hypertriglyceridemia
ClinicalTrials.gov Identifier: NCT06347003

Study Name: Study of Plozasiran in Adults With Severe Hypertriglyceridemia (SHASTA-4)
Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Plozsiran in Adults With Severe Hypertriglyceridemia
ClinicalTrials.gov Identifier: NCT06347016

Study Name: Phase 3 Study of Plozasiran in Adults With Hypertriglyceridemia (MUIR-3)
Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Plozasiran in Adults With Hypertriglyceridemia
ClinicalTrials.gov Identifier: NCT06347133

Zodasiran (ARO-ANG3)

Zodasiran (formerly ARO-ANG3) is designed to reduce production of angiopoietin-like protein 3 (ANGPTL3), a liver synthesized inhibitor of lipoprotein lipase and endothelial lipase. ANGPTL3 inhibition has been shown to lower serum LDL, serum and liver triglyceride and has genetic validation as a novel target for cardiovascular disease. The Company is currently investigating zodasiran in two Phase 2b clinical trials.

Dyslipidemia and Hypertriglyceridemia: Dyslipidemia and hypertriglyceridemia are risk factors for atherosclerotic coronary heart disease and cardiovascular events.

Study Name: Study of ARO-ANG3 in Adults With Mixed Dyslipidemia (ARCHES-2)
A Double-blind, Placebo-controlled Phase 2b Study to Evaluate the Efficacy and Safety of ARO-ANG3 in Adults With Mixed Dyslipidemia
ClinicalTrials.gov Identifier: NCT04832971

Study Name: Study of ARO-ANG3 in Participants With Homozygous Familial Hypercholesterolemia (HoFH) (GATEWAY)
Phase 2 Study to Evaluate the Safety and Efficacy of ARO-ANG3 in Subjects with Homozygous Familial Hypercholesterolemia (HoFH)
ClinicalTrials.gov Identifier: NCT05217667

ARO-PNPLA3

ARO-PNPLA3 (formerly JNJ-75220795) is an investigational RNAi therapeutic designed to reduce liver expression of patatin-like phospholipase domain containing 3 (PNPLA3) as a potential treatment for patients with metabolic-dysfunction associated steatohepatitis (MASH). PNPLA3 has strong genetic and preclinical validation as a driver of fat accumulation and damage in the livers of patients who carry the common 1148M mutation. Former licensee Janssen Pharmaceuticals, Inc. investigated ARO-PNPLA3 in two Phase 1 clinical trials.

MASH: MASH is a subgroup of steatotic liver disease (MASLD) in which hepatic cell injury and inflammation has developed over background steatosis. The I148M genetic variant in the PNPLA3 gene is involved with the underlying pathophysiology and is a known risk factor for hepatic steatosis, steatohepatitis, elevated plasma liver enzyme levels, hepatic fibrosis and cirrhosis. The rising prevalence of MASH presents a significant health burden in many developed countries.

ARO-INHBE

ARO-INHBE is designed to reduce the hepatic expression of the INHBE gene and its secreted gene product, Activin E. INHBE is a promising genetically validated target in which loss-of-function INHBE variants in humans are associated with lower risk of obesity and metabolic diseases, such as type 2 diabetes. The Company has filed for regulatory clearance to initiate a Phase 1/2a clinical trial of ARO-INHBE.

ARO-RAGE

ARO-RAGE is designed to reduce production of the Receptor for Advanced Glycation End products (RAGE) as a potential treatment for various inflammatory pulmonary diseases. The Company is currently investigating ARO-RAGE in a Phase 1/2a clinical trial.

Study Name: Study of ARO-RAGE in Healthy Subjects and Patients With Inflammatory Lung Disease
A Phase 1/2a Study Evaluating the Effects of ARO-RAGE in Healthy Subjects and Patients With Inflammatory Lung Disease
ClinicalTrials.gov Identifier: NCT05276570

ARO-MUC5AC

ARO-MUC5AC is designed to reduce production of mucin 5AC (MUC5AC) as a potential treatment for various muco-obstructive pulmonary diseases. The Company is currently investigating ARO-MUC5AC in a phase 1/2a clinical trial.

Study Name: Study of ARO-MUC5AC in Healthy Subjects and Patients With Muco-Obstructive Lung Disease
A Phase 1/2a Study to Evaluate the Effects of ARO-MUC5AC in Healthy Subjects and Patients with Muco-Obstructive Lung Disease
ClinicalTrials.gov Identifier: NCT05292950

ARO-MMP7

ARO-MMP7 is designed to reduce expression of matrix metalloproteinase 7 (MMP7) as a potential treatment for Idiopathic Pulmonary Fibrosis (IPF). The Company is currently investigating ARO-MMP7 in a Phase 1/2a clinical trial.

Study Name: Study of ARO-MMP7 Inhalation Solution in Healthy Subjects and Patients With Idiopathic Pulmonary Fibrosis
A Phase 1/2a Study Evaluating the Effects of ARO-MMP7 Inhalation Solution in Healthy Subjects and Patients With Idiopathic Pulmonary Fibrosis
ClinicalTrials.gov Identifier: NCT05537025

ARO-DUX4

ARO-DUX4 is designed to target the gene that encodes human double homeobox 4 (DUX4) protein as a potential treatment for patients with facioscapulohumeral muscular dystrophy.

Facioscapulohumeral Muscular Dystrophy: Facioscapulohumeral muscular dystrophy (FSHD) is an autosomal dominant disease associated with the failure to maintain complete epigenetic suppression of DUX4 expression in differentiated skeletal muscle, leading to overexpression of DUX4, which is myotoxic and can lead to muscle degeneration. As DUX4 expression is recognized as the cause of muscle pathology in FSHD patients, the Company believes that the selective targeting and knockdown of DUX4 using RNAi may prevent or reverse downstream myotoxicity and lead to muscle repair and improvement in muscle function in patients. There are currently no effective treatments specifically for FSHD.

Study Name: Study of ARO-DUX4 in Adult Patients With Facioscapulohumeral Muscular Dystrophy Type 1
A Phase1/2a Dose-Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ARO-DUX4 in Adult Patients With Facioscapulohumeral Muscular Dystrophy Type 1.
ClinicalTrials.gov Identifier: NCT06131983

ARO-DM1

ARO-DM1 is designed to reduce expression of the dystrophia myotonica protein kinase (DMPK) gene. There is currently no approved disease-modifying therapy for type 1 myotonic dystrophy (DM1). Treatments have focused on symptomatic management, including physical therapy, exercise, ankle-foot orthoses, wheelchairs, and other assistive devices. The Company is currently investigating ARO-DM1 in a Phase 1/2a clinical trial.

Type 1 Myotonic Dystrophy: Type 1 myotonic dystrophy is an autosomal dominant, debilitating, chronic progressive multisystem disorder characterized by an expansion of a highly unstable CUG^{exp} in the DMPK gene. Patients with DM1 have muscle weakness and wasting, myotonia, cataracts, and often have cardiac conduction abnormalities, and may become physically disabled and have a shortened life span.

Study Name: Study of ARO-DM1 in Subjects With Type 1 Myotonic Dystrophy
A Phase 1/2a Dose-Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ARO-DM1 in Subjects With Type 1 Myotonic Dystrophy Who Are $\geq$18 to $\leq$ 65 Years
ClinicalTrials.gov Identifier: NCT06138743

ARO-ATXN2

ARO-ATXN2 is designed to reduce the expression of the ATXN2 gene as a potential treatment for spinocerebellar ataxia 2 (SCA2). SCA2 is a progressive cerebellar ataxia with instability of stance, speech and swallow disorder, pain, spasticity, and ocular signs, caused by gain of function of mutant expanded polyQ ATXN2 protein. The Company is currently investigating ARO-ATXN2 in a Phase 1 clinical trial.

Study Name: Study of ARO-ATXN2 Injection in Adults With Spinocerebellar Ataxia Type 2
A Phase 1 Placebo-Controlled Dose Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ARO-ATXN2 in Adult Subjects With Spinocerebellar Ataxia Type 2
ClinicalTrials.gov Identifier: NCT06672445

ARO-C3

ARO-C3 is designed to reduce production of complement component 3 (C3) as a potential therapy for patients with various complement mediated or complement associated renal diseases. The Company is currently investigating ARO-C3 in a Phase 1/2a clinical trial.

Complement-Mediated Renal Disease: A number of rare renal diseases result from uncontrolled activation of the alternative pathway of complement, leading to progressive glomerular damage, proteinuria, hematuria, and impaired kidney function, and often resulting in end-stage renal disease (ESRD). In addition, dysregulation of the alternative

complement pathway has been shown to play a role in the pathogenesis and progression of disease in some of the more common glomerulopathies. Silencing C3 may be a therapeutic approach for treatment of these conditions.

Study Name: Study of ARO-C3 in Adult Healthy Volunteers and Patients With Complement-Mediated Renal Disease
A Phase 1/2a Dose-Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and/or Pharmacodynamics of ARO-C3 in Adult Healthy Volunteers and in Adult Patients With Complement-Mediated Renal Disease
ClinicalTrials.gov Identifier: NCT05083364

ARO-CFB

ARO-CFB is designed to reduce hepatic expression of complement factor B (CFB), which plays an important regulatory role in amplifying complement alternative pathway activation and has been identified as a promising therapeutic target. ARO-CFB is being developed as a potential treatment for complement mediated kidney diseases such as immunoglobulin A nephropathy (IgAN), which is the most common glomerular disease worldwide and carries a high lifetime risk of progression to end-stage renal disease. Additionally, ARO-CFB may have clinical applications in non-renal diseases involving complement activation. The Company is currently investigating ARO-CFB in a Phase 1/2a clinical trial.

Complement-Mediated Disease: A number of rare renal diseases result from uncontrolled activation of the alternative pathway of complement, leading to progressive glomerular damage, proteinuria, hematuria, and impaired kidney function, and often resulting in end-stage renal disease (ESRD). In addition, dysregulation of the alternative complement pathway has been shown to play a role in the pathogenesis and progression of disease in some of the more common glomerulopathies. Silencing CFB may be a therapeutic approach for treatment of these conditions.

Study Name: Study of ARO-CFB in Adult Healthy Volunteers and Patients With Complement-Mediated Kidney Disease
A Phase 1/2a Dose-Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Doses of ARO-CFB in Adult Healthy Volunteers and Adult Patients With Complement-Mediated Kidney Disease
ClinicalTrials.gov Identifier: NCT06209177

Collaboration and License Agreements

Glaxosmithkline Intellectual Property (No. 3) Limited ("GSK")

GSK-HSD License Agreement

On November 22, 2021, GSK and the Company entered into an Exclusive License Agreement (the "GSK-HSD License Agreement"). Under the GSK-HSD License Agreement, GSK has received an exclusive license for GSK-4532990 (formerly ARO-HSD). The exclusive license is worldwide with the exception of greater China. GSK is wholly responsible for all clinical development and commercialization of GSK-4532990 in its territory. GSK dosed the first patient in a Phase 2b trial in March 2023.

GSK-4532990

GSK-4532990 (formerly ARO-HSD) is designed to reduce production of HSD17B13, a hydroxysteroid dehydrogenase involved in the metabolism of hormones, fatty acids and bile acids. Published human genetic data indicate that a loss of function mutation in HSD17B13 provides strong protection against metabolic-dysfunction associated steatohepatitis (MASH) cirrhosis and alcoholic hepatitis and cirrhosis. GSK is conducting Phase 2b clinical trials in patients with MASH and alcohol-related liver disease (ALD).

Metabolic-Dysfunction Associated Steatohepatitis: MASH is liver inflammation and damage caused by a buildup of fat in the liver. This can cause scarring of the liver and in advanced cases can lead to cirrhosis. Alcoclıol-related liver disease (ALD) represents a spectrum of liver injury resulting from alcohol use, ranging from hepatic steatosis to more advances forms including alcoholic hepatitis (AH), alcohol-associated cirrhosis (AC), and acute AH presenting as acute-on-chronic liver failure.

Study Name: Phase 2b Study of GSK4532990 in Adults With MASH (HORIZON)
17 β-Hydroxysteroid Dehydrogenase Type 13 Minimization for the Treatment of MASH (HORIZON): A Double-Blind, Placebo-Controlled Phase 2b Study to Evaluate the Efficacy and Safety of GSK4532990 in Adults With Pre-Cirrhotic Metabolic-Dysfunction Associated Steatohepatitis
ClinicalTrials.gov Identifier: NCT05583344

GSK-HBV Agreement

On December 11, 2023, the Company entered into an Amended and Restated License Agreement with GSK (the "GSK-HBV Agreement") pursuant to which GSK received a worldwide, exclusive license to develop and commercialize daplusiran/tomligisiran (GSK5637608, formerly JNJ-3989), the Company's third-generation subcutaneously administered RNAi therapeutic candidate being developed as a potential therapy for patients with chronic hepatitis B virus infection. GSK5637608 had previously been licensed to Janssen Pharmaceuticals, Inc. ("Janssen") in October 2018. GSK is currently in the process of initiating a Phase 2 study of daplusiran/tomligisiran followed by bepirovirsen in patients with chronic hepatitis B.

Study Name: A Study of Sequential Therapy With Daplusiran/Tomligisiran (DAP/TQM) Followed by Bepirovirsen in Participants Living With Chronic Hepatitis B (CHB) (B-UNITED)
A Phase 2b, Multi-centre, Randomized, Partially Placebo-controlled, Double-blind Study to Investigate the Safety and Efficacy of Sequential Therapy With Daplusiran/Tomligisiran Followed by Bepirovirsen in Participants With Chronic Hepatitis B Virus on Background Nucleos(t)Ide Analogue Therapy (B-United)
ClinicalTrials.gov Identifier: NCT06537414

Takeda Pharmaceutical Company Limited ("Takeda")

On October 7, 2020, Takeda and the Company entered into an Exclusive License and Co-Funding Agreement (the "Takeda License Agreement"). Under the Takeda License Agreement, Takeda and the Company co-develop the Company's Fazirsiran program (formerly TAK-999 and ARO-AAT), the Company's second-generation subcutaneously administered RNAi therapeutic candidate being developed as a treatment for liver disease associated with alpha-1 antitrypsin deficiency. Within the United States, fazirsiran, if approved, will be co-commercialized under a 50/50 profit sharing structure. Outside the United States, Takeda received an exclusive license to commercialize fazirsiran and will lead the global commercialization strategy, while the Company will be eligible to receive tiered royalties of 20% to 25% on net sales.

Fazirsiran

Fazirsiran is a subcutaneously administered RNAi therapeutic being developed as a treatment for liver disease associated with alpha-1 antitrypsin deficiency (AATD), which is a rare genetic disorder that severely damages the liver and lungs of affected individuals. Fazirsiran is designed to reduce production of the mutant Z-AAT protein by silencing the AAT gene in order to prevent accumulation of Z-AAT in the liver, allow clearance of the accumulated Z-AAT protein, prevent repeated cycles of cellular damage, and possibly prevent or even reverse the progression of liver fibrosis.

Goal of Fazirsiran Treatment: The goal of Fazirsiran treatment is prevention and potential reversal of Z-AAT accumulation-related liver injury and fibrosis. Reduction of inflammatory Z-AAT protein, which has been clearly defined as the cause of progressive liver disease in AATD patients, is important as it is expected to halt the progression of liver disease and allow fibrotic tissue repair.

Alpha-1 Antitrypsin Deficiency (AATD): AATD is a genetic disorder associated with liver disease in children and adults, and pulmonary disease in adults. AAT is a circulating glycoprotein protease inhibitor that is primarily synthesized and secreted by liver hepatocytes. Its physiologic function is the inhibition of neutrophil protease to protect healthy lung tissues during inflammation and prevent tissue damage. The most common disease variant, the Z mutant, has a single amino acid substitution that results in improper folding of the protein. The mutant protein cannot be effectively secreted and accumulates in globules in the hepatocytes. This triggers continuous hepatocyte injury, leading to fibrosis, cirrhosis, and increased risk of hepatocellular carcinoma.

Current Treatments: Individuals with the homozygous PiZZ genotype have severe deficiency of functional AAT leading to pulmonary disease and hepatocyte injury and liver disease. Lung disease in this patient population is frequently treated with AAT augmentation therapy. However, augmentation therapy does nothing to treat liver disease, and there is no specific therapy for hepatic manifestations. There is a significant unmet need as liver transplant, with its attendant morbidity and mortality, is currently the only available treatment.

Clinical Trials:

Study Name: Study to Check the Safety of Fazirsiran and Learn if Fazirsiran Can Help People With Liver Disease and Scarring (Fibrosis) Due to an Abnormal Version of Alpha-1 Antitrypsin Protein (REDWOOD)
REDWOOD – A Randomized, Double-blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of fazirsiran in the Treatment of Alpha-1 Antitrypsin Deficiency-Associated Liver Disease With METAVIR Stage F2 to F4 Fibrosis
ClinicalTrials.gov Identifier: NCT05677971

Study Name: An Extension Study to Learn About the Long-Term Safety of Fazirsiran and if Fazirsiran Can Help People With Alpha-1 Antitrypsin Liver Disease
A Phase 3, Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of fazirsiran in Participants With Alpha-1 Antitrypsin Deficiency-Associated Liver Disease
ClinicalTrials.gov Identifier: NCT05899673

Study Name: Study to Learn About the Safety of Fazirsiran and if it Can Help People With Alpha-1 Antitrypsin Liver Disease With Mild Liver Scarring (Fibrosis)
A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Safety and Efficacy of Fazirsiran in the Treatment of Alpha-1 Antitrypsin Deficiency-Associated Liver Disease With METAVIR Stage F1 Fibrosis
ClinicalTrials.gov Identifier: NCT06165341

Amgen Inc. ("Amgen")

On September 28, 2016, Amgen and the Company entered into two collaboration and license agreements and a common stock purchase agreement. Under the Second Collaboration and License Agreement (the "Olpasiran Agreement"), Amgen received a worldwide, exclusive license to the Company's novel RNAi olpasiran (previously referred to as AMG 890 or ARO-LPA) program. These RNAi molecules are designed to reduce elevated lipoprotein(a), which is a genetically validated, independent risk factor for atherosclerotic cardiovascular disease. Under the Olpasiran Agreement, Amgen is wholly responsible for clinical development and commercialization.

In November 2022, Royalty Pharma Investments 2019 ICAV ("Royalty Pharma") and the Company entered into a Royalty Purchase Agreement (the "Royalty Pharma Agreement"). In consideration for the payments under the Royalty Pharma Agreement, Royalty Pharma is entitled to receive all royalties otherwise payable by Amgen to the Company under the Olpasiran Agreement. The Company remains eligible to receive up to an additional $485.0 million in remaining development, regulatory and sales milestone payments payable from Amgen and Royalty Pharma.

Olpasiran

Olpasiran is designed to reduce production of apolipoprotein A, a key component of lipoprotein(a), which has been genetically linked with increased risk of cardiovascular diseases, independent of cholesterol and LDL levels. Amgen completed a Phase 2 clinical study evaluating the efficacy, safety, and tolerability of olpasiran in subjects with elevated levels of lipoprotein(a). Amgen reported Phase 2 clinical results at the American Heart Association (AHA) Scientific Sessions in November 2022 and simultaneously published in the New England Journal of Medicine. Amgen began evaluating olpasiran in a Phase 3 study to assess the impact of olpasiran on major cardiovascular events in participants with atherosclerotic cardiovascular disease and elevated lipoprotein(a), in a double-blind, randomized, placebo-controlled, multi center study in December 2022.

Study Name: Olpasiran Trials of Cardiovascular Events and Lipoprotein(a) Reduction (OCEAN(a)) - Outcomes Trial
A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Olpasiran on Major Cardiovascular Events in Participants With Atherosclerotic Cardiovascular Disease and Elevated Lipoprotein(a)
ClinicalTrials.gov Identifier: NCT05581303

C. Intellectual Property and Other Key Agreements

The Company controls approximately 667 issued patents (including 427 directed to RNAi trigger molecules; 144 directed to targeting groups or targeting compounds; and one for hydrodynamic gene delivery), including European validations, and approximately 745 currently pending patent applications worldwide from 92 different patent families. The Company's patent applications have been filed throughout the world, including, in the United States, Argentina, ARIPO (Africa Regional Intellectual Property Organization), Australia, Brazil, Canada, Chile, China, Eurasian Patent Organization, Europe, GCC (Gulf Cooperation Council), Hong Kong, Israel, India, Indonesia, Iraq, Jordan, Japan, Lebanon, Mexico, New Zealand, OAPI (African Intellectual Property Organization), Peru, Philippines, Russian Federation, South Africa, Saudi Arabia, Singapore, South Korea, Thailand, Taiwan, Uruguay, Venezuela, and Vietnam.

RNAi Triggers: The Company owns issued patents or has filed patent applications directed to RNAi trigger molecules, which serve as the foundation of the Company's TRiM™ platform, and are targeted to reduce expression of various gene targets. However, the Company cannot guarantee that issued patents will be enforceable or provide adequate protection for the Company, or that pending patent applications will result in issued patents. These patents and patent applications include the following:

Patent Group	Estimated Year(s) of Expiration*
AAT	2035, 2038
ANGPTL3	2038
APOC3	2035, 2038
ATXN2	2044
C3	2043
CFB	2044
COVID	2043
Cx43	2029
DM1	2043
DUX4	2041
Factor 12	2036, 2038
FRP-1	2026
HBV	2032, 2036, 2037
HIF1A	2026
HIF2α	2034, 2036, 2040
HRH1	2027
HSD17B13	2039
HSF1	2030, 2032
KRAS	2033
LPA	2036
MARC1	2044
MMP7	2042
Mob-5	2027
MUC5AC	2042
P2X3	2027
PCSK9	2044
PDtype4	2026
PI4Kinase	2028
PNPLA3	2041
RAGE (AGER)	2042
RRM2	2031
SOD1	2043
SYK	2027
TNF-α	2027, 2028
TSLP	2044
XDH	2042
α-ENaC	2028, 2038
β-Catenin	2033
β-ENaC	2031, 2040

*Assuming issuance of any pending patent applications, and excluding any patent term adjustments or patent term extensions.

***Delivery Technologies*:** The delivery technology-related patents and patent applications, which include components used in the Company's TRiM™ platform, have been filed and/or issued in various jurisdictions worldwide including the United States, Argentina, Australia, Brazil, Canada, China, Eurasian Patent Organization, Europe (including validations in France, Germany, Italy, Spain, Switzerland, United Kingdom), GCC (Gulf Cooperation Council), Israel, India, Japan, Lebanon, Mexico, New Zealand, Philippines, Russia, South Africa, South Korea, Singapore,

Taiwan, and Uruguay. The Company also controls a patent directed to hydrodynamic nucleic acid delivery that issued in the United States. However, the Company cannot guarantee that issued patents will be enforceable or provide adequate protection for the Company, or that pending patent applications will result in issued patents. These various groups of patents and applications are set forth below:

Patent Group	Estimated Year(s) of Expiration*
Targeting ligands and other RNAi delivery and platform technologies	
CNS Intrathecal Delivery Platform	2043
Adipose Delivery Platform	2044
Biologically cleavable linkers	2036
LDLR targeting	2028
Muscle delivery platform	2041
Peptide targeting (CPP-Arg)	2028
Peptide targeting (YM3-10H)	2032
Physiologically labile linkers	2036
PK/PD lipid modifiers	2041
RNAi agent design (5′-phosphate mimic)	2037
Targeting groups (Galactose derivative ligands)	2037
Targeting groups (Galactose derivative trimer-PK)	2031
Targeting groups (αvβ3/αvβ5 integrin)	2034, 2038, 2039
Targeting groups (αvβ6 integrin)	2037, 2038, 2041
Transferrin targeting	2028
Trialkyne linkers	2039
Hydrodynamic delivery	
Third iteration	2024

*Assuming issuance of any pending patent applications, and excluding any patent term adjustments or patent term extensions.

The RNAi and drug delivery patent landscapes are complex and rapidly evolving. As such, the Company may need to obtain additional patent licenses prior to commercialization of its candidates. Please see "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

Acquisition of Assets from Novartis

On March 3, 2015, Novartis and the Company entered into an Asset Purchase and Exclusive License Agreement (the "RNAi Purchase Agreement") pursuant to which the Company acquired Novartis's RNAi assets and rights thereunder. Pursuant to the RNAi Purchase Agreement, the Company acquired or was granted a license to certain patents and patent applications owned or controlled by Novartis related to RNAi therapeutics, was assigned Novartis's rights under a license from Alnylam Pharmaceuticals, Inc. ("Alnylam") (the "Alnylam-Novartis License") and acquired a license to certain additional Novartis assets (the "Licensed Novartis Assets"). The patents acquired from Novartis include multiple patent families covering delivery technologies and RNAi-trigger design rules and modifications. The Licensed Novartis Assets include an exclusive, worldwide right and license, solely in the RNAi field, with the right to grant sublicenses through multiple tiers under or with respect to certain patent rights and know how relating to delivery technologies and RNAi-trigger design rules and modifications. Under the assigned Alnylam-Novartis License, the Company acquired a worldwide, royalty-bearing, exclusive license with limited sublicensing rights to existing and future Alnylam intellectual property (including intellectual property that came under Alnylam's control on or before March 31, 2016), excluding intellectual property concerning delivery technology, to research, develop and commercialize 30 undisclosed gene targets.

Non-Exclusively Licensed Patent Rights from Roche

On October 21, 2011, the Company acquired the RNAi therapeutics business of Hoffmann-La Roche, Inc. and F. Hoffmann-La Roche Ltd. (collectively, "Roche"). The acquisition provided the Company with two primary sources of value:

existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

4N

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

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

Section 1: General Information

Facility Name: Regeneron Pharmaceuticals, Inc.

Physical Address: 350 Tempel Lane

City: East Greenbush State: NY Zip: 12061

Mailing Address (if different from physical address): c/o State License Servicing, 225 Dolson Ave, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.regeneron.com

Name of Designated Representative (DR): Stephen Zoeller

Licensing Company Email: RGP@slsny.com DR Email: stephen.zoeller@regeneron.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Drugs (Biologics)	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Manufacturers		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Reference Appendix A

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: NY

Parent Company (if any): Publicly Traded: REGN

Corporation Name: Regeneron Pharmaceuticals, Inc.

Mailing Address: c/o State License Servicing, 225 Dolson Ave, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Email: RGP@slsny.com

Contact Person Name: Christine Cannon

Date of SEC Registration: 02APR1991 | SEC Registration Number: 0000872589 | Stock Exchange Symbol: REGN

N/A **Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A **Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A **Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Appendix A

Regeneron Pharmaceuticals, Inc., located at 350 Tempel Lane, East Greenbush, NY 12061, has not engaged in the sale, dispensing, or distribution of pharmaceutical products over the past year.

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA #: 3015581066	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** See Company Particulars	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A - No CS	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Regeneron Pharmaceuticals, Inc.

Facility Name

Rajesh Girdhari Ahuja

Print Name of Authorized Person Submitting Application

Rajesh G. Ahuja

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

09 MAY 2025

Date

Board Use Only	Date Received: 6/9/25	Amount: $1000 - ck 1692

An official website of the United States government Here's how you know

Proof of FDA

FDA

Home > Drug Databases > DECRS > Search Result

Share Tweet LinkedIn Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *regeneron pharma*

Showing 1 to 1 of 1 entries (filtered from 2 total entries) Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Regeneron Pharmaceuticals, Inc.	3015581066	118205659	ANALYSIS; LABEL; MANUFACTURE; PACK; RELABEL; REPACK; STERILIZE	350 Tempel Ln, East Greenbush, New York (NY) 12061, United States (USA)	12/31/2024

Previous 1 Next

Data Current Through: Tuesday, Jul 23, 2024

New Search

Company Particulars

Regeneron Pharmaceuticals, Inc.

Corporate Address: 777 Old Saw Mill River Road, Tarrytown, NY 10591 USA
FEIN: 13-3444607
www.regeneron.com

Drug Labeler Code: 61755
Incorporation State: NY
Incorporation Date: 1/11/1988

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
TEP	350 Tempel Lane East Greenbush, NY 12061 County: Rensselaer	3015581066	N/A - No CS	118205659	No	(518) 488-6000	N/A

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Stephen Edward Zoeller	[redacted]	VP Internal Fill/Finish MFG		[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Publicly Traded: REGN							

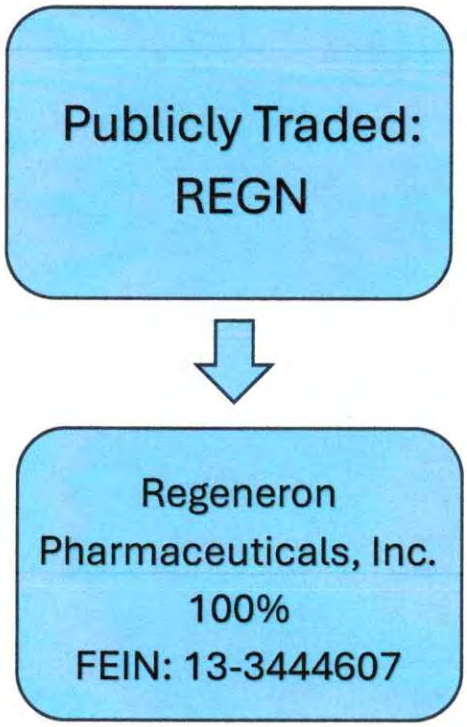
LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Benjamin T Yocum	[redacted]	SVP Manufacturing Operations		[redacted]		
Mark A Volpe		Senior Vice President, Tax				
Rajesh Girdhari Ahuja		Senior Vice President Fill/Finish & External Manufacturing				
Richard Gluckselig		VP, Associate General Counsel & Assistant Secretary				
Leonard N Brooks		Senior Vice President, Treasurer				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
CT Corporation			

Regeneron Pharmaceuticals, Inc. Ownership Chart



Appendix A

Regeneron Pharmaceuticals, Inc., located at 350 Tempel Lane, East Greenbush, NY 12061, has not engaged in the sale, dispensing, or distribution of pharmaceutical products over the past year.

Good Standing

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

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

Entity Name:	REGENERON PHARMACEUTICALS, INC.
DOS ID Number:	1226128
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	01/11/1988
Statement Status:	CURRENT
Statement Due Date:	01/31/2026

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

STATE OF NEW YORK ★ DEPARTMENT OF STATE ★ EXCELSIOR E PLURIBUS UNUM

WITNESS my hand and official seal of the Department of State, at the City of Albany, on May 22, 2025 at 03:25 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100008078949 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

Home State (NY) Permit

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2024-27

NAME OF SUPERVISOR
RAJESH AHUJA

THIS IS TO CERTIFY

REGENERON PHARMACEUTICALS, INC.
350 TEMPEL LANE
EAST GREENBUSH, NY 12061

is duly recorded as a

REGISTERED MANUFACTURER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWENTY-FOURTH DAY OF APRIL, 2024.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF MARCH, 2027.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
039232

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

Home State (NY) License Verification



REGENERON PHARMACEUTICALS, INC.

GENERAL INFO | ENFORCEMENT ACTIONS

Registration No: 039232

No Enforcement Actions Found

June 3, 2025 01:49 PM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=039232&professionCode=020

REGENERON PHARMACEUTICALS, INC.

GENERAL INFO | ENFORCEMENT ACTIONS

Type	Manufacturer
Legal Name	REGENERON PHARMACEUTICALS, INC.
Trade Name	---
Street Address	350 TEMPEL LANE EAST GREENBUSH NY 12061
Registration No	039232
Date First Registered	April 24, 2024
Registration Begins	April 24, 2024
Registered Through	March 31, 2027
Supervisor	ZOELLER STEPHEN
Establishment Status	Active
Successor	NONE

June 3, 2025 01:49 PM (ET)
https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=039232&professionCode=020

Client#: 206216 REGENPHARM

ACORD™ CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 7/18/2025

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

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

PRODUCER	CONTACT NAME: Chelsea Miller	
Conner Strong & Buckelew PO Box 99106 Camden, NJ 08101	PHONE (A/C, No, Ext): 856-479-2069	FAX (A/C, No):
	E-MAIL ADDRESS: cmiller@connerstrong.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Federal Insurance Company	20281
INSURED Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591-6707	INSURER B : Chubb Insurance Company of New Jersey	41386
	INSURER C : The Phoenix Insurance Company	25623
	INSURER D :	
	INSURER E :	
	INSURER F :	

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			35895885	05/15/2025	05/15/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$25,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$Excluded
	OTHER:							$
C	AUTOMOBILE LIABILITY			8103T58580A25I2	05/15/2025	05/15/2026	COMBINED SINGLE LIMIT (Ea accident)	$2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	X UMBRELLA LIAB X OCCUR			79868130	05/15/2025	05/15/2026	EACH OCCURRENCE	$10,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$10,000,000
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED?	N / A					E.L. EACH ACCIDENT	$
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

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

Re: Regeneron Pharmaceuticals, Inc. - 350 Tempel Lane, East Greenbush, NY 12061 is included as an insured.

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

W. Michael Fitzgerald

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Regeneron Pharmaceuticals, Inc. MDEG License # (if applicable): N/A

Physical Address: 350 Tempel Lane

City: East Greenbush State: NY Zip: 12061

Mailing Address (if different from physical address): c/o State License Servicing, 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.regeneron.com

Licensing Company Email: RGP@slsny.com

Section 2: Personal Information

First: Stephen Middle: Edward Last: Zoeller

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

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

Mailing Address: [redacted]

City: Clifton Park State: NY Zip: [redacted]

Telephone: [redacted] Email: stephen.zoeller@regeneron.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Marylhurst University		09/2009	- 08/2011
Address	**City**	**State**	**Zip**
17600 Pacific Highway	Marylhurst	Oregon	97036
Diploma/Degree obtained, if any			
Master of Business Administration, General Management			
School Name		From - To (MM/YY – MM/YY)	
Purdue University		08/1987 - 05/1991	
Address	City	State	Zip
610 Purdue Mall	West Lafayette	Indiana	47907
Diploma/Degree obtained, if any			
Bachelor of Science, Construction Engineering and Management			
School Name		From - To (MM/YY – MM/YY)	
St. Xavier High School		09/1983 - 06/1987	
Address	City	State	Zip
1609 Poplar Level Rd.	Louisville	KY	40217
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2022 - Present	[redacted]	Clifton Park	NY	[redacted]
From - To (MM/YY – MM/YY)		City	State	
03/2007 - 09/2022		Tigard	OR	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Regeneron Pharmaceuticals			09/2022 - Present
Business Address	**City**	**State**	**Zip**
350 Tempel Lane	East Greenbush	NY	12061
Phone	**Title**	**Number of Employed Hours**	
(518) 488-6000	VP Internal Fill/Finish MFG	~ 5240 Hours	

Description of Duties
The VP Internal Fill/Finish Manufacturing Operations is accountable for clinical and commercial drug product manufacturing operations. This is a leadership role with focus on the start-up and execution of GMP operations for all production areas, ensuring the facility is properly staffed and trained and supporting a production planning process that is dynamic and flexible to meet the needs of Regeneron's patients. The VP Internal Fill/Finish will also be responsible for implementing a cross-functional site leadership team and serving as a key member of various management teams within Industrial Operations and Product Supply

Business Name			From - To (MM/YY – MM/YY)
Genentech, Inc.			09/2020 - 07/2022
Business Address	**City**	**State**	**Zip**
4625 NE Brookwood Pkwy.	Hillsboro	OR	97124
Phone	**Title**	**Number of Employed Hours**	
(503) 992-3600	Senior Director, Lyophilized Products & Packaging Value S	~ 3,800 Hours	

Description of Duties

Site senior leadership team member; Responsible for planning, scheduling, drug product and finished goods manufacturing and release operations, including technical transfer and product launch activities; Responsible for collaborating company wide on strategic initiatives.

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Stephen Edward Zoeller, **certify that as the MDEG Administrator for**

Regeneron Pharmaceuticals, Inc.,

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

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

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

Stephen Edward Zoeller
Print Name (First, Last)

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

14Apr 2025
Date

Board Use Only	Date Received: 6/18/25

Employee list

REGENERON
SCIENCE TO MEDICINE®

81 Columbia Turnpike
Rensselaer, NY 12144
518.488.6000

The Regeneron Pharmaceuticals, Inc. facility located at 350 Tempel Lane East Greenbush, NY has approximately 2,000 people onsite.

List of Regeneron Pharmaceuticals, Inc. employees located at 350 Tempel Lane, East Greenbush, NY 10591 as of 16th of July 2025.

Stacey DeMille	Richard Coppey	Michael Holbert	Louis Peluso	Ashley Hayes	Lauran Emerson	Michael Carpentier
Patrick McDonough	Stephanie Palacios	Jennifer Perez	Timothy Riehlman	Nicole Williams	Adam Warner	Vanessa Jackson
Nicholas Quill	Susan Farrell	Juston Poulima	Bradley Cottrell	Megan Giamei	Delwone Howard	Shannon Schyberg
Kim Brookman	Becky Mahar	Oliver Mehner	Carl Springli	J.R. Jackson	Katie Resch	Bruce Walton
Sarah Stern	Brian Byer	Tyler Shattuck	Ronald Johnson	Randy MacDonald	Donald Cross	Christine Gray
Matthew Henkel	Kevin Lennon	Michael Adams	Dale Weeks	Tyler Gansfuss	Brianna Nolette	Ufuoma Anidi
Jeffrey Talbot	Erica Reynolds	John Bernaski	Joseph Palladino	Will Ferris	Bryn Lappies	John Collins
Kathleen McCarthy	Brodie France	Rachael Cartier	Sushil Bhatia	Arielle Twardowski	James Callahan	Meghan Seely
Joseph Grimaldi	Hillari Patschureck	Kelly Wahrlich	Victor Labault Lopez	Joey Priola	Sean Hennings	Kaleigh Koreman
Carlucio Sorriento	Scott Piper	Chad Rytel	Jorge Padilla-Zamudio	James LaFave	Christine Zhao	Blake Campanella
Adam Duerr	Rebecca Farinacci	Mycala Brown	Vedangi Sample	Jack Minassian	James Meister	Manoj Ganesh
Dillon Bethoney	Inthi Sikkander	Matthew Harrison	Zizhao Liu	James Snyder	Danial Morse	Thomas Howson
Sarit Lilo	Matthew Shadikhan	Ken Shin	David Vaysman	James Tompkins	Andrew Lutringer	Jonathan Mackerer
Colleen McGrath	Tiffany House	Michael Lanzillo	Thomas Rudolph	Kyle Curtis	Erica Weldin	Chuck DeCitise
Maureen Moore	Alec Gerson	Cameron Anderson	Aaron Maki	Daniel Norton	Andrew Croft	Nela Martinovic
Margaret Little	Chinh Nguyen	Jenna Tramaglini	Carl Adamczak	Donald Griffin	Martin Candee	Maxwell Smith
John Imhoff	Maggie Butner	Katie Francis McPherson	Danielle Heller	Jackie Brisson	Michael DiMasi	Paul Zawistowski
Isaac Gonzalez	Carly Fuhrman	Gary Ellis	Jennifer Kelliher	Trevor Lisky	Fritz Henze	Brittany Tanner
Shawn Shaffer	Jillian Knapik	Joseph Foland	Brenna Couture	David Marrow	Kristen Empie	Ryan Yakal
Barry Stone	Stacey Helming	Kylie Ring	Jen Montimurro	Tyler Gilbert	Kelsey Rasefske	Jackie Hennings
William Rice	Alison Pagano	Megan Cormace	Dylan Evarts	Katherine Hartmann	Maria Torina	Lilly Pu
Mary Buckley	Marlana Ackley	Jeffrey Liberty	Michael Gills	Shawn Taylor	Jessica Campanella	Alissa Green
Daniel Olsen	Kasie Warrington	Michael Kruczlnicki	Louis Bryant	Alicia Palmer	Christopher Johnson	Julia Marger
Jamie Ortegel	Felix Rodriguez	Anthony Cormace	James Dawson	Patrick Schrader	Paul Olsen	James Maddex
Jameson McGrath	Courtney Fennelly	David Harwood	Brigidanne Flynn	Keith Wilkinson	Ryan Donovan	Patrick Whitesell
Edesse Murphy	Jeffrey Crannell	Kevin Milne	Justin Lynam	Kenneth Mahar	Louisa Carr	Timothy Stearns
Bradley Kervin	Nathan Boehm	Evan O'Brien	Melissa Fuhrman	Russell Jones	Sarah Faas	Thomas Beusse
Jessica Cirillo	Heather DeFilippo	Will Maier	Danielle Allen	Benjamin Phelan	Mike Seraj	Melissa Snare
Jen Wicks	Nike Green	Nancy Ferrigan	Talisha Phaeton	Michael Stalbird	Kyle Olmsted	Cathleen Schiraldi
Nicole Barbato	Timothy Whalen	Joshua Keyoskey	Michael Quagliano	Erin Kane	Daniel Stiles	Sarah Dix
Megan Crabtree	Kathleen Crouse	Ashley Loggins	Megan Pike	Abby Brown	Shannon DiPrima	Nathan Pleskach

REGENERON CONFIDENTIAL

Alex Athanassiadis	Laura Hynes	Elizabeth Fordyce	David Connor	Shea Sullivan	Paul Bigwarfe	Terry Danko
Alexandria Brooks	Kenji Tanaka Henao	Jacob Miller	Alexander Leshkevich	Erin Purr	Jamie Ash	Rob O'Brien
Alyssa Krok	Scott Rue	Rachel Netzband	Stephanie Monteau	Jack Vite	Jiffry Ismail	Richard Carkner
Noah Bolduc	Yuan Wang	Mahlon Schaffer	Samantha Frye	Lori Benedict	Troy Bombard	Tequila Malchow
Adrianna Mathis	Alexandra Benson	Steven Sarris	Holly Rehm	Lauren Reed	Jesse Holt	Hua Ling
Rachel Mullen	Joshua Lavelle	Christopher Clemens	Manuel Pena	Nicholas Mabee	Lance Van Tassel	Kim Cushing
Crystal Riordan	Heather D'Orazio	David Steward	Meaghan O'Keefe	Matthew ONeill	Abigail Gelder	Kristin Schmitz
Kevin Brennan	Alex Camacho Garcia	Meranda Ruff	Ted DeConno	Joseph Hunziker	Morgan Konecny	Seamus O'Connor
Dylan Westbrook	Michael Mineau	Wendella Wilson	Carolyn Thomson	James Sumner	Ashley Anderson	Emma Boucher
Asiya Ejaz	Frank Coons	Alice Betzhold	Janel Cross	Zachary Peterson	Ashley Gibbons	Audrey Perrott
Mary Pastorelli	Natalie Wijayatilleke	Jared Watson	Nick StJohn	Stephen Dowd	Dwyer Stuart	Scott Bayer
Carlos Morales Otero	Machayla Donovan	Meryem Ozen	Brandon Pinho	Maria Mateo Santos	Kierstyn Gurney	Trevor Morelli
Stephin Wallace	Sara Thompson	Melanie Psota	Siu Wah Wong-Deyrup	Yannie Mei	Kevin Farrell	Joe Sinisgalli Jr
Beverly Walker	Lucas Gomez-Freschi	Sean Dinn	Kelly Vest	Tyler Lee	Eric Richter	Joe Thornton
Andrew Parnes	Rachael Skipp	Andrew Pollack	Christina Riley	Shawn Moseley	Lindsey Sherwood	Jason LoVullo
Lauren Licari	Megan Bathrick	Tyler Krumm	Ryan Dickson	Erica Morera	Michael Tomik	Karen Harkness
Kayla Stuart	Cody Daigle	Adam Yost	John McCauley	Timothy Palmer	Eric Padua	Brendon VanVlack
Moiz Malik	Meagan Vanderover	Kyle Youlen	Rosemary Matala	Beth Vogel	Williard Werner	Nicole Patent
Katharine Ferrone	Juan Buritica	Elise Viola	Emily Mosher	Arjana Zyka	Benjamin Cummings	Sean Hennessey
Matt Drum	Jennifer Ryan	Michael Lieberman	Anthony Bracken	Randall Sweet	Anna Mink	Anthony Costello
Kathryn Hodge	Durrell Scott	Cody Koonz	Patrick Duffy	Brandy Jones	Mia Berkowitz	John Orth
Josh Fleming	Jordan Young	Elizabeth Foster	Andrew Bennett	Joe Kuehner	Alex Bajzer	Stephanie Burns
Jonah Marwin	Kimberley Leavitt	Evelyn Draus	Evan Capolino	Tyrone Taylor Smith	Sarah DeCicco	Nipul Patel
Reginald Smith	Kyle Lacey	Vanessa Eston-Amor	Hanna Boehm	Ryan Burke	Nicholas Pakatar	Alishia Gariepy
Kali Moran	Adam Dollard	Mark Hinsdale	Jenette DiLaura	Ashley Close	Michael Natole	Lai-Ming Cheung
Daniel Robeson	Paul Flayter	Wenqin He	Matt Kyea	Miranda Kinn	Christina Eker	Jeremy Stevens
Caryn Coughtry	Sean Ostrander	Keith Anderson	Mary Hamilla	Julia McKay	Rachel Carr	Yarelis Harris
Christopher Sevinsky	Frankie Santiago	Kyle LaMantia	Hannah Smith	Eric Shierly	Mark Ring	Michael Orlowski
Josh McAllister	Shawn Carney	Mark Mazzeo	Jared Pleibel	Jason Van Buren	Derek Green	Zoe Ogden
Tabassum Rahman	Alix Affinito	Charles Chiang	Royce Duda	Jayne Kenneally	Vincent Shortsleeve	Chantel Mochon
Shuang Chu	Christopher Murphy	Cassandra Corey	Steven Caminiti	Ra'Daisha Croley	Sarah Moscowitz	Jonathan Palazeke

REGENERON CONFIDENTIAL

Matthew Provost	Maria Lleras	Steven Malek	Jen O'Brien	Alvin Lutchmidat	Hayley Rivers	Greta Van Slyke
Michael Donlick	Crystal Georgescu Farrell	Mckenzie Marois	Nathan Lapinski	Ariel Rourke	Josh Gorton	Quinn Connors
Michael Bryant	James Hennessy	Allysa Swilley	Carli Hathaway	Dave Massey	Lauren Petersen	Courtney Vito
Mary Zarnowski	Clare Ryan	Zach Michaud	Cassandra King	Ian Welsh	Francisca Essel	George Opoku-Kusi
Julia Wilkes	Kevin Bourassa	Maribel Santos	Chris Hutnick	Michael Barry	Garrett Pitcher	Tyler Wilkinson
Ian Wyatt	Shaun Kasper	Michael Bolognani	Megan Ashline	Scott Kleeschulte	Kaitlyn Franz	Harleen Kaur
Shina Okunoye	Matthew Smith	Chana Ritter	Gregory Jackson	Sameera Sinha Nallanthighal	Matthew Feeley	Suchin Sharma
Jaime Frattellone	Connor Kelly	Virgil Terry	Nicole Lapointe	Kristina Crandall	Thomas Fimbel	Vanessa Acosta
Malik Padellan	Leander Petersen	Tyrone Frierson	Joshua Zalepeski	Kyle Marion	Candice Gordon	Xinyi Sui
Brianna Johnson	Tarah Harrington	Heather Moore	Michelle Dowling	Bryan Daumont	Lucy Lin	Matthew Schulze
Dennis Castagnola	John Heck	Justin Ramsden	Alex Snyder	Adam Kaarstad	Melissa Lancellotti	Benjamin Geveke
Vinnie Cuttle	Nino Gagliardi	Kate Pritchard	Bethany Smith	Joseph Galluppi	Ivan Rivera Torres	Ben Funyak
Thierry Comeau	Dante Sanford	Rashida Abraham	Chloe Lewandowski	Isaiah Scurry	Philip Yeh	Angela Ngo
Jibin Chacko	Liliana Braun	Marcos Doherty	Betsy Luciano Rivera	Caitlin Sahm	Aaron Edgar	Jaimie Lessard
Norberto Taveras	Jason Ingraham	John Murray	Eric Steffek	Amanda Demeter	Savannah Gero	Madison Turcotte
Corey Squires	Phil Kramer	Evan Biittig	Elizabeth Desmonie	Eric Milanese	Mariana Rosario	Lauren Sanford
Hunter Redden	Kelly Bromley	Evan Moisidis	Ellie McGhee	Haley Morgan	Malia Stenske	Holly Rousseau
Stephen Frost	Dylan Proctor	Rose Baltazar	Kathleen Flores	Judy LaPlante	William Ryder	Joe Wang
Bradley Duncan	Reilly Breen	Abdou-Ganiou Gountante	Michael Losee	Skylar Riccardi	Zac Anderson	Lauren Dantz
John Kasumba	Sean Jackson	Bryan Woh	Morgan Osborn	Rachel Giovannone	Jack Loonan	Rick Petersen
Ryan Reavey	Austin Nydegger	Michael Hug	Nick Downey	Thomas Hudson	Colby Dowell	Samuel Bobbette
Randall Yeomans	Tiara Kruzinski	Hannah Pariseau	Alexander Jeseo	Chong Ou	Steve Zoeller	Douglas Overbaugh
Jessica Burns	Bryan Morgan	Ahmad Al Sharbati	Massimo DiCaprio	Brittany Genzmann	Serigne Thiam	Michael Ferracane
Shavonna Bentley	Jeff Durosier	Kaitlyn Catlin	Ryan Kapusinsky	Amber Vosburgh	Rebecca Kent	Brandon Kenealy
Gabriel Carreau	Quinn McDonald	Skylar Van Alstyne	Danielle Gagnon	Mathew Goberdhan	Shazad Suchit	Matthew Estrella
Ciera Fylipek	Glenn Smith	Brian Brown Jr	April Arroyo	Mehmood Aslam	Nick Winget	Jessica Guay
Serena Wu	Mark Simmons	Emily Crofter	Debbie Cook	Jared Daus	Zachary Molisky	Ovie Obaro
Evangelos Townsend	Riva Taksir	Madeline Schanz	Eneida Steffek	Samantha Humiston	Alexandra Peasley	Josiah Westfall
Mari Cortes-Mendoza	Jose Morales	Meghan Volcko	Clair Gameng	Derek Alcott	Bobby Javaid	Emily Yakal
Travis Jefferds	Bridget Engel	Natalia Valentin	Samson Bourgeois	Joseph Borello	Anthony Robinson	Michael Bishop
Maria Tchamova	Steve Rabady	Mirco Sorci	Pedro Perez-Diaz	Emily Prince	Saiful Basir	Eric Denny

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Lisa Gourlay	Lauryn Pianelli	Paige Keneston-Gumaer	Faran Antoni	Laura Klang	Joseph Wood	Cory Warrings
MichaelJohn Twohig	Indigo Nagle	Hailey Popielarz	Deyshawn Thomas	Sarah Gardner	Augustine Vielkind	Rachel Curtis
Weici Fang	Noelle Petersen	Jason Klusewitz	Nathan Dellevigne	Nada Mohamed	Swetal Patel	Bijin Kurian
Brandon Wolf	Marcellus Jones	Justin Bueno	Lindsey Lipari	Jonathan Reyes	Andy Amor	Jason Yee
Tannya Romero	Philippe Viray	Patrick Pendergrass	Morgan Matthews	Michael Bissaillon	Oliver Chaires	Peter Charde
Benjamin Wallin	Cheryl Farrell	Jonathan Willman	Andrea Smith	Maria Pascual	Anna Shukla	Mark Drahushuk
Fatoumata Camara	Francesca Sajedi	Yariet Guzman Diaz	Justin Kraft	Fernando Moreta	Erin Edgar	Amanda Obaro
Stephanie Belden	Daina Malinoski	Seth Oeser	Natalie Tremblay	Michelle Lin	Nathan Phillips	Frederick Morine
Garrett Lea	Scout Noble-Buono	Raymond Bunkofske	Joanna Xiao	Stephen Vanyo	Beril Goncu	Dalila Yeend
Brandon Marino	Chris Falkowitz	Bryan Mcnall	Chelsea Lounsbury	Ariel Dobies	Norman Plummer	Amber Walters
Stephanie Cuomo	Kitty Mattina	Pat Faughnan	James Daley Jr	Melanie deLaurentis	Zackery Morine	Darrin Chatman
Andrew Hann	Sean Garrow	Lauren Alonzo	Amanda Riley	Ryan Brown	Mariam Escander	Dylan Stufflebeam
Taylor LaFountain	Marcella Powell	Sarah Connelly	Bryan Shults	Owen Perry	Shane Kramer	Shelly Li
Kelley Wells	Corey Freemire	Cassidy Sheehan	Timothy Czajka	Mark Hamilton	Nakya Bennermon	Meghan Borger
John Pruyn	Jeanell Babcock	Jacob Clouse	Señia Quevedo	Nicholas Esposito	Justin Loudis	Laurie Anne Danaher
Scott Waite	Sean Duncan	Venkat Ramana Goli	Neal Tommasini	Matthew Furlong	Jennifer Scully	Marissa Whitman
Luke Van Aller	Kyle Machia	Justin Allisha	Gary Shroat	Erin Barrett	Martin Bond	PJ Ladopoulos
Gabriel Columna	Brett McMullin	Nicole Knowles	Jeff Sheridan	Mohammed Khan	Cody Lane	Cody Gifford
Adriana DeVoe	Branden Wolfe	Genna Mahabeer	Christopher Bernaski	Chandra Harvey	Robert Stevens	Brian Wingert
Anya Uberbacher	Anna Campanella	Joseph Petkoff	Abby Stewart	Mason Weems	Nicholas Corah	Jason Wassell
Jessica Cavalieri	Justin Ruiz	Monica McGauley	Casey Pollock	Kerry Kleinertz	Edward Freisinger	Marc Massena
Paul Purcell	Matt Krambeck	Andy Bain	Casey Su-Morrill	Daniel Dodaro	Becca Tharu	Derek VanAppledorn
Stephen Lajeunesse	Nasir Ahmad	Anna Sesonske	Joseph Payne	Amanda Saca	Louis Storti	Brenda Pomales-Santiago
Mary Grace McIntyre	Kevin Parks	Kent McCalister	Angelica Costello	Elaheh Movahed	John Courter	Davis Anderson
Taylor Knapp	DaYana Henry	Rachel Panetta	Jaycee Greer	Chad Cronce	Sheryl Lashoff	Edwin Vilanova-Velez
Mona Khalid	Ted Loney	Eric Eulau	Jeffrey Munger	Richard Smith	Steve Quay	Alison Secor
Christopher Reynolds	Michelle Harden	Michael Hamlin	Nick Koester	Maia Baskerville	Enrique Ramirez Diaz	Isabel Jones
Pamela Wright	Phillip Yunginger	Wito Gonzalez	Bill Blatz	Derick Kehn	Andrew Oathout	Gideon Dawes
Sabrina Medina	Kathryn Powers	Maria Carr	Anthony Crespo	Chrissy Merchant	Jesse Gonzalez-Gomez	Byron Hopkins
Zachary DeBiase	Amy Smith	Shannon Lake	Matthew Smith	Sarah Kotchey	Darby Shaw	Roger Jaynes Jr
Lucas Smith	Nathaniel Johnson	Scott Jackson	Patrick Glickman	Hector Ramos	Troy Windover	Michael Chamberlain

Donald Bougher	Edward Yoli	Roman Rasiak	Jacqui Cali	John Hunt	Cody Richardson-Tilford
Galit Hirsch-Thieme	Sheila Murenzi	Erin Maloney	Ashraf Alsabbagh	Craig Skiba	Kelly Nolan
Brendan Coletta	Brannon Anders	Alayna Appolon	Kayla Ospitale	Tyler Weiss	Humza Ahmed
Katy Chau-Westfall	Kiaria Womack	Thilini Amarakoon	Franklin Desarden	Ashley Pangburn	Jennifer Hebert
Fox Shivik	John Aptt	Emmanuel Velez Brito	Amanda Hutsell	Allison Busch	Zachary Snide
Brandon Meltz	Chelsea Budhraj	Lauren Nolet	Rachel Seaman	Randy White	Michelle Ames
Aaron Herman	Jackie Cheng	Nicholas Scott	Zachary Shaw	Danny Biette	Eddie Garcia
Jennifer Steward	Tim Rytel	Humza Rasool	Lingyun Li	Abby Colvin	Kevin Karr-McGraw
Nate Quichocho	Sarah Bradley	Kevin Murphy	Alice Croteau	Michael Koperniak	Lori Townsend
Michael Miller	Gregory Hebert	Chelsea Washington	Nicholas Cerone	Lucas Bruce	Anton Beletskii
Joe Wood	Denny Mars	Rajen Somwaru	Alexandra Barbato	Annabelle Dupre	
Cole Hoover	Damir Talic	Krishna Prakash	Emillee Robords	Larry Forgue	
Tony Morales	Kyle Powell	Allison Cilke	Austin Lefort	Fredric Malmberg	
Emily Moss	Jessica Lee	Samantha Gladd	Amy Pelletier	Casey Van Nostrand	
Jacob Halle	Max Campos	Geoff Fox	Heather Kennish	James Ring	
Taina Quiñones	Matthew Charde	Dmitrii Ivashchenko	Todd Dean	Daniel Lioi	
Celia Davis	Michelle Huff	Peter Rotella-Iamb	Swarup Dey	Kristen Foster	
Aaron Premo	Dianne Valera	Erik Knight	Adrian Novas	Paul Oravsky	
Briana Cavalieri	Adriana Morales	Irina Abrahamson	Cathy Gebe	Thomas Blesser	
Kimber OBrien	Matthew Shea	Christopher Brandon	Said Messerour	Matt Jackson	
Kylie Ryan Szczurek	Aria Galindez	Kaleb Rock	Jules Kirkland	Katherine Sharifipour	
Ryan Soron	Wentana Ghile	Muhammad Siddiqi	Jeffrey Thomson	Tom Jing	
Dylan Kolb	Hannah Miller	Kevin Mullen	Jet Starkings	James Blanch	
Evan Schnell	Coleman Jennes	Johanan Perez	David Gomez	Drance Rice	
Nabin Kandel	Kirsten Smith	Sumit Kamat	Robert Zawistowski	Tammy Baird	
Bhartie Dhanraj	Brittney Maring	Ryan Board	Alexander Bayne	Kristofer Heller	
Sarah Miller	Jonah Smith	Kyle Roach	Nico Caprara	Meaghan Cellio	
Ingrid Vega	Rilke Griffin-Hare	John Trasorras	Roger Therrien	Paige Lafrance	
Tiya Yang	John Gleason	Usha Bhadai	Jacob Hathaway	Amanda Campbell	
Kaitlin DeLoria	Benjamin Nightingale	Kaitlyn Foley	James Groom	Ethan Mitzner	
Gavin Barone	Jackson Greenier	Sage Smith	Jeffrey Schneiderheinze	Terri Rogers	

REGENERON CONFIDENTIAL

Bond

NEVADA STATE BOARD OF PHARM
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. LPM9428711

Application/License No. _____

Regeneron Pharmaceuticals, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 777 Old Saw Mill River Road, Tarrytown, NY 10591-6707 (Address of Applicant/Principal), as PRINCIPAL, and Fidelity and Deposit Company of Maryland (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1299 ZURICH WAY, 10TH FLOOR, SCHAUMBURG, IL 60196 - 1056 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 10/22/2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of October, 20 24.

APPLICANT/PRINCIPAL

COMPANY

Leonard Brooks
Authorized Representative

SURETY

Fidelity and Deposit Company of Maryland

Donna M. Chiancone
Surety Company's Representative

Donna M. Chiancone, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Gisela C. Marin
Witness

Robin Doherty
Witness

SIGNED and SEALED in the presence of:

Lori N. Baybutt
Witness Lori N. Baybutt

Witness Travis W. Shaffer

Countersigned by:

Nevada ~~Resident~~ Agent Donna M. Chiancone
Non-Resident

ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"), by Robert D. Murray, Vice President, in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and appoint Donna M. Chiancone, its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings,** and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said **ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND**, this 10th day of October, A.D. 2023.

ATTEST:
ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND

By: Robert D. Murray
Vice President

By: Dawn E. Brown
Secretary

State of Maryland
County of Baltimore

On this 10th day of October, A.D. 2023, before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Robert D. Murray, Vice President and Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, deposeth and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Genevieve M. Maison

GENEVIEVE M. MAISON
NOTARY PUBLIC
BALTIMORE COUNTY MD
My Commission Expires JANUARY 27, 2025

Authenticity of this bond can be confirmed at bondvalidator.zurichna.com or 410-559-8790

EXTRACT FROM BY-LAWS OF THE COMPANIES

"Article V, Section 8, Attorneys-in-Fact. The Chief Executive Officer, the President, or any Executive Vice President or Vice President may, by written instrument under the attested corporate seal, appoint attorneys-in-fact with authority to execute bonds, policies, recognizances, stipulations, undertakings, or other like instruments on behalf of the Company, and may authorize any officer or any such attorney-in-fact to affix the corporate seal thereto; and may with or without cause modify of revoke any such appointment or authority at any time."

CERTIFICATE

I, the undersigned, Vice President of the ZURICH AMERICAN INSURANCE COMPANY, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing Power of Attorney is still in full force and effect on the date of this certificate; and I do further certify that Article V, Section 8, of the By-Laws of the Companies is still in force.

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the ZURICH AMERICAN INSURANCE COMPANY at a meeting duly called and held on the 15th day of December 1998.

RESOLVED: "That the signature of the President or a Vice President and the attesting signature of a Secretary or an Assistant Secretary and the Seal of the Company may be affixed by facsimile on any Power of Attorney...Any such Power or any certificate thereof bearing such facsimile signature and seal shall be valid and binding on the Company."

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at a meeting duly called and held on the 5th day of May, 1994, and the following resolution of the Board of Directors of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at a meeting duly called and held on the 10th day of May, 1990.

RESOLVED: "That the facsimile or mechanically reproduced seal of the company and facsimile or mechanically reproduced signature of any Vice-President, Secretary, or Assistant Secretary of the Company, whether made heretofore or hereafter, wherever appearing upon a certified copy of any power of attorney issued by the Company, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seals of the said Companies, this 22nd day of October, 2024.

SEAL SEAL SEAL

MJ Pethick

By: Mary Jean Pethick
Vice President

TO REPORT A CLAIM WITH REGARD TO A SURETY BOND, PLEASE SUBMIT A COMPLETE DESCRIPTION OF THE CLAIM INCLUDING THE PRINCIPAL ON THE BOND, THE BOND NUMBER, AND YOUR CONTACT INFORMATION TO:

Zurich Surety Claims
1299 Zurich Way
Schaumburg, IL 60196-1056
reportsfclaims@zurichna.com
800-626-4577

Authenticity of this bond can be confirmed at bondvalidator.zurichna.com or 410-559-8790

THE FIDELITY AND DEPOSIT COMPANY

OF MARYLAND
1299 Zurich Way Schaumburg, IL 60196

Statement of Financial Condition
As Of December 31, 2023

ASSETS

Bonds		$ 185,599,944
Stocks		17,844,130
Cash and Short-Term Investments		16,050,471
Reinsurance Recoverable		77,886,252
Federal Income Tax Recoverable		0
Other Accounts Receivable		3,369,205
TOTAL ADMITTED ASSETS		$ 300,750,002

LIABILITIES, SURPLUS AND OTHER FUNDS

Reserve for Taxes and Expenses		$ 480,301
Ceded Reinsurance Premiums Payable		43,278,637
Remittances and Items Unallocated		868
Payable to parents, subs and affiliates		36,355,555
Securities Lending Collateral Liability		0
TOTAL LIABILITIES		$ 80,115,362
Capital Stock, Paid Up	$ 5,000,000	
Surplus	220,634,640	
Surplus as regards Policyholders		220,634,640
TOTAL		$ 300,750,002

Securities carried at $78,634,211 in the above statement are deposited with various states as required by law.

Securities carried on the basis prescribed by the National Association of Insurance Commissioners. On the basis of market quotations for all bonds and stocks owned, the Company's total admitted assets at December 31, 2023 would be $289,024,276 and surplus as regards policyholders $208,908,914.

I, LAURA J. LAZARCZYK, Corporate Secretary of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said Company on the 31st day of December, 2023.

Laura J. Lazarczyk

Corporate Secretary

State of Illinois
City of Schaumburg } SS:

Subscribed and sworn to, before me, a Notary Public of the State of Illinois, in the City of Schaumburg, this 15th day of March, 2024.

Notary Public

RYAN HORGAN
Official Seal
Notary Public - State of Illinois
My Commission Expires Dec 10, 2024

SEC Filing

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 000-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**13-3444607**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

777 Old Saw Mill River Road Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 847-7000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol*	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**REGN**	**NASDAQ Global Select Market**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant was $76.7 billion, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2023, the last trading day of the registrant's most recently completed second fiscal quarter. For purposes of this calculation only, the registrant has assumed that all of its directors and executive officers, and no other persons, are its affiliates. This determination of affiliate status is not necessarily a determination for other purposes.

The number of shares outstanding of each of the registrant's classes of common stock as of January 25, 2024:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,818,146
Common Stock, $.001 par value	107,943,750

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2024 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 92 to 96 of this filing.

REGENERON PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
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"Altibodies™," "ARCALYST®," "Evkeeza®," "EYLEA®," "EYLEA® HD," "Inmazeb®," "Libtayo®," "Praluent®" (in the United States), "REGEN-COV®," "Regeneron®," "Regeneron Genetics Center®," "RGC®," "*Veloci-Bi*®," "*VelociGene*®," "*VelociHum*®," "*VelociMab*®," "*VelocImmune*®," "*VelociMouse*®," "*VelociSuite*®," "*VelociT*®," "Veopoz™," and "ZALTRAP®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners. This report refers to products of Regeneron Pharmaceuticals, Inc., its collaborators, and other parties. Consult the product label in each territory for specific information about such products.

PART I

Item 1. Business

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (where applicable, together with its subsidiaries, "Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others:

- *the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation those discussed or referenced in this report, Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs;*
- *the likelihood and timing of achieving any of our anticipated development milestones referenced in this report;*
- *safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials;*
- *the likelihood, timing, and scope of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for Regeneron's Products, including without limitation those discussed or referenced in this report;*
- *the extent to which the results from the research and development programs conducted by us and/or our collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval;*
- *ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy;*
- *determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates;*
- *competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates;*
- *uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties on the commercial success of Regeneron's Products and Regeneron's Product Candidates;*
- *our ability to manufacture and manage supply chains for multiple products and product candidates;*
- *the ability of our collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates;*
- *the availability and extent of reimbursement of Regeneron's Products from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid;*
- *coverage and reimbursement determinations by such payors and new policies and procedures adopted by such payors;*
- *unanticipated expenses;*
- *the costs of developing, producing, and selling products; our ability to meet any of our financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance;*
- *the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated;*
- *the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on our business; and*
- *risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings described further in Note 16 to our Consolidated Financial Statements included in this report), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including without limitation those described in Note 16 to our Consolidated Financial Statements included in this report), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition.*

These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various

factors identified under Part I, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events, or otherwise.

General

Regeneron Pharmaceuticals, Inc. is a fully integrated biotechnology company that invents, develops, manufactures, and commercializes medicines for people with serious diseases. Our products and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, hematologic conditions, infectious diseases, and rare diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to build on that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to advance as an integrated, multi-product biotechnology company that provides patients and medical professionals with important medicines for preventing and treating human diseases.

Selected financial information is summarized as follows:

	Year Ended December 31,		
(In millions, except per share data)	**2023**	**2022**	**2021**
Revenues	$ 13,117.2	$ 12,172.9	$ 16,071.7
Net income	$ 3,953.6	$ 4,338.4	$ 8,075.3
Net income per share - diluted	$ 34.77	$ 38.22	$ 71.97

For purposes of this report, references to our products encompass products marketed or otherwise commercialized by us and/or our collaborators or licensees and references to our product candidates encompass product candidates in development by us and/or our collaborators or licensees (in the case of collaborated or licensed products or product candidates under the terms of the applicable collaboration or license agreements), unless otherwise stated or required by the context.

Products

Products that have received marketing approval are summarized in the table below. Certain products have also received marketing approval in countries outside the United States, European Union ("EU"), or Japan.

		Territory		
Product	**Disease**	**U.S.**	**EU**	**Japan**
EYLEA® HD (aflibercept) Injection 8 mg[a]	Wet age-related macular degeneration ("wAMD")	✔	✔	✔
	Diabetic macular edema ("DME")	✔	✔	✔
	Diabetic retinopathy ("DR")	✔		
EYLEA® (aflibercept) Injection[a]	wAMD	✔	✔	✔
	DME	✔	✔	✔
	DR	✔		
	Macular edema following retinal vein occlusion ("RVO"), which includes macular edema following central retinal vein occlusion ("CRVO") and macular edema following branch retinal vein occlusion ("BRVO")	✔	✔	✔
	Myopic choroidal neovascularization ("mCNV")		✔	✔
	Neovascular glaucoma ("NVG")			✔
	Retinopathy of prematurity ("ROP")	✔	✔	✔
Dupixent® (dupilumab) Injection[b]	Atopic dermatitis (in adults, adolescents, and pediatrics aged 6 months and older)	✔	✔	✔
	Asthma (in adults and adolescents)	✔	✔	✔

Product *(continued)*	Disease	Territory		
		U.S.	EU	Japan
Dupixent (dupilumab) Injection[b] *(continued)*	Asthma (in pediatrics 6–11 years of age)	✔	✔	
	Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	✔	✔	✔
	Eosinophilic esophagitis ("EoE") (in adults and adolescents)	✔	✔	
	EoE (in pediatrics 1–11 years of age)	✔		
	Prurigo nodularis	✔	✔	✔
Libtayo® (cemiplimab) Injection[c]	Metastatic or locally advanced first-line non-small cell lung cancer ("NSCLC")	✔	✔	
	Metastatic or locally advanced first-line NSCLC (in combination with chemotherapy)	✔	✔	
	Metastatic or locally advanced basal cell carcinoma ("BCC")	✔	✔	
	Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	✔	✔	
	Metastatic or recurrent second-line cervical cancer		✔	✔
Praluent® (alirocumab) Injection[d]	LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD")	✔	✔	
	HeFH in pediatrics and adolescents (8–17 years of age)		✔	
	Cardiovascular risk reduction in patients with established cardiovascular disease	✔	✔	
	Homozygous familial hypercholesterolemia ("HoFH")	✔		
REGEN-COV®[e]	COVID-19		✔	✔
Kevzara (sarilumab) Injection[b]	Rheumatoid arthritis ("RA")	✔	✔	✔
	Polymyalgia rheumatica ("PMR")	✔		
Evkeeza® (evinacumab) Injection[f]	HoFH (in adults, adolescents, and pediatrics aged 5 years and older)	✔	✔	✔
Inmazeb® (atoltivimab, maftivimab, and odesivimab) Injection	Infection caused by *Zaire ebolavirus*	✔		
Veopoz™ (pozelimab) Injection	CD55-deficient protein-losing enteropathy ("CHAPLE") (in adults, adolescents, and pediatrics aged 1 year and older)	✔		
ARCALYST® (rilonacept) Injection[g]	Cryopyrin-associated periodic syndromes ("CAPS"), including familial cold auto-inflammatory syndrome ("FCAS") and Muckle-Wells syndrome ("MWS") (in adults and adolescents)	✔		
	Deficiency of interleukin-1 receptor antagonist ("DIRA") (in adults, adolescents, and pediatrics)	✔		
	Recurrent pericarditis (in adults and adolescents)	✔		
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[h]	Metastatic colorectal cancer ("mCRC")	✔	✔	✔

Note: Refer to table below (net product sales of Regeneron-discovered products) for information regarding whether net product sales for a particular product are recorded by us or others. In addition, unless otherwise noted, products in the table above are generally approved for use in adults in the above-referenced diseases.

[a] In collaboration with Bayer outside the United States. Aflibercept 8 mg is known as EYLEA HD in the United States and EYLEA 8 mg in other countries.

[b] In collaboration with Sanofi

[c] In collaboration with Sanofi prior to July 2022. Effective July 2022, the Company is solely responsible for the development, commercialization, and manufacturing of Libtayo. Refer to "Collaboration, License, and Other Agreements" section below for further details.

[d] The Company is solely responsible for the development and commercialization of Praluent in the United States and Sanofi is responsible for the development and commercialization of Praluent outside the United States.

[e] In collaboration with Roche. Product is known as REGEN-COV in the United States and Ronapreve™ in other countries.

[f] The Company is solely responsible for the development and commercialization of Evkeeza in the United States and Ultragenyx is responsible for the development and commercialization of Evkeeza outside the United States.

[g] Kiniksa is solely responsible for the development and commercialization of ARCALYST.

[h] Sanofi is solely responsible for the development and commercialization of ZALTRAP.

Net product sales of Regeneron-discovered products consist of the following:

	Year Ended December 31,								
	2023			2022			2021		
(In millions)	U.S.	ROW[g]	Total	U.S.	ROW	Total	U.S.	ROW	Total
EYLEA HD[a]	$ 165.8	$ —	$ 165.8	$ —	$ —	$ —	$ —	$ —	$ —
EYLEA[a]	$ 5,719.6	$ 3,495.2	$ 9,214.8	$ 6,264.6	$ 3,382.8	$ 9,647.4	$ 5,792.3	$ 3,450.9	$ 9,243.2
Total EYLEA HD and EYLEA	$ 5,885.4	$ 3,495.2	$ 9,380.6	$ 6,264.6	$ 3,382.8	$ 9,647.4	$ 5,792.3	$ 3,450.9	$ 9,243.2
Dupixent[b]	$ 8,855.6	$ 2,732.5	$ 11,588.1	$ 6,668.0	$ 2,013.2	$ 8,681.2	$ 4,713.0	$ 1,485.3	$ 6,198.3
Libtayo[c]	$ 538.8	$ 330.0	$ 868.8	$ 374.5	$ 203.5	$ 578.0	$ 306.3	$ 151.9	$ 458.2
Praluent[d]	$ 182.4	$ 456.5	$ 638.9	$ 130.0	$ 337.4	$ 467.4	$ 170.0	$ 251.1	$ 421.1
REGEN-COV[e]	$ —	$ 618.8	$ 618.8	$ —	$ 1,769.6	$ 1,769.6	$ 5,828.0	$ 1,745.9	$ 7,573.9
Kevzara[b]	$ 214.7	$ 171.2	$ 385.9	$ 199.7	$ 158.3	$ 358.0	$ 161.9	$ 176.1	$ 338.0
Other products[f]	$ 150.5	$ 67.4	$ 217.9	$ 56.1	$ 69.1	$ 125.2	$ 25.9	$ 86.4	$ 112.3

[a] Regeneron records net product sales of EYLEA HD and EYLEA in the United States, and Bayer records net product sales outside the United States. The Company records its share of profits in connection with sales outside the United States.

[b] Sanofi records global net product sales of Dupixent and Kevzara. The Company records its share of profits in connection with global sales of Dupixent and Kevzara.

[c] Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. The parties equally shared profits/losses in connection with global sales of Libtayo. Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States and pays Sanofi a royalty on global sales. Refer to "Collaboration, License, and Other Agreements" section below for further details. Included in this line item for the years ended December 31, 2023 and 2022 is approximately $6 million and $34 million, respectively, of net product sales recorded by Sanofi in connection with sales in certain markets outside the United States (Sanofi recorded net product sales in such markets during a transition period until inventory on hand as of July 1, 2022 had been sold through to the end customers).

[d] Regeneron records net product sales of Praluent in the United States. Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales.

[e] Regeneron records net product sales of REGEN-COV in the United States and Roche records net product sales of Ronapreve outside the United States. The parties share gross profits from global sales of REGEN-COV and Ronapreve based on a pre-specified formula.

[f] Included in this line item are products which are sold by the Company and others. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Revenues" for a complete listing of net product sales recorded by the Company. Not included in this line item are net product sales of ARCALYST subsequent to the first quarter of 2021, which are recorded by Kiniksa.

[g] Rest of world ("ROW")

Programs in Clinical Development

Product candidates in clinical development, which are being developed by us and/or our collaborators, are summarized in the table below.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development (including any post-approval studies), uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes to drug pricing and reimbursement regulations and requirements, and changes in the competitive landscape affecting a product candidate. The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results.

Refer to Part I, Item 1A. "Risk Factors" for a description of risks and uncertainties that may affect our clinical programs. Any of such risks and uncertainties may, among other matters, negatively impact the development timelines set forth in the table below.

Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
			Ophthalmology			
EYLEA HD (aflibercept) 8 mg[a]			–RVO		–Approved by U.S. Food and Drug Administration ("FDA") for wAMD, DME, and DR –Approved by European Commission ("EC") and Japan's Ministry of Health, Labour and Welfare ("MHLW") for wAMD and DME –Reported positive two-year data from Phase 3 studies in wAMD and DME	–Initiate Phase 3 study in RVO (mid-2024) to enable FDA submission
EYLEA (aflibercept)[a]					–Approved by FDA for ROP	
Pozelimab[f] **(REGN3918)** *Antibody to C5*						–Initiate Phase 3 study in combination with cemdisiran in geographic atrophy (second half 2024)
			Immunology & Inflammation			
Dupixent (dupilumab)[b] *Antibody to IL-4R alpha subunit*		–Ulcerative colitis –Eosinophilic gastroenteritis (Phase 2/3)	–Chronic obstructive pulmonary disease ("COPD")[d] –Bullous pemphigoid[c] –Chronic spontaneous urticaria ("CSU") –Chronic pruritus of unknown origin	–EoE in pediatrics (1–11 years of age) (EU) –COPD with type 2 inflammatory phenotype (U.S. and EU) –CSU in adults and adolescents (Japan)	–Approved by EC for atopic dermatitis in pediatrics (6 months–5 years of age) –Approved by MHLW for atopic dermatitis in pediatrics and adolescents (6 months–14 years of age) –Approved by FDA for EoE in pediatrics (1–11 years of age) –Approved by EC for EoE in adults and adolescents –Approved by MHLW for prurigo nodularis	–EC decision on regulatory submission for EoE in pediatrics (second half 2024) –FDA decision on supplemental Biologics License Application ("sBLA") (mid/second half 2024) and EC decision on regulatory submission (second half 2024) for COPD with type 2 inflammatory phenotype

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
Dupixent (dupilumab)[b] *(continued)*					–Reported that Phase 3 BOREAS trial in COPD with evidence of type 2 inflammation met its primary and all key secondary endpoints; presented at 2023 American Thoracic Society International Conference and published in *New England Journal of Medicine* –Reported that results from interim analysis of replicate Phase 3 NOTUS trial in COPD with evidence of type 2 inflammation met its primary endpoint –FDA issued Complete Response Letter ("CRL") for sBLA for CSU due to requirement for additional efficacy data –Phase 3 trial in chronic cold induced urticaria did not meet its required efficacy endpoints –Discontinued further clinical development in allergic fungal rhinosinusitis and chronic rhinosinusitis without nasal polyposis	–MHLW decision on regulatory submission for CSU in adults and adolescents (first half 2024) –Report results from ongoing Phase 3 trial in CSU (in biologic-naïve patients) (fourth quarter 2024) –Report results from Phase 3 trial in bullous pemphigoid (second half 2024) –Initiate Phase 1 study in severe food allergy following transient linvoseltamab treatment (2024)
Kevzara (sarilumab)[b] *Antibody to IL-6R*		–Polyarticular-course juvenile idiopathic arthritis ("pcJIA") (pivotal study) –Systemic juvenile idiopathic arthritis ("sJIA") (pivotal study)		–PMR (EU) –pcJIA (U.S. and EU)	–Approved by FDA for PMR	–EC decision on regulatory submission for PMR (second half 2024) –FDA decision on sBLA (target action date of June 10, 2024) and EC decision (second half 2024) on regulatory submission for pcJIA

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
Itepekimab[b] (REGN3500) *Antibody to IL-33*			–COPD[e]		–Phase 3 COPD program passed interim futility analysis conducted by Independent Data Monitoring Committee ("IDMC")	–Report results from Phase 3 study in COPD (2025)
REGN5713-5714-5715 *Multi-antibody therapy to Bet v 1*			–Birch allergy			
			Solid Organ Oncology			
Libtayo (cemiplimab)[g] *Antibody to PD-1*		–Neoadjuvant CSCC –First-line NSCLC, BNT116[f] combination	–Adjuvant CSCC		–Approved by EC for first-line NSCLC, chemotherapy combination	–Conduct interim analysis from Phase 3 study in adjuvant CSCC (second half 2024)
Fianlimab[f] (REGN3767) *Antibody to LAG-3*	–Solid tumors and advanced hematologic malignancies	–First-line advanced NSCLC (Phase 2/3) (pivotal study)	–First-line metastatic melanoma[e] –First-line adjuvant melanoma		–Presented positive data from Phase 1 trial (in combination with Libtayo) in advanced melanoma at 2023 American Society of Clinical Oncology ("ASCO") Annual Meeting	–Initiate potentially pivotal Phase 2 study (in combination with Libtayo) in perioperative melanoma (first half 2024) –Initiate Phase 2 study (in combination with Libtayo) in perioperative NSCLC (first half 2024) –Initiate Phase 2 study (in combination with Libtayo) in perioperative head and neck squamous cell carcinoma (2024) –Report potentially pivotal initial results from Phase 2/3 study in first-line metastatic melanoma (second half 2024) –Report initial data from Phase 2/3 study in first-line advanced NSCLC (second half 2024)
Vidutolimod *Immune activator targeting TLR9*		–Solid tumors				

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
Ubamatamab[f] (REGN4018) *Bispecific antibody targeting MUC16 and CD3*		–Platinum-resistant ovarian cancer			–Presented results from Phase 1/2 study (in combination with Libtayo) in platinum-resistant ovarian cancer at European Society for Medical Oncology ("ESMO") Congress	
REGN5668[a] *Bispecific antibody targeting MUC16 and CD28*	–Platinum-resistant ovarian cancer					
REGN5678 *Bispecific antibody targeting PSMA and CD28*	–Prostate cancer				–Discontinued enrollment in cohorts in combination with full-dose Libtayo (cemiplimab) –Expanded enrollment in monotherapy cohort	–Initiate cohorts in combination with REGN4336 in metastatic castration-resistant prostate cancer (first half 2024)
REGN4336 *Bispecific antibody targeting PSMA and CD3*	–Prostate cancer					
Davutamig (REGN5093) *Bispecific antibody targeting two distinct MET epitopes*	–MET-altered advanced NSCLC					
REGN5093-M114 *Bispecific antibody-drug conjugate targeting two distinct MET epitopes*	–MET overexpressing advanced cancer					
REGN6569 *Antibody to GITR*	–Solid tumors					
REGN7075 *Bispecific antibody targeting EGFR and CD28*	–Solid tumors					–Initiate dose-expansion cohorts (in combination with Libtayo) in EGFR-high tumors (first half 2024)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
			Hematology			
Pozelimab[f] (REGN3918) *Antibody to C5*			–Myasthenia gravis, cemdisiran combination[c][k] –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination[c][k]		–Veopoz (pozelimab) approved by FDA for CHAPLE in adults and children aged 1 year and older, monotherapy	
Odronextamab[m] (REGN1979) *Bispecific antibody targeting CD20 and CD3*	–Certain B-cell malignancies[c]	–B-cell non-Hodgkin lymphoma ("B-NHL") (pivotal study)	–Follicular lymphoma ("FL") –Diffuse large B-cell lymphoma ("DLBCL")	– Relapsed/refractory FL and DLBCL (U.S. and EU)	–Presented updated data from trials in patients with relapsed/refractory FL and DLBCL at American Society of Hematology ("ASH") Annual Meeting	–FDA decision on BLA (target action date of March 31, 2024) and EC decision on regulatory submission (second half 2024) for relapsed/refractory FL and DLBCL
REGN5837[p] *Bispecific antibody targeting CD22 and CD28*	–B-NHL					
Linvoseltamab[f] (REGN5458) *Bispecific antibody targeting BCMA and CD3*	–Multiple myeloma[c][e]	–Multiple myeloma (pivotal study)[c][e] –Earlier (pre-malignant) multiple myeloma	–Multiple myeloma[c][e]	– Relapsed/refractory multiple myeloma (U.S. and EU)	–Presented updated positive data from pivotal trial in multiple myeloma at ASCO and ASH Annual Meetings	–FDA decision on BLA (second half 2024) and EC decision on regulatory submission (first half 2025) for relapsed/refractory multiple myeloma
REGN5459[f] *Bispecific antibody targeting BCMA and CD3*	–Transplant desensitization in patients with chronic kidney disease					
REGN7257 *Antibody to IL2Rg*	–Aplastic anemia					
NTLA-2001[j] *TTR gene knockout using CRISPR/Cas9*	–Transthyretin ("ATTR") amyloidosis[c]		–ATTR amyloidosis with cardiomyopathy ("ATTR-CM")			
REGN9933 *Antibody to Factor XI*		–Thrombosis				–Report results from Phase 2 study in thrombosis (second half 2024)
REGN7508 *Antibody to Factor XI*	–Thrombosis					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
REGN7999 *Antibody to TMPRSS6*	–Transfusion dependent iron overload					
			Internal Medicine/Genetic Medicines			
Praluent (alirocumab) *Antibody to PCSK9*			–HeFH in pediatrics and adolescents	–HeFH in pediatrics and adolescents (8–17 years of age) (U.S.)	–Approved by EC for HeFH in pediatrics and adolescents (8–17 years of age)	–FDA decision on sBLA for HeFH in pediatrics and adolescents (target action date of March 10, 2024)
Evkeeza[f][f] (evinacumab) *Antibody to ANGPTL3*					–Approved by FDA and EC for HoFH in pediatrics (5–11 years of age) and MHLW for HoFH in adults, adolescents, and pediatrics	
Garetosmab[f] (REGN2477) *Antibody to Activin A*			–Fibrodysplasia ossificans progressiva ("FOP")[c][d][e]			
Trevogrumab[f] (REGN1033) *Antibody to myostatin (GDF8)*						–Initiate Phase 2 study in combination with semaglutide with and without garetosmab (mid-2024)
Mibavademab[f] (REGN4461) *Agonist antibody to leptin receptor ("LEPR")*		–Generalized lipodystrophy[d][e]			–Presented results from Phase 2 study in generalized lipodystrophy at ENDO 2023	
REGN5381/REGN9035 *Agonist antibody to NPR1/reversal agent to REGN5381*	–Reversal agent in healthy volunteers	–Heart failure			–Resumed enrollment in previously paused Phase 1 and Phase 2 studies following protocol amendments –Reported positive initial data from Phase 1 trial in healthy volunteers	
REGN7544 *Antagonist antibody to NPR1*	–Healthy volunteers					
ALN-HSD[o] *RNAi therapeutic targeting HSD17B13*		–Nonalcoholic steatohepatitis ("NASH")				

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
ALN-PNP[k] *RNAi therapeutic targeting PNPLA3*	–NASH					
ALN-APP[k] *RNAi therapeutic targeting APP*	–Early-onset Alzheimer's disease[q]				–Reported positive interim data from single dose part of Phase 1 trial in early-onset Alzheimer's disease	
DB-OTO *AAV-based gene therapy*	–Hearing loss in pediatrics[c] (Phase 1/2)				–Reported preliminary, positive safety and efficacy results from first patient dosed in Phase 1/2 trial in pediatrics with hearing loss	
"Next Generation" Covid Antibody[l] *Antibody to SARS-CoV-2 variants*	–Healthy volunteers					
REGN13335 *Antagonist antibody to PDGF-B*	–Healthy volunteers					

Note: For purposes of the table above, a program is classified in Phase 1, 2, or 3 clinical development after recruitment for the corresponding study or studies has commenced.

[a] In collaboration with Bayer outside the United States

[b] In collaboration with Sanofi

[c] FDA granted orphan drug designation

[d] FDA granted Breakthrough Therapy designation

[e] FDA granted Fast Track designation

[f] Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on sales of the product, if any.

[g] Studied as monotherapy and in combination with other antibodies and treatments

[h] Information in this column relates to U.S., EU, and Japan regulatory submissions only

[i] We and the Biomedical Advanced Research and Development Authority ("BARDA") of the U.S. Department of Health and Human Services ("HHS") are parties to an agreement whereby HHS provides certain funding to support research and development activities.

[j] In collaboration with Intellia

[k] In collaboration with Alnylam

[l] In collaboration with Ultragenyx outside the United States

[m] FDA granted Fast Track designation for follicular lymphoma and diffuse large B-cell lymphoma

[n] Studied in combination with ubamatamab

[o] Alnylam elected to opt-out of the product candidate. Under the terms of our agreement, Alnylam is entitled to receive royalties on sales of the product, if any.

[p] Studied in combination with odronextamab

[q] Part B of the study (multi-dose regimen) placed on partial clinical hold in the U.S. by the FDA due to findings observed in prior non-clinical chronic toxicology studies

[r] BioNTech's BNT116 is an mRNA cancer vaccine.

[s] Under the terms of our license agreement for the combination consisting of cemdisiran and pozelimab, Alnylam is entitled to receive royalties on sales of the combination (if any), as well as sales milestones.

Additional Information - Clinical Development Programs

EYLEA HD (aflibercept) 8 mg

In August 2023, the FDA approved the BLA for EYLEA HD for the treatment of patients with wAMD, DME, and DR.

Previously, in June 2023, the FDA issued a CRL for the EYLEA HD BLA. The CRL was issued solely due to unresolved observations resulting from a May 2023 FDA inspection at a third-party contract manufacturing organization, Catalent, that the Company engaged to complete vial-filling for EYLEA HD. With the approval of EYLEA HD, the pre-approval inspection issues related to the BLA had been addressed.

In June 2023 and August 2023, the Company announced top-line, two-year (96 weeks) data for EYLEA HD from the pivotal PHOTON trial in patients with DME and the pivotal PULSAR trial in patients with wAMD, respectively. In addition, in July 2023, the results from the PHOTON trial were presented at the American Society of Retina Specialists annual meeting. During both trials, EYLEA HD patients were initially randomized to either 12- or 16-week dosing intervals (after three initial monthly doses) and were able to shorten or extend dosing intervals if pre-specified criteria were met. The longer-term data among EYLEA HD patients who completed the trials demonstrated that the vast majority of patients were able to maintain or further extend these dosing intervals through two years with:

PHOTON:

- 89% maintaining ≥12-week dosing intervals through two years, compared to 93% through one year (48 weeks)
- 84% maintaining ≥16-week dosing intervals through two years, compared to 89% maintaining a 16-week dosing interval through one year
- 44% meeting the criteria for ≥20-week dosing intervals by week 96, including 17% and 27% who were eligible for 20- and 24-week dosing intervals, respectively

PULSAR:

- 88% on a ≥12-week dosing interval at the end of two years
- 78% maintaining ≥12-week dosing intervals through two years, compared to 83% throughout the first year of study (48 weeks)
- 71% meeting the extension criteria for even longer dosing intervals, including 47% for ≥20-week intervals and 28% for 24-week intervals
- those assigned to ≥16-week dosing regimen at baseline, 70% maintaining ≥16-week dosing intervals throughout the two-year study period; at the end of two years, 78% were eligible for ≥16-week dosing, with 53% eligible for ≥20-dosing week intervals.

The visual gains for EYLEA HD remained consistent with the first year of the trials. In both PHOTON and PULSAR, the safety of EYLEA HD also continued to be similar to EYLEA through two years and remained consistent with the known safety profile of EYLEA from previous clinical trials for DME and wAMD.

In May 2023, Bayer announced that it initiated a Phase 3 study to evaluate the efficacy and safety of EYLEA HD at extended dosing intervals compared to the standard of care, EYLEA, in RVO to support potential future regulatory submissions outside the United States.

Dupixent

COPD

In March 2023, the Company and Sanofi announced that the primary and all key secondary endpoints were met in the BOREAS trial (the first of two Phase 3 trials) in adults currently on maximal standard-of-care inhaled therapy (triple therapy) with uncontrolled COPD and evidence of type 2 inflammation. In this trial, patients receiving Dupixent experienced a 30% reduction in moderate or severe acute COPD exacerbations (rapid and acute worsening of respiratory symptoms) compared to placebo over 52 weeks, while also demonstrating significant improvements in lung function, quality of life, and COPD respiratory symptoms.

In November 2023, the Company and Sanofi announced that the replicate Phase 3 NOTUS trial met its primary endpoint, showing Dupixent significantly reduced exacerbations by 34% compared to placebo over 52 weeks in patients with moderate-to-severe COPD with evidence of type 2 inflammation, confirming results from the BOREAS pivotal trial. Given the overwhelming positive efficacy of the primary endpoint in the interim analysis from the NOTUS trial, the results will be considered the primary analysis of the trial. In December 2023, the Company and Sanofi submitted the data from this interim analysis of the NOTUS trial, along with the results from the Phase 3 BOREAS trial, to the FDA.

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NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Regeneron Pharmaceuticals, Inc.

Physical Address: 81 Columbia Turnpike

City: Rensselaer State: NY Zip: 12144

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.regeneron.com

Name of Designated Representative (DR): Benjamin T Yocum

Licensing Company Email: RGP@slsny.com DR Email: benjamin.yocum@regeneron.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Drugs (Biologics)	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Manufacturers		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: NY

Parent Company (if any): Publicly Traded: REGN

Corporation Name: Regeneron Pharmaceuticals, Inc.

Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Email: RGP@slsny.com

Contact Person Name: Christine Cannon

Date of SEC Registration: 04/02/1991 | SEC Registration Number: 0000872589 | Stock Exchange Symbol: REGN

N/A **Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A **Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A **Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Appendix A

Catalent in Bloomington - 1300 South Patterson Drive, Bloomington, IN 47403

Sanofi Le Trait in France -Sanofi-Winthrop LeTrait Magasin Reception D21 Boulevard Industriel Le Trait 76580 France

Baxter in Germany -Kanstrasse 2, 33790 Halle/Westfalen, Germany

Bayer DE in Germany - Bayer Consumer Care AG DSV Air & Sea GmbH AM Sudpark 10 Kelsterbach 65451 Germany

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA #: 1000514603	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** See Company Particulars	✓			
• **List of all corporation shareholders and their percent ownership.**	N/A	✓		
• **List of all partners and their percent ownership.**	N/A		✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/	N/A	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/	N/A	✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A - No CS	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A - No MDEG	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A - No MDEG	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.	N/A	✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.	N/A	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Regeneron Pharmaceuticals, Inc.

Facility Name

Rajesh Girdhari Ahuja

Print Name of Authorized Person Submitting Application

Rajesh G. Ahuja

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

28 JAN 2025

Date

Board Use Only	Date Received: 5/28/25	Amount: $1000-CK 11691

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New Search

Search Results for *Regeneron Pharmaceuticals, Inc.*

Showing 1 to 2 of 2 entries

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Regeneron Pharmaceuticals, Inc.	1000514603	945589711	ANALYSIS; API MANUFACTURE; LABEL; MANUFACTURE	81 Columbia Turnpike, Rensselaer, New York (NY) 12144, United States (USA)	12/31/2024
Regeneron Pharmaceuticals, Inc.	3015581066	118205659	ANALYSIS; LABEL; MANUFACTURE; PACK; RELABEL; REPACK; STERILIZE	350 Tempel Ln, East Greenbush, New York (NY) 12061, United States (USA)	12/31/2024

Previous 1 Next

Data Current Through: Monday, Sep 30, 2024

New Search

Regeneron Pharmaceuticals, Inc.

Corporate Address: 777 Old Saw Mill River Road, Tarrytown, NY 10591 USA
FEIN: 13-3444607
www.regeneron.com

Drug Labeler Code: 61755
Incorporation State: NY
Incorporation Date: 1/11/1988

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
CLB	81 Columbia Turnpike Rensselaer, NY 12144 County: Rensselaer	1000514603	N/A - No CS	945589711	No	(518) 488-6000	

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Benjamin T Yocum	[redacted]	SVP Manufacturing Operations		[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Publicly Traded: REGN							

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Benjamin T Yocum	[redacted]	SVP Manufacturing Operations		[redacted]		
Mark A Volpe		Senior Vice President, Tax				
Rajesh Girdhari Ahuja		Senior Vice President Fill/Finish & External Manufacturing				
Richard Gluckselig		VP, Associate General Counsel & Assistant Secretary				
Leonard N Brooks		Senior Vice President, Treasurer				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
CT Corporation			

3PLS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Integrated Commercialization Solutions (ICS)	420 International Blvd Suite 500 Brooks, KY 40109					

Company Particulars

Good Standing

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

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

Entity Name:	REGENERON PHARMACEUTICALS, INC.
DOS ID Number:	1226128
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	01/11/1988
Statement Status:	CURRENT
Statement Due Date:	01/31/2026

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

WITNESS my hand and official seal of the Department of State, at the City of Albany, on May 22, 2025 at 03:25 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100008078949 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2024-27

NAME OF SUPERVISOR
BENJAMIN T. YOCUM

THIS IS TO CERTIFY

REGENERON PHARMACEUTICALS, INC.
81 COLUMBIA TPKE.
RENSSELAER, NY 12144

is duly recorded as a

REGISTERED MANUFACTURER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF SEPTEMBER, 2024.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF AUGUST, 2027.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
022168

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

HS License

New York State
EDUCATION DEPARTMENT
Office of the Professions

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No Official Val

REGENERON PHARMACEUTICALS, INC.

[redacted] ENFORCEMENT ACTIONS

Type	Manufacturer
Legal Name	REGENERON PHARMACEUTICALS, INC.
Trade Name	---
Street Address	81 COLUMBIA TPKE. RENSSELAER NY 12144
Registration No	022168
Date First Registered	September 06, 1995
Registration Begins	September 01, 2024
Registered Through	August 31, 2027
Supervisor	YOCUM BENJAMIN
Establishment Status	Active
Successor	NONE

September 30, 2024 02:19 PM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=022168&professionCode=020

Employee List

REGENERON
SCIENCE TO MEDICINE®

81 Columbia Turnpike
Rensselaer, NY 12144
518.488.6000

The Regeneron Pharmaceuticals, Inc. facility located at 81 Columbia Turnpike Rensselaer, NY 12144 has approximately 2,000 people onsite.

List of Regeneron Pharmaceuticals, Inc. employees located at 81 Columbia Turnpike, Rensselaer, NY 12144 as of 16th of July 2025.

Cory Budesheim	Daniel Janos	Shawn Redden	Blake Trzesiara	Robert Hansen	Isaac Arginteanu	Jon Stephan
Andrew Edmans	Zeyad Yaghi	Ray Rossetti	Brandon Cook	Justin Bellaire	Josh Lassiter	Meeghan Arno
Benjamin Smith	David Karbassi	Nicholas D'Orazio	Joseph Parente	John Bellerose	Bridget Saunders	Melissa Chin
Christopher Spinelli	Kurt Conety	Grady Picinich	Steven Thomas	James Deyling	Samuel Guagliardo	Benjamin Coyle
Kyleigh Maguire	Sean Droogan	Sean Conway	Brian Root	Patrick Harrison	Brittany Lundy	Robert Lemieux
Michael Epstein	Alissa Reyes	Taylor Wright	Michael Algozzine	Wade Rathbun	Ryan Uttendorfer	Kirk Manke
Bryan Seebald	Amanda Rimsa	Lan Cantrell	Brendan Service	Garold Rabinovich	Henry Kwarteng	Ken Zyryi
Lauren Shepard	Jason Coty	Lindsay Fitzpatrick	Kimberley McGarrity	Bryan Louie	Patrick Murray	Sian Sealy
Bruce Carmany	Matthew Dudick	William Grimaldi	David Paul	Drew Burns	Natalie Rodriguez	Ethan Dobson
John Adams	Levi Jennes	Greg Johnson	Jeffrey Slaven	Shayne Mowery	Erin Moss	Jonathan George
Ryan Loggins	Byron Meadows	Jason Biasini	Kyle Jones	Erin Boyle	Henry Fisher	Spencer Junco
Daniel Donatelli	Augustus Thorkildsen	Keith Martin	Wesley Thompson	Stacey Widera	Cassandra Calderon	Ken Wait
Michael Fortuna	Kaitlyn McMullen	Kayla Donatelli	Omar Mir	Melissa Rourke	Damon Cole	Christopher Pacelli
Cody Clifford	Michael Simons	Victoria Villeneuve	Kody Kowalowski	Jeffrey Sitarski	Bria Dawson	Rachel Redman
Danielle Thorp	Joseph Paternoster	Paul Gavett	James Cross	John Nicolella	Gerald Clifton	Alexis Ponte
Rebekah Kennedy	Kimberly Doherty	Lindsay Algozzine	Dominic DeMaria	Philip Mucci	Shiava Morris	Saeyd Qasem
Mercy Alila-Dorbor	Christopher Burns	William Chin	James Redden	Shawn Lemerise	Ferdinand Rillo	Joseph Caldara
Trevor Morris	Maureen Hughes	Caitlin Diffley	Lanilei Doctora	William Wilsey	Justin Arsenault	Lauren Raymond
Dennis Brown	Angelo Marino	Samuel Mackerer	Nicholas Racicot	Ashley Lebby	Shannon Rafferty	Victoria Davis
Christopher Sawyer	Matthew Crescimanno	Devon McMahon	Lexi Cerone	Michael Lilly	Daniel Cancro	Joshua Gordon
Jessica Vaughn	Tristan Spaulding	Alyssa Tozzi	William Anderson	Alex Lewis	Peter Flannery	Aaron Delurey
Daniel Danckwerth	Jermaine Riggsbee	Corey Shaw	Matthew McClenahan	Luke Benzing	Michaela Torres	Alex Gilgore
Jacob Thorp	Michael Matteo	Laura Valentin	Hannah Kutil	Dylan Hover	Chatham Borsh	Jesse Njifua Forchap
Chelsea Anderson	Matthew McDonough	Victoria Richards	Evan Sakowski	Hailey Nelson	Robert Norton	David Abplanalp
Adam Rimawi	Kerri Honan	Peter Betrus	Breanna Bernardi	Paige Jones	ToniAnn Posillico	Olena DeCoste
Joshua Forand	Alexandria Konkol-Choi	Zachary Miller	Zoe DuBois	Eric Linkowski	Chu Chen	Alexander Bantis
Kelsey Ferris	Stephanie Sawicz	Juliano Caprara	Paul Schultz	Samuel Perry	Francesca Randazzo-Anderson	Kathy Despart
Zachary Smith	Jessica Danison	Nicholas Cocilova	Glenville Caines	Matthew Glackin	Jacqui Sofia	Stephanie Crane
Zachary Hurley	Kevin Dickinson	Anthony Gatta	Jonathan Shannon	Daniel Marino	Christina Alix	Noah Johnston
Shane Scoons	Kayla Springli	Breon Burgos	Brendan Morgan	Dylan Latham	Philip Rice	Jesse Martino
Mike Kaloustian	Dana Castillo	Jim Bernstein	Benjamin Callahan	Kristin McDougle	Jeevan Narendran	Andrew Villanueva

REGENERON CONFIDENTIAL

Cameron Wariner	Sarah McGrath	Jeffrey Blay	Hydee Yonkers	Joshua Smith	Trevor Typhair	Hannah Laffend
Emily Kunzmann	Patrick Rolseth	Thomas Arroyo	Joseph Klem	Billie Hens	Allison Tarantino	Alfred Yeung
Blake Burger	Lucas Puertas	Sterlene Negron-Walton	Elias Hayati	Liam Swiatek	Liam Mallon	Kevin Curtin
David Tannenbaum	Christina Zenteno	Warren Chaney	Dylan Yeomans	Nguyen Huynh	Steven Vautrin	Fawzee Animashaun
Sherin Vaidian	Lauren Latham	Michael Bicknell	Benjamin Moolick	Marcus Romano	Travis Mannix	Kem Mattocks-King
Bayo Akinola	Jillian Gavin	Christopher Bowdish	Kevin Cunningham	Luke Rasmussen	Scott Aubin	Madison DeRidder
Anthony D'Orazio	Sammy Pappas	Evan Diamond	Katarzyna Matacchiero	Nicholas Parenteau	Joseph Santagato	Brian Mullin
Sydney Carrow	Amanda Darmohraj	Robert Hendricks	Victoria Lynn Stalker	Erik Fast	Wilson Cortes	Erin Conner
Derek LaBaff	Jordan Ganance	Christina Marra	Cameron Curtiss	Noah Clifton	Ann Marie Rickson	Stephen Sgambati
Luke Perez	Daniel Sacchetti	Hunter Berrus	Remy Strang	Julia Caparaz	Casie Henderson	Justine Buchanan
Stephanie Lall	Alec Cohen	Vanessa Ho	Luke O'Brien	Barbara Hill	Leah Noldy	Mohammed Rony
Brian Davis	Daniel Tedesco	Lorena McCabe	Enrico Battibulli	Allane Roc	Carolanne Switzer	Ian Park
Nicholas Corbett	Richard Grable	Kevin Sayers	Austin Moehringer	Nicholas Snyder	Toby Cooper	Georgette Gordon
Justin Rajkowski	Michael Commisso	Patrick LaComb	Samantha Ahearn	Mary Hupe	Amanda Pasquini	Jennifer Rem
Andrew Boughton	Courtney Dorsey	Greg McMullin	Carson Dunbar	Patrice Rogers	Faith Gilbert	Mary deVries
Isabel Beaver	Justin Crump-King	Ronell Kirven	Matthew Liquori	Anthony Savoia	Seamus Wolfe	Kaicey Sardina
Caroline DiBacco	Colin Aldrich	Zackary La Porta	Taylor Thompson	Grant Anicete	James Pasquino	Cody Egelston
Madden Rowlee Belote	Michael Mohney	Chase Cortez	Emily Stewart	Patrick Van Epps	Bailey Benson	Edmund Rozell
Connor Rivage	Matthias Gaige	Johanna Buitrago	Sarah Thomann	Mehgan McMullen	Albert Malorku	Joseph Gallea
Lindsey Hodges	Paige Byrne	Ray Anthony Harris	John Morales	Gregory Zotta	Michael Casey	Kennedy Walsh
Gabrielle Dordoni	Frank Mosher	Laci Cahill	JR Barkamian	Matthew Lotano	Abigail Kopp	Nicholas Ferrara
Gregory Hennings	Kimberly Meagher	JiaPing Weng	Graham Wright	Kasandra Horesky	Alyssa Shaw	Sophia Raymond
Fabio Carvalho	Jeremy Dagner	Megan Haskin	Mitchell McDonald	Connor Salisbury	Andrew Morgan	Susannah Dickson
Jeffrey Salada	Victor Rodriguez	Yella Drummer	Dhruv Patel	Randi Broadwell	Ce'Nedra Morales	Christopher Dorgan
Gabriel Zenteno	Jeffrey Winklarek	JoVaughna Honeyghan	Maria Zara	Assunta Vona	Henry Hance	Michael Kowlessar
Leith MacDonald	Alexandra Betrus	Cody Cooper	Marisa Piezzo	Brittni Sardina	Katie Cherry	Marissa Cimmino
Joshua Blancovich	Scott Reilly	Alexandra DiLillo	Emily Bond	Sandra Marsh	Justin Holmberg	Marina Angelini
Elizabeth Alderman	Logan Landrum	Madison Sames	Stephan Geneus	Margaret Hodson	Tara Westfall-Conheady	Taylor Chappel
Nicolas Gural	Kendall Gardner	Kyle LaMora	Rayane Djedid	Tucker Olsen	Christina Billa	Claire Morrow
Andrew Lutjen	Jeff Slingerland	Lynn Manning	Jeron Zieger	Kyle Lawyer	Juliet Bashford	Timothy Renteria
Katelyn McGee	Deepika Karbassi	Gavin Kelley	Alicia Schmaler	James Horsley	Dan Gegenheimer	Amburlin Wilhoite

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Joshua Myers	Jule Gapp	Kelly Hunter	Brianna Swanson	Gabriela Sigda	Ryan Couchman	Shweta Mane
James Devine	Rob Zajesky	Ethan Ballard	Chas Premo	Allison Santora	Jacob Sieg	Kevin Kent
Steve Rumfelt	Thomas Drucker	Sarah Poetzsch	Elkana Diaz	Carlo Lim	Delia Ofori	Alexander Spensieri
Gary Roback	Sarah Zonca	Cory Schneider	Frank Calacone	Brandon Ross	Kyle Lentz	Adriana Meléndez
Laura Montesano	Jennifer Schneider	Alexus Smith	Jihad Eisa	Karys Gutierrez	Frederic Nentwick	Deanna D'Innocenzo
Elena Khorolskaya	Jonah Fulger	Katherine Reimers	Demi Trinci	Aidan Quigley	Francisco Caamano	Katherine Villamil
Leon Ho	Ryan Hathaway	Kyle Schongar	Johnny Hoang	Anne Sabatino	Amber Scarabaggio	Kate-lyn Krajci
Ghani Aslam	Haley Strizzi	Carolyn Crowley	Sam Robinson	Jennie Bergin	Joshua White	Michael Rotondo
Melissa Dietzel	Derek Nilsen	Sean Strizzi	Makenzie Hynes	Michael Crodelle	Winnieva Deronceray	Sabina Khan
Joseph Titman	Allison Pereira	John Keneston	Julia Wilson	Nicholas Loukides	Joseph Sweeney	Carlos Rojas
Maria Rasoully	Christopher Titman	Henry Heroux	Conor O'Toole	Daniella Duglin	Paul Johnson	Nicholas Brownell
Austin Van Vorst	Matthew Ragosta	Wyatt Wells	Alex Kucinski	Danielle Berkowitz	Zoila Urena	Sam Sears
Tori Kehl	Conway Vumbaco	Nicholas Wildman	Benjamin Burke	Peter Russell	Samantha Erb	Tatyana Bazile
Timothy Peck	Max Abbott	Mark Nowey	William Ross	Arthur Worrad	Emmett Hayes	Alyssa Ross
Paul Lineback	Jakub Mierzwa	Patricia Doney	Trevor de las Alas	Malachi Decker	Ykim Anderson	Dani Isma
Justin Reetz	Alexandra Robeson	Amanda Stewart	Joshua Greenwood	Sarah Wescott	Steve Orenstein	Jenna Mulvaney
Taylor Nichols	Kelsie Hawkins	Cindy VanVranken	Sara Boehm	Max Root	Akshay Thakur	Nicholas Stokes
Mathew Miele	Matthew McHugh	Renee Trotta	Rachel Williams	Justin Markley	Amanda Levey	Nicholas Yang
Taras Korostil	Rachel Dykstra	Kevin McClements	Peter Yaple	John Pologa	Jennifer Shorkey	Alba Rodriguez
Nathalie Millien	Jennifer Stone	Lynn Thomas	Tyler Sitterly	Alexsis Melendez	Abigail Bandl	Lizzy Burridge
Claude Mercier	Bill Heacox	Cheyenne Lifite	Ryan Wood	John Harrison	Jasper Wright	Katelyn Chang
Ashley Albright	Kristina Mills	Nicholas Harding	Roberto Recchia	Tottiyona Mentor	Rachel Mannino	Madalyn Hammes
Kai Jones	Clare Lawson	Basil Mundackal	Mitch Sayer	David Carroll	Eddie Zhu	Austin Langenbach
Joanna Wong	Ashley Tahal	Rachel Cecco	Robert Staton	Matthew Barmore	Nicholas Couse	Jake McDermott
Alexander Simmons	Michael Walsh	CAILEY DEDELL	Nicholas Chiorgno	Chelsey Eighmey	Charisse Martin	James Sommer
Kyle Wood	Jake Phillips	Leighann Kemp	Genesis Alvarado	Michael Haight	Mickey Koone	John Yonkers
Ian Cepiel	Andrew Eget	Mohammed Alwuhaili	Felicity Orgill	Christa Harder	Dejaun Harris	Katie Weisheit
Kevin Shaw	Laurena Olsson	Julia Dickson	Giovanni D'Ambro	Sarah Carlo	Debra Sheppard	Mark Whittaker
Aimee Cole	Rea Forseti	James Doran	Vince Tillack	Peter Mitchell	Kelly Correa	Megan Schubmehl
Jenny Tu	Daniel Caridi	Hope Woodruff	Eileen Collado Soler	Emily Biernacki	Kevin Klusewitz	Michael Szumowski
Shannon Wilkinson	Nicholo Cianfarani	Gaganjot Sekhon	Drew Cassidy	Tristin Houck	Jeffrey Hartle	Richard Wood

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Samantha Paduani	Gretchen Wetzel	Nicholas Dixon	Aanyah Jhonson-Whyte	James Flacke	Ava Dallas	Michelle Costanzo
Aaron Cotsonas	Tyler Mead	Allison Loiselle	Caitlin Shepherd	Kaeleigh Benson	Emma Bourgeois	Tahya Hurn
Alexandra Montero	Sarah Flynn	Megan Wortman	William Dell'Anno	Cameron Bilyeu	Justin Van Dyk	Korbin Bowker-Kuhnen
William Szeliga	Quinn Cavanaugh	David Elze	Esko Mason	Edward Short	Alyssa Schoonmaker	Chris DaCosta
Jolie Ngo	David Rabe	Joseph Rizzo	Mustafa Shehadeh	Miranda Porter	Flow Cincoo	Pierre Bellevue
Franklin Rings	Laniris Pena	Rachel Saulsbery	Stephen Ferraro	Jhos Duff	Destanie Ortega	Samantha Mendoza
Isaiah Moore	Reginald Bernard	Joshua Izzo	Christopher Karwan	Christopher Bergamini	Tiffany Dwyer	Angelique Hirsch
Kara LaBarge	Dezerae Hoang	Alyssa Johnson	Jonathan Mcelroy	Sohan Rambharose	Lenore Martin	Christian Toma
Natalie Kiernan	Jenna Retell	Olivia Powhida	Stefan Buechele	Alec Walter	Zachary Barr	Michael Battisti
Rachel Kearns	Max Surprenant	Jacob Koneeny	Layne Kostrubanic	Paige Howard	Kelly Flatebo	Rebecca Gressler
James Burnell	Jahmelli Rodriguez	Brianna Bootier	Elizabeth Lambert	Bohdan El-Fawal	Marco DeAngelis	Maya McDonald
Katherine Drogo	Therese Howell	David Thomas	Tim Sullivan	Yanni Correa	Michaela Lynch	Sierra Young
Leeana Karria	Thomas Flannery	Manny Ramos De Alba	Kaitlyn Pike	Isaiah Rodriguez	Salim Magane	Dylan Cheung
Matthew VanWormer	Rebecca Bennett	Kaylee Croshier	Kyle Loux	Cailee Navarro	Sofia Migalko	Daniel Reedy
Michael Sotile	Emil Giordano	Isabella Rusiecki	Joshua Manchester	Christian Natal	Jamie Benton	Alice Knott
Carlo Ferrandino	Zahrea Hill	Matthew Timoney	Joe Gelina	Ben Todt	Jose Perez-Calderin	Kyle Perdew
Daniel Aleman	Aliza Ramdass	Marissa Walerstein	Rachel Micallef	Taimur Syed	Christopher Armand	Rikki-Lynn Trinci
Aaliyah Ali	Shane Walsh	Miguel Beckford	Morgan Razzano	Yeji Cho	Dustin LaBar	Esmeralda Merino Lopez
Brett Ingersoll	Colin Bertomeu	Alexandria Tipple	Samuel Garrison	Kabeer Amin	Grace Seager	Samantha Schnell
Frank Stieler	Shannon Meier	Eric Colvin	Evan Protsman	Corey Eyler	Daniel Prentice	Andrew Washburn
Nicole White	Madison Bidwell	Ryan Assini	Paul Fernandez	Brianna Roopnarain	Gabrielle Watson	Arianna Papas
Alex Birchmore	Nick Hansen	Devin Gaige	Eduardo Melendez	Briland Nkamany	Matishka Cole	Kathryn Suter
Brynn Walsh	Desmond Williams	Sarah Robbins	Domingo Garcia	Luke Mattice	Ahmed Elhag	Lucia D'Acchille
Brock Layden	Matthew Stuts	Arber Cuko	Kyle Kassmann	Daniel Purtell	Burnell Pokhai	Katherine Jones
Jacob Schwartz	Alex Oliver	Alex Warn	Kyle Billings	Joe Richards	Ruthann Flick	Joseph Hoskins
Kyle DiCaprio	Omer Omer	Mikayla Wason	Natalie Tidings	Dajuan Hudson	Bridget Shanahan	John Mickel
Sakil Islam	Eric Fillingham	Lesley Bradshaw	Mercy Adu	Stephanie Hightower	Abigail Ernestine	Jeremy Costa
Sydney Russ	Cameron Gallo	Selena Sweet	Andrew Cooper	David Nicolella	Meara McManus	Illandria Graham
Arline Camilo Hernandez	Christopher Caiazza	Sahera Ahmad	Chris Manzino	Altaff Najib	Eddie Daub	Richel Boroh
Matthew Rogers	Dylan Caprara	Brendan Kelly	Liam Jordan	Linnea D'Acchille	Carter Bach	Christopher Gould
Leah Gagliardi	Blake Battistoni	Raymond McCarthy	Keith Gresens	Ethan Knapp	Patrick Grant	Samuel Guano

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Danny Townsend	Roger Becker	Sabrina Alam	Earl Turner	Peter Rankin	Fares Saed	Davis Ramkissoon	Ismail Sufi
Simon Masih	Leighton Mayers	Ben Criscione	Alexandra Ryan	Ahsraful Shamrat	Tibi Munyam	Andres Lin Huang	Ajit Saran
Bridget Aduasare	Isaac Torres	Haden Florn	Victoria Apodaca	Emily Rzonca	Emma Voska	Veronica Turek	Janusz Wojcik
Jessica Neiles	Tamia Wellington	Nicole Miklinski	Christopher Carr	Tyler Biernacki	Ethan Selly Yamie	Braiton Barber	Nate Wellington
Patrick Hopsicker	Nick Cotter	Shruti Kamat	Julianne Fogg	Nicole Villinski	Taylor Ralston	Ryan O'Connor	Alyssa Lindheimer
Diya Vimal	Fabiola Gomez	Jennifer Chukwu	Randal Bemis	James Ramsey	Erin Wildman	Alexander Krause	Matthew D'Orlando
Meaghan Brennan	Joseph Wozlonis	Erika Yates	Noah Chojnacki	Emma Soltis	Ahmed Hassan	Bubacar Ndoye	Kelly Cross
Sara Zafian	Travis Bradley	Kossiwa Amevor	Jaime Davis	Srishti Pal	Prince Asante	Makenna Fahsel	Rachel Kim
Alejandro Lopez	Deja Perkins	Shamieka Avent	Kaitlyn Nichols	Meghana Chirra	Sarmi Paul	Abbey Wood	Cassidy Dennis
Chris Buregeya	Cassiel Achan	Alexis Alexander	Shelly Berry	Luke Kovalcin	Elisabeth Luttman	Jack North	Derek Dieterle
Mark Sabatino	August Moore	Thomas Barbee	Kristie Morton	Jonathan Dieterich	Nathan Bobal	Grace Matthews	Mike Adetunji
Chancey Troyer	Wyatt Mosher	Winie Chery	Ty Mclean	Berfu Cicek	Rachel Brous	Joshua Mann	David Berglund
Thomas Allen	Shania Reid	Sarah Rivet	Charles Castelli	Lee MacCrea	Christopher Schule	Jordan Poon	Peter Rasmussen
Ornella Hare	Madelyn Graham	Jack Farrell	Tighe Hartloff	Matthew Walls	Kem Onyinanya	Brandon Poli	Alisya Reza
Derek Ogi	Chris Donohue	Clyde Senat	Jim Russell	Matthew Talbot	Ann MacIntosh	Will McCulley	Daniel Rohrbach
Dhamar Blanco	Hannah Stovall	Mae Goh	Hayley Swint	Samantha Biaesch	Alexandra Cymbal	Amanda Krueger	Kelsey Granger
Rebekah Yoo	Celines Santiago	Matthew Blizinski	Jonathan Rothbaum	Mark Ouzi	Diya Krishnan	Evan Werner	Darien Smith
Hope Hiscock	Andrew Reilly	Matthew Connolly	Jude Odoi	Marta Jewett	Ana Gama	Simran Kumar	Sophia Rzonca
Samin Islam	Katie Slaver	Sukhpal Kingra	Jaycee Wojcik	Andy Zhang	Ellie Bae	Maria Favella	Grace Killian
Karly Hastings	Jeremiah Kneeland	Faith Jano	Logan Jeffers	Brianna Moser	Sarah Smolinski	Sungmin Hwang	Sofia Mullin
Hillary Bennett	Tyler Gantz	Sam Kubow	Bharity Premnauth	Brian Flynn	Daniel Jerez	Emely Pena	Kimberly Sundy
Grace Zuchowski	Lukas Sodergren	Alexa Quispe Choquehuanca	Rawan Moussa	Tommy Anderson	Patrick Marsch	Aery Wynne	David Lugo
Farishta Hamdard	Megan Fitzpatrick	Vanessa Serna Villa	Gabriella Maslar	Alexander Evans	Adelle Hamilton	Kaley Roberts	Kia Haering
Cameron Becerril	Cassandra Davis	Bri-Anna Burke	Megan LaBaff	Charli Goverski	Zoë Henzel	Sarab Ali	Anastasia Klingel
Keira Cohen	Christopher Lamirande	Aira Ysadelle Abiera	Antonios Patetsos	Mack Roarke	Olivia Howard	Konnor Fink	Melvin Rodriguez
Emma Tambacas	Clay Newkirk	Celina Tomlinson	Lauren Leatso	Bill Hynes	Ananya Kumar	Devin Gozdenovich	Komlavi Touglo
Brendan Waldorf	Matthew Lang	Jake Antosh	Arianna Dougherty	Jose Perez-Lopez	Sevi Travis	Alex Droney	Julia Thompson
Katie Knudsen	Leah Pagan	Samantha Zavala	Kelly Sanders	Erin Smyntek	Shreya Hariharan	Maxwell Gillogly	Drew Silvernail
Calvin Johnson	Sophia Ryan	Satyam Talele	Xavier Roman	Mia Ciliberti	Vander Hart	Alex Trotter	Elli Jun
Adrian Joachim	Riham Islam	Jevon Benson	Eliza Matatt	Vishwa Patel	Sara Coons	Shayla Timmons	Donovan Kerns
Brett White	Elaaf Alsharbati	Jordan Scott	Joseph Wah	Mackenzie Whiting	Keerthana Vijayaragavan	Matt Graham	MJ Dougherty

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Maisie Moses	Maria Villacreses
Benjamin Yocum	Lucas Bayne
Katelyn Yong	Matthew Korenewsky
Erin Berry	Michael Van Etten
Dawson Tupponce	Herarto Gunopawiro
Melissa Trinidad	Joseph Skinner
Luke Scott	Tyler Boyle
Michael Morrison	James McLaughlin
Nicholas Butler	Peter Henchey
Daniela DiCarlo	Samuel Smith
Kayla Sinclair	Ayako Kubo
Bianca Hart	Justin Karwatowski
Jaelen Richardson	Benjamin Tobin
Roshni Nair	Deborah Peterson
Andrew Rophael	Timothy Sarasin
Marcus Alston	Jonathan Taylor
Chris Samuel	Bryan Weisheit
Jermai Williams	Michael O'Hara
Tanner Mathews	Eric Hilton
Caleb Gradoni	Kayleigh Hodgens
Devin Hammill	Patrick Schuttig
Sophia Rizzo	Christopher Santo
Avery Robinson-Becker	James Barber
Christian Suastegui	Marley Sanin
Kendal Phinney	Bethany Klob
Brooklyn Nguyen	Jennifer ElSawi
Carter Washock	Michael Gaylo
Areej Chishti	Ricky Millien
Ellen Luke	Connor Shapiro
Philip Maiello	Joseph Marini

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SEC Filing

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 000-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**13-3444607**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

777 Old Saw Mill River Road Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 847-7000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol*	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**REGN**	**NASDAQ Global Select Market**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant was $76.7 billion, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2023, the last trading day of the registrant's most recently completed second fiscal quarter. For purposes of this calculation only, the registrant has assumed that all of its directors and executive officers, and no other persons, are its affiliates. This determination of affiliate status is not necessarily a determination for other purposes.

The number of shares outstanding of each of the registrant's classes of common stock as of January 25, 2024:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,818,146
Common Stock, $.001 par value	107,943,750

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2024 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 92 to 96 of this filing.

REGENERON PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
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"Altibodies™," "ARCALYST®," "Evkeeza®," "EYLEA®," "EYLEA® HD," "Inmazeb®," "Libtayo®," "Praluent®" (in the United States), "REGEN-COV®," "Regeneron®," "Regeneron Genetics Center®," "RGC®," "*Veloci-Bi®*," "*VelociGene®*," "*VelociHum®*," "*VelociMab®*," "*VelocImmune®*," "*VelociMouse®*," "*VelociSuite®*," "*VelociT®*," "Veopoz™," and "ZALTRAP®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners. This report refers to products of Regeneron Pharmaceuticals, Inc., its collaborators, and other parties. Consult the product label in each territory for specific information about such products.

PART I

Item 1. Business

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (where applicable, together with its subsidiaries, "Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others:

- *the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation those discussed or referenced in this report, Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs;*
- *the likelihood and timing of achieving any of our anticipated development milestones referenced in this report;*
- *safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials;*
- *the likelihood, timing, and scope of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for Regeneron's Products, including without limitation those discussed or referenced in this report;*
- *the extent to which the results from the research and development programs conducted by us and/or our collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval;*
- *ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy;*
- *determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates;*
- *competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates;*
- *uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties on the commercial success of Regeneron's Products and Regeneron's Product Candidates;*
- *our ability to manufacture and manage supply chains for multiple products and product candidates;*
- *the ability of our collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates;*
- *the availability and extent of reimbursement of Regeneron's Products from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid;*
- *coverage and reimbursement determinations by such payors and new policies and procedures adopted by such payors;*
- *unanticipated expenses;*
- *the costs of developing, producing, and selling products; our ability to meet any of our financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance;*
- *the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated;*
- *the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on our business; and*
- *risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings described further in Note 16 to our Consolidated Financial Statements included in this report), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including without limitation those described in Note 16 to our Consolidated Financial Statements included in this report), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition.*

These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various

factors identified under Part I, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events, or otherwise.

General

Regeneron Pharmaceuticals, Inc. is a fully integrated biotechnology company that invents, develops, manufactures, and commercializes medicines for people with serious diseases. Our products and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, hematologic conditions, infectious diseases, and rare diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to build on that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to advance as an integrated, multi-product biotechnology company that provides patients and medical professionals with important medicines for preventing and treating human diseases.

Selected financial information is summarized as follows:

	Year Ended December 31,		
(In millions, except per share data)	2023	2022	2021
Revenues	$ 13,117.2	$ 12,172.9	$ 16,071.7
Net income	$ 3,953.6	$ 4,338.4	$ 8,075.3
Net income per share - diluted	$ 34.77	$ 38.22	$ 71.97

For purposes of this report, references to our products encompass products marketed or otherwise commercialized by us and/or our collaborators or licensees and references to our product candidates encompass product candidates in development by us and/or our collaborators or licensees (in the case of collaborated or licensed products or product candidates under the terms of the applicable collaboration or license agreements), unless otherwise stated or required by the context.

Products

Products that have received marketing approval are summarized in the table below. Certain products have also received marketing approval in countries outside the United States, European Union ("EU"), or Japan.

Product	Disease	Territory		
		U.S.	EU	Japan
EYLEA® HD (aflibercept) Injection 8 mg[a]	Wet age-related macular degeneration ("wAMD")	✔	✔	✔
	Diabetic macular edema ("DME")	✔	✔	✔
	Diabetic retinopathy ("DR")	✔		
EYLEA® (aflibercept) Injection[a]	wAMD	✔	✔	✔
	DME	✔	✔	✔
	DR	✔		
	Macular edema following retinal vein occlusion ("RVO"), which includes macular edema following central retinal vein occlusion ("CRVO") and macular edema following branch retinal vein occlusion ("BRVO")	✔	✔	✔
	Myopic choroidal neovascularization ("mCNV")		✔	✔
	Neovascular glaucoma ("NVG")			✔
	Retinopathy of prematurity ("ROP")	✔	✔	✔
Dupixent® (dupilumab) Injection[b]	Atopic dermatitis (in adults, adolescents, and pediatrics aged 6 months and older)	✔	✔	✔
	Asthma (in adults and adolescents)	✔	✔	✔

Product *(continued)*	Disease	Territory		
		U.S.	EU	Japan
Dupixent (dupilumab) Injection[b] *(continued)*	Asthma (in pediatrics 6–11 years of age)	✔	✔	
	Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	✔	✔	✔
	Eosinophilic esophagitis ("EoE") (in adults and adolescents)	✔	✔	
	EoE (in pediatrics 1–11 years of age)	✔		
	Prurigo nodularis	✔	✔	✔
Libtayo® (cemiplimab) Injection[c]	Metastatic or locally advanced first-line non-small cell lung cancer ("NSCLC")	✔	✔	
	Metastatic or locally advanced first-line NSCLC (in combination with chemotherapy)	✔	✔	
	Metastatic or locally advanced basal cell carcinoma ("BCC")	✔	✔	
	Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	✔	✔	
	Metastatic or recurrent second-line cervical cancer		✔	✔
Praluent® (alirocumab) Injection[d]	LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD")	✔	✔	
	HeFH in pediatrics and adolescents (8–17 years of age)		✔	
	Cardiovascular risk reduction in patients with established cardiovascular disease	✔	✔	
	Homozygous familial hypercholesterolemia ("HoFH")	✔		
REGEN-COV®[e]	COVID-19		✔	✔
Kevzara (sarilumab) Injection[b]	Rheumatoid arthritis ("RA")	✔	✔	✔
	Polymyalgia rheumatica ("PMR")	✔		
Evkeeza® (evinacumab) Injection[f]	HoFH (in adults, adolescents, and pediatrics aged 5 years and older)	✔	✔	✔
Inmazeb® (atoltivimab, maftivimab, and odesivimab) Injection	Infection caused by *Zaire ebolavirus*	✔		
Veopoz™ (pozelimab) Injection	CD55-deficient protein-losing enteropathy ("CHAPLE") (in adults, adolescents, and pediatrics aged 1 year and older)	✔		
ARCALYST® (rilonacept) Injection[g]	Cryopyrin-associated periodic syndromes ("CAPS"), including familial cold auto-inflammatory syndrome ("FCAS") and Muckle-Wells syndrome ("MWS") (in adults and adolescents)	✔		
	Deficiency of interleukin-1 receptor antagonist ("DIRA") (in adults, adolescents, and pediatrics)	✔		
	Recurrent pericarditis (in adults and adolescents)	✔		
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[h]	Metastatic colorectal cancer ("mCRC")	✔	✔	✔

Note: Refer to table below (net product sales of Regeneron-discovered products) for information regarding whether net product sales for a particular product are recorded by us or others. In addition, unless otherwise noted, products in the table above are generally approved for use in adults in the above-referenced diseases.

[a] In collaboration with Bayer outside the United States. Aflibercept 8 mg is known as EYLEA HD in the United States and EYLEA 8 mg in other countries.

[b] In collaboration with Sanofi.

[c] In collaboration with Sanofi prior to July 2022. Effective July 2022, the Company is solely responsible for the development, commercialization, and manufacturing of Libtayo. Refer to "Collaboration, License, and Other Agreements" section below for further details.

[d] The Company is solely responsible for the development and commercialization of Praluent in the United States and Sanofi is responsible for the development and commercialization of Praluent outside the United States.

[e] In collaboration with Roche. Product is known as REGEN-COV in the United States and Ronapreve™ in other countries.

[f] The Company is solely responsible for the development and commercialization of Evkeeza in the United States and Ultragenyx is responsible for the development and commercialization of Evkeeza outside the United States.

[g] Kiniksa is solely responsible for the development and commercialization of ARCALYST.

[h] Sanofi is solely responsible for the development and commercialization of ZALTRAP.

Net product sales of Regeneron-discovered products consist of the following:

	Year Ended December 31,								
	2023			2022			2021		
(In millions)	U.S.	ROW[g]	Total	U.S.	ROW	Total	U.S.	ROW	Total
EYLEA HD[a]	$ 165.8	$ —	$ 165.8	$ —	$ —	$ —	$ —	$ —	$ —
EYLEA[a]	$ 5,719.6	$ 3,495.2	$ 9,214.8	$ 6,264.6	$ 3,382.8	$ 9,647.4	$ 5,792.3	$ 3,450.9	$ 9,243.2
Total EYLEA HD and EYLEA	$ 5,885.4	$ 3,495.2	$ 9,380.6	$ 6,264.6	$ 3,382.8	$ 9,647.4	$ 5,792.3	$ 3,450.9	$ 9,243.2
Dupixent[b]	$ 8,855.6	$ 2,732.5	$ 11,588.1	$ 6,668.0	$ 2,013.2	$ 8,681.2	$ 4,713.0	$ 1,485.3	$ 6,198.3
Libtayo[c]	$ 538.8	$ 330.0	$ 868.8	$ 374.5	$ 203.5	$ 578.0	$ 306.3	$ 151.9	$ 458.2
Praluent[d]	$ 182.4	$ 456.5	$ 638.9	$ 130.0	$ 337.4	$ 467.4	$ 170.0	$ 251.1	$ 421.1
REGEN-COV[e]	$ —	$ 618.8	$ 618.8	$ —	$ 1,769.6	$ 1,769.6	$ 5,828.0	$ 1,745.9	$ 7,573.9
Kevzara[b]	$ 214.7	$ 171.2	$ 385.9	$ 199.7	$ 158.3	$ 358.0	$ 161.9	$ 176.1	$ 338.0
Other products[f]	$ 150.5	$ 67.4	$ 217.9	$ 56.1	$ 69.1	$ 125.2	$ 25.9	$ 86.4	$ 112.3

[a] Regeneron records net product sales of EYLEA HD and EYLEA in the United States, and Bayer records net product sales outside the United States. The Company records its share of profits in connection with sales outside the United States.

[b] Sanofi records global net product sales of Dupixent and Kevzara. The Company records its share of profits in connection with global sales of Dupixent and Kevzara.

[c] Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. The parties equally shared profits/losses in connection with global sales of Libtayo. Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States and pays Sanofi a royalty on global sales. Refer to "Collaboration, License, and Other Agreements" section below for further details. Included in this line item for the years ended December 31, 2023 and 2022 is approximately $6 million and $34 million, respectively, of net product sales recorded by Sanofi in connection with sales in certain markets outside the United States (Sanofi recorded net product sales in such markets during a transition period until inventory on hand as of July 1, 2022 had been sold through to the end customers).

[d] Regeneron records net product sales of Praluent in the United States. Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales.

[e] Regeneron records net product sales of REGEN-COV in the United States and Roche records net product sales of Ronapreve outside the United States. The parties share gross profits from global sales of REGEN-COV and Ronapreve based on a pre-specified formula.

[f] Included in this line item are products which are sold by the Company and others. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Revenues" for a complete listing of net product sales recorded by the Company. Not included in this line item are net product sales of ARCALYST subsequent to the first quarter of 2021, which are recorded by Kiniksa.

[g] Rest of world ("ROW")

Programs in Clinical Development

Product candidates in clinical development, which are being developed by us and/or our collaborators, are summarized in the table below.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development (including any post-approval studies), uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes to drug pricing and reimbursement regulations and requirements, and changes in the competitive landscape affecting a product candidate. The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results.

Refer to Part I, Item 1A. "Risk Factors" for a description of risks and uncertainties that may affect our clinical programs. Any of such risks and uncertainties may, among other matters, negatively impact the development timelines set forth in the table below.

Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
			Ophthalmology			
EYLEA HD (aflibercept) 8 mg[a]			–RVO		–Approved by U.S. Food and Drug Administration ("FDA") for wAMD, DME, and DR –Approved by European Commission ("EC") and Japan's Ministry of Health, Labour and Welfare ("MHLW") for wAMD and DME –Reported positive two-year data from Phase 3 studies in wAMD and DME	–Initiate Phase 3 study in RVO (mid-2024) to enable FDA submission
EYLEA (aflibercept)[a]					–Approved by FDA for ROP	
Pozelimab[f] **(REGN3918)** *Antibody to C5*						–Initiate Phase 3 study in combination with cemdisiran in geographic atrophy (second half 2024)
			Immunology & Inflammation			
Dupixent (dupilumab)[b] *Antibody to IL-4R alpha subunit*	–Ulcerative colitis –Eosinophilic gastroenteritis (Phase 2/3)		–Chronic obstructive pulmonary disease ("COPD")[d] –Bullous pemphigoid[c] –Chronic spontaneous urticaria ("CSU") –Chronic pruritus of unknown origin	–EoE in pediatrics (1–11 years of age) (EU) –COPD with type 2 inflammatory phenotype (U.S. and EU) –CSU in adults and adolescents (Japan)	–Approved by EC for atopic dermatitis in pediatrics (6 months–5 years of age) –Approved by MHLW for atopic dermatitis in pediatrics and adolescents (6 months–14 years of age) –Approved by FDA for EoE in pediatrics (1–11 years of age) –Approved by EC for EoE in adults and adolescents –Approved by MHLW for prurigo nodularis	–EC decision on regulatory submission for EoE in pediatrics (second half 2024) –FDA decision on supplemental Biologics License Application ("sBLA") (mid/second half 2024) and EC decision on regulatory submission (second half 2024) for COPD with type 2 inflammatory phenotype

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
Dupixent (dupilumab)[b] *(continued)*					–Reported that Phase 3 BOREAS trial in COPD with evidence of type 2 inflammation met its primary and all key secondary endpoints; presented at 2023 American Thoracic Society International Conference and published in *New England Journal of Medicine* –Reported that results from interim analysis of replicate Phase 3 NOTUS trial in COPD with evidence of type 2 inflammation met its primary endpoint –FDA issued Complete Response Letter ("CRL") for sBLA for CSU due to requirement for additional efficacy data –Phase 3 trial in chronic cold induced urticaria did not meet its required efficacy endpoints –Discontinued further clinical development in allergic fungal rhinosinusitis and chronic rhinosinusitis without nasal polyposis	–MHLW decision on regulatory submission for CSU in adults and adolescents (first half 2024) –Report results from ongoing Phase 3 trial in CSU (in biologic-naive patients) (fourth quarter 2024) –Report results from Phase 3 trial in bullous pemphigoid (second half 2024) –Initiate Phase 1 study in severe food allergy following transient linvoseltamab treatment (2024)
Kevzara (sarilumab)[b] *Antibody to IL-6R*		–Polyarticular-course juvenile idiopathic arthritis ("pcJIA") (pivotal study) –Systemic juvenile idiopathic arthritis ("sJIA") (pivotal study)		–PMR (EU) –pcJIA (U.S. and EU)	–Approved by FDA for PMR	–EC decision on regulatory submission for PMR (second half 2024) –FDA decision on sBLA (target action date of June 10, 2024) and EC decision (second half 2024) on regulatory submission for pcJIA

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
Itepekimab[b] (REGN3500) *Antibody to IL-33*			–COPD[c]		–Phase 3 COPD program passed interim futility analysis conducted by Independent Data Monitoring Committee ("IDMC")	–Report results from Phase 3 study in COPD (2025)
REGN5713-5714-5715 *Multi-antibody therapy to Bet v 1*			–Birch allergy			
			Solid Organ Oncology			
Libtayo (cemiplimab)[g] *Antibody to PD-1*		–Neoadjuvant CSCC –First-line NSCLC, BNT116[f] combination	–Adjuvant CSCC		–Approved by EC for first-line NSCLC, chemotherapy combination	–Conduct interim analysis from Phase 3 study in adjuvant CSCC (second half 2024)
Fianlimab[f] (REGN3767) *Antibody to LAG-3*	–Solid tumors and advanced hematologic malignancies	–First-line advanced NSCLC (Phase 2/3) (pivotal study)	–First-line metastatic melanoma[e] –First-line adjuvant melanoma		–Presented positive data from Phase 1 trial (in combination with Libtayo) in advanced melanoma at 2023 American Society of Clinical Oncology ("ASCO") Annual Meeting	–Initiate potentially pivotal Phase 2 study (in combination with Libtayo) in perioperative melanoma (first half 2024) –Initiate Phase 2 study (in combination with Libtayo) in perioperative NSCLC (first half 2024) –Initiate Phase 2 study (in combination with Libtayo) in perioperative head and neck squamous cell carcinoma (2024) –Report potentially pivotal initial results from Phase 2/3 study in first-line metastatic melanoma (second half 2024) –Report initial data from Phase 2/3 study in first-line advanced NSCLC (second half 2024)
Vidutolimod *Immune activator targeting TLR9*		–Solid tumors				

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
Ubamatamab[f] (REGN4018) *Bispecific antibody targeting MUC16 and CD3*		–Platinum-resistant ovarian cancer			–Presented results from Phase 1/2 study (in combination with Libtayo) in platinum-resistant ovarian cancer at European Society for Medical Oncology ("ESMO") Congress	
REGN5668[n] *Bispecific antibody targeting MUC16 and CD28*	–Platinum-resistant ovarian cancer					
REGN5678 *Bispecific antibody targeting PSMA and CD28*	–Prostate cancer				–Discontinued enrollment in cohorts in combination with full-dose Libtayo (cemiplimab) –Expanded enrollment in monotherapy cohort	–Initiate cohorts in combination with REGN4336 in metastatic castration-resistant prostate cancer (first half 2024)
REGN4336 *Bispecific antibody targeting PSMA and CD3*	–Prostate cancer					
Davutamig (REGN5093) *Bispecific antibody targeting two distinct MET epitopes*	–MET-altered advanced NSCLC					
REGN5093-M114 *Bispecific antibody-drug conjugate targeting two distinct MET epitopes*	–MET overexpressing advanced cancer					
REGN6569 *Antibody to GITR*	–Solid tumors					
REGN7075 *Bispecific antibody targeting EGFR and CD28*	–Solid tumors					–Initiate dose-expansion cohorts (in combination with Libtayo) in EGFR-high tumors (first half 2024)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
			Hematology			
Pozelimab[f] (REGN3918) *Antibody to C5*			–Myasthenia gravis, cemdisiran combination[g,ff] –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination[g,hh]		–Veopoz (pozelimab) approved by FDA for CHAPLE in adults and children aged 1 year and older, monotherapy	
Odronextamab[m] (REGN1979) *Bispecific antibody targeting CD20 and CD3*	–Certain B-cell malignancies[ii]	–B-cell non-Hodgkin lymphoma ("B-NHL") (pivotal study)	–Follicular lymphoma ("FL") –Diffuse large B-cell lymphoma ("DLBCL")	–Relapsed/refractory FL and DLBCL (U.S. and EU)	–Presented updated data from trials in patients with relapsed/refractory FL and DLBCL at American Society of Hematology ("ASH") Annual Meeting	–FDA decision on BLA (target action date of March 31, 2024) and EC decision on regulatory submission (second half 2024) for relapsed/refractory FL and DLBCL
REGN5837[p] *Bispecific antibody targeting CD22 and CD28*	–B-NHL					
Linvoseltamab[f] (REGN5458) *Bispecific antibody targeting BCMA and CD3*	–Multiple myeloma[g,jj,kk]	–Multiple myeloma (pivotal study)[g,kk] –Earlier (pre-malignant) multiple myeloma	–Multiple myeloma[g]	–Relapsed/refractory multiple myeloma (U.S. and EU)	–Presented updated positive data from pivotal trial in multiple myeloma at ASCO and ASH Annual Meetings	–FDA decision on BLA (second half 2024) and EC decision on regulatory submission (first half 2025) for relapsed/refractory multiple myeloma
REGN5459[f] *Bispecific antibody targeting BCMA and CD3*	–Transplant desensitization in patients with chronic kidney disease					
REGN7257 *Antibody to IL2Rg*	–Aplastic anemia					
NTLA-2001[ll] *TTR gene knockout using CRISPR/Cas9*	–Transthyretin ("ATTR") amyloidosis[ll]		–ATTR amyloidosis with cardiomyopathy ("ATTR-CM")			
REGN9933 *Antibody to Factor XI*		–Thrombosis				–Report results from Phase 2 study in thrombosis (second half 2024)
REGN7508 *Antibody to Factor XI*	–Thrombosis					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[b]	2023 and 2024 Events to Date	Select Upcoming Milestones
REGN7999 *Antibody to TMPRSS6*	–Transfusion dependent iron overload					
			Internal Medicine/Genetic Medicines			
Praluent (alirocumab) *Antibody to PCSK9*			–HeFH in pediatrics and adolescents	–HeFH in pediatrics and adolescents (8–17 years of age) (U.S.)	–Approved by EC for HeFH in pediatrics and adolescents (8–17 years of age)	–FDA decision on sBLA for HeFH in pediatrics and adolescents (target action date of March 10, 2024)
Evkeeza[f][i] (evinacumab) *Antibody to ANGPTL3*					–Approved by FDA and EC for HoFH in pediatrics (5–11 years of age) and MHLW for HoFH in adults, adolescents, and pediatrics	
Garetosmab[f] (REGN2477) *Antibody to Activin A*			–Fibrodysplasia ossificans progressiva ("FOP")[g][h][k]			
Trevogrumab[f] (REGN1033) *Antibody to myostatin (GDF8)*						–Initiate Phase 2 study in combination with semaglutide with and without garetosmab (mid-2024)
Mibavademab[f] (REGN4461) *Agonist antibody to leptin receptor ("LEPR")*		–Generalized lipodystrophy[g][k]			–Presented results from Phase 2 study in generalized lipodystrophy at ENDO 2023	
REGN5381/REGN9035 *Agonist antibody to NPR1/reversal agent to REGN5381*	–Reversal agent in healthy volunteers	–Heart failure			–Resumed enrollment in previously paused Phase 1 and Phase 2 studies following protocol amendments	
					–Reported positive initial data from Phase 1 trial in healthy volunteers	
REGN7544 *Antagonist antibody to NPR1*	–Healthy volunteers					
ALN-HSD[m] *RNAi therapeutic targeting HSD17B13*		–Nonalcoholic steatohepatitis ("NASH")				

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2023 and 2024 Events to Date	Select Upcoming Milestones
ALN-PNP[k] *RNAi therapeutic targeting PNPLA3*	–NASH					
ALN-APP[k] *RNAi therapeutic targeting APP*	–Early-onset Alzheimer's disease[q]				–Reported positive interim data from single dose part of Phase 1 trial in early-onset Alzheimer's disease	
DB-OTO *AAV-based gene therapy*	–Hearing loss in pediatrics[c] (Phase 1/2)				–Reported preliminary, positive safety and efficacy results from first patient dosed in Phase 1/2 trial in pediatrics with hearing loss	
"Next Generation" Covid Antibody[l] *Antibody to SARS-CoV-2 variants*	–Healthy volunteers					
REGN13335 *Antagonist antibody to PDGF-B*	–Healthy volunteers					

Note: For purposes of the table above, a program is classified in Phase 1, 2, or 3 clinical development after recruitment for the corresponding study or studies has commenced.

[a] In collaboration with Bayer outside the United States

[b] In collaboration with Sanofi

[c] FDA granted orphan drug designation

[d] FDA granted Breakthrough Therapy designation

[e] FDA granted Fast Track designation

[f] Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on sales of the product, if any.

[g] Studied as monotherapy and in combination with other antibodies and treatments

[h] Information in this column relates to U.S., EU, and Japan regulatory submissions only

[i] We and the Biomedical Advanced Research and Development Authority ("BARDA") of the U.S. Department of Health and Human Services ("HHS") are parties to an agreement whereby HHS provides certain funding to support research and development activities.

[j] In collaboration with Intellia

[k] In collaboration with Alnylam

[l] In collaboration with Ultragenyx outside the United States

[m] FDA granted Fast Track designation for follicular lymphoma and diffuse large B-cell lymphoma

[n] Studied in combination with ubamatamab

[o] Alnylam elected to opt-out of the product candidate. Under the terms of our agreement, Alnylam is entitled to receive royalties on sales of the product, if any.

[p] Studied in combination with odronextamab

[q] Part B of the study (multi-dose regimen) placed on partial clinical hold in the U.S. by the FDA due to findings observed in prior non-clinical chronic toxicology studies

[r] BioNTech's BNT116 is an mRNA cancer vaccine.

[s] Under the terms of our license agreement for the combination consisting of cemdisiran and pozelimab, Alnylam is entitled to receive royalties on sales of the combination (if any), as well as sales milestones.

Additional Information - Clinical Development Programs

EYLEA HD (aflibercept) 8 mg

In August 2023, the FDA approved the BLA for EYLEA HD for the treatment of patients with wAMD, DME, and DR.

Previously, in June 2023, the FDA issued a CRL for the EYLEA HD BLA. The CRL was issued solely due to unresolved observations resulting from a May 2023 FDA inspection at a third-party contract manufacturing organization, Catalent, that the Company engaged to complete vial-filling for EYLEA HD. With the approval of EYLEA HD, the pre-approval inspection issues related to the BLA had been addressed.

In June 2023 and August 2023, the Company announced top-line, two-year (96 weeks) data for EYLEA HD from the pivotal PHOTON trial in patients with DME and the pivotal PULSAR trial in patients with wAMD, respectively. In addition, in July 2023, the results from the PHOTON trial were presented at the American Society of Retina Specialists annual meeting. During both trials, EYLEA HD patients were initially randomized to either 12- or 16-week dosing intervals (after three initial monthly doses) and were able to shorten or extend dosing intervals if pre-specified criteria were met. The longer-term data among EYLEA HD patients who completed the trials demonstrated that the vast majority of patients were able to maintain or further extend these dosing intervals through two years with:

PHOTON:

- 89% maintaining ≥12-week dosing intervals through two years, compared to 93% through one year (48 weeks)
- 84% maintaining ≥16-week dosing intervals through two years, compared to 89% maintaining a 16-week dosing interval through one year
- 44% meeting the criteria for ≥20-week dosing intervals by week 96, including 17% and 27% who were eligible for 20- and 24-week dosing intervals, respectively

PULSAR:

- 88% on a ≥12-week dosing interval at the end of two years
- 78% maintaining ≥12-week dosing intervals through two years, compared to 83% throughout the first year of study (48 weeks)
- 71% meeting the extension criteria for even longer dosing intervals, including 47% for ≥20-week intervals and 28% for 24-week intervals
- those assigned to ≥16-week dosing regimen at baseline, 70% maintaining ≥16-week dosing intervals throughout the two-year study period; at the end of two years, 78% were eligible for ≥16-week dosing, with 53% eligible for ≥20-dosing week intervals.

The visual gains for EYLEA HD remained consistent with the first year of the trials. In both PHOTON and PULSAR, the safety of EYLEA HD also continued to be similar to EYLEA through two years and remained consistent with the known safety profile of EYLEA from previous clinical trials for DME and wAMD.

In May 2023, Bayer announced that it initiated a Phase 3 study to evaluate the efficacy and safety of EYLEA HD at extended dosing intervals compared to the standard of care, EYLEA, in RVO to support potential future regulatory submissions outside the United States.

Dupixent

COPD

In March 2023, the Company and Sanofi announced that the primary and all key secondary endpoints were met in the BOREAS trial (the first of two Phase 3 trials) in adults currently on maximal standard-of-care inhaled therapy (triple therapy) with uncontrolled COPD and evidence of type 2 inflammation. In this trial, patients receiving Dupixent experienced a 30% reduction in moderate or severe acute COPD exacerbations (rapid and acute worsening of respiratory symptoms) compared to placebo over 52 weeks, while also demonstrating significant improvements in lung function, quality of life, and COPD respiratory symptoms.

In November 2023, the Company and Sanofi announced that the replicate Phase 3 NOTUS trial met its primary endpoint, showing Dupixent significantly reduced exacerbations by 34% compared to placebo over 52 weeks in patients with moderate-to-severe COPD with evidence of type 2 inflammation, confirming results from the BOREAS pivotal trial. Given the overwhelming positive efficacy of the primary endpoint in the interim analysis from the NOTUS trial, the results will be considered the primary analysis of the trial. In December 2023, the Company and Sanofi submitted the data from this interim analysis of the NOTUS trial, along with the results from the Phase 3 BOREAS trial, to the FDA.

4P

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: TriSalus Life Sciences, Inc.

Physical Address: 6272 W. 91st Avenue

City: Westminster State: CO Zip: 80031

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 8883215212 Website: https://trisaluslifesci.com/

Name of Designated Representative (DR): Michael Aymami

Licensing Company Email: michael.aymami@trisaluslifesci.c DR Email: Trisalus@iqvia.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): N/A

Corporation Name: TriSalus Life Sciences, Inc.

Mailing Address: 6272 W. 91st Avenue

City: Westminster State: Colorado Zip: 80031

Telephone: 888-321-5212 Email: michael.aymami@trisaluslifesci.com

Contact Person Name: Michael Aymami

Date of SEC Registration: 08/31/2023 | SEC Registration Number: 0001826667 | Stock Exchange Symbol: TLSI

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

TriSalus Life Sciences, Inc.

Facility Name

Michael Aymami

Print Name of Authorized Person Submitting Application

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

01 AUG 2024

Date

Board Use Only	Date Received: 9/5/24	Amount: $1000-ck 657878

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Surefire Medical, Inc.
Business Trade Name:
TriSalus Life Sciences

6272 W 91st Ave
Westminster, CO 80031
Registration Number: 3010909876
FEI Number*: 3010909876
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
TriSalus Life Sciences[6]
6272 W. 91st Avenue
Westminster, CO US 80031
Owner/Operator Number: 10038066[7]

Official Correspondent:
Michael Aymami
TriSalus Life Sciences
6272 W. 91st Avenue
Westminster, CO 80031
Phone: 303-2434969

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 05/27/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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TriSalus Life Sciences, Inc.

6272 W. 91st Avenue, Westminster, Colorado 80031

8883215212

OFFICER NAME	TITLE
Jody Devlin-	President Commercial Operations
Jennifer Stevens	CRO
Sean Murphy	Chief Financial Officer

Delaware

The First State

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

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

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "TRISALUS LIFE SCIENCES, INC." WAS INCORPORATED ON THE ELEVENTH DAY OF SEPTEMBER, A.D. 2020.

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

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

3643084 8300

SR# 20250836801

Authentication: 203049101

Date: 02-28-25

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

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

TRISALUS LIFE SCIENCES, INC.

is an entity formed or registered under the law of Delaware . has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 20091399943 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 08/28/2024 that have been posted, and by documents delivered to this office electronically through 08/29/2024 @ 11:15:00 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 08/29/2024 @ 11:15:00 in accordance with applicable law. This certificate is assigned Confirmation Number 16342703 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

Below are your electronic wallet cards to use as proof of your license. You can also print your license at any time by visiting www.colorado.gov/dora/DPO_Print_License and following the instructions listed.

If you would like a more durable wallet card option, you can order one for a fee by visiting www.nasbastore.org and selecting the "Colorado License Cards" link on the left hand side of the page. If you prefer, you can also contact NASBA by phone at 1-888-925-5237 or by email at nasbastore@nasba.org.

Should you have questions about your credential, or need other information please contact our Customer Service Team at 303-894-7800 or dora_dpo_licensing@state.co.us.

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
TriSalus Life Sciences, Inc.

Manufacturer

MFR.0001058 — **Number**
11/01/2024 — **Issue Date**
Active — **Credential Status**
10/31/2026 — **Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp
Credential Holder Signature

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
TriSalus Life Sciences, Inc.

Manufacturer

MFR.0001058 — **Number**
11/01/2024 — **Issue Date**
Active — **Credential Status**
10/31/2026 — **Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp
Credential Holder Signature

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 09/06/2024

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

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

PRODUCER Willis Towers Watson Northeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: WTW Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@wtwco.com
INSURED Trisalus Life Sciences, Inc. 6272 W 91st Ave Westminster, CO 80031	INSURER A: Federal Insurance Company — NAIC # 20281 INSURER B: At-Bay Specialty Insurance Company — 19607 INSURER C: Palomar Excess and Surplus Insurance Compa — 16754 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W34644092 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [X] LOC [ ] OTHER:			36069238	08/31/2024	08/31/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ $
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			73623666	08/31/2024	08/31/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ 1,000,000 $ $ $ $
A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			78194684	08/31/2024	08/31/2025	EACH OCCURRENCE AGGREGATE [ ]	$ 9,000,000 $ 9,000,000 $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A (Mandatory In NH) If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $
A	Product Liability			36069239	08/31/2024	08/31/2025	Each Occurrence Aggregate Retention	$10,000,000 $10,000,000 $25,000

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

Policy includes coverage for Human Clinical Trials testing the insured's products.

SEE ATTACHED

CERTIFICATE HOLDER

Evidence of Insurace

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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SR ID: 26398947 BATCH: 3609593

AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Willis Towers Watson Northeast, Inc.	TriSalus Life Sciences, Inc. 6272 W 91st Ave Westminster, CO 80031
POLICY NUMBER See Page 1	
CARRIER See Page 1 — NAIC CODE: See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

INSURER AFFORDING COVERAGE: At-Bay Specialty Insurance Company NAIC#: 19607

POLICY NUMBER: ATB676339103 EFF DATE: 08/31/2024 EXP DATE: 08/31/2025

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Cyber Liability	Each Claim	$3,000,000
	Aggregate	$3,000,000

INSURER AFFORDING COVERAGE: Palomar Excess and Surplus Insurance Company NAIC#: 16754

POLICY NUMBER: PLM-CB-XQXYV56ER-002 EFF DATE: 08/31/2024 EXP DATE: 08/31/2025

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Cyber Liability	Each Occurrence	$2,000,000
	Aggregate	$2,000,000

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: TriSalus Life Sciences, Inc. MDEG License # (if applicable): _____

Physical Address: 6272 W. 91st Avenue

City: Westminster State: CO Zip: 80031

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 8883215212 Website: https://trisaluslifesci.com/

Licensing Company Email: michael.aymami@trisaluslifesci.c

Section 2: Personal Information

First: Michael Middle: _____ Last: Aymami

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

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

Mailing Address: 6272 W. 91st Avenue,

City: Westminster State: _____ Zip: 80031

Telephone: [redacted] Email: Trisalus@iqvia.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)
CADUCHINO HIGHSCHOOL			08/89 - 05/93
Address	**City**	**State**	**Zip**
1501 MAGNOLIA HIGH	SAN BRUNO	CA	94066
Diploma/Degree obtained, if any			

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

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

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
			80031
Diploma/Degree obtained, if any			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2017-Present	[redacted]	Erie	Colorado	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name		From - To (MM/YY – MM/YY)
TRISMUS LIFE SCIENCES		07/20 - current
Business Address	**City**	**State / Zip**
6272 W. 91ST AVE	WESTMINSTER	CO 80031
Phone	**Title**	**Number of Employed Hours**
303243 4968	DIRECTOR REGULATORY, M.A.	35,040
Description of Duties		
ALL DEVICE REGULATORY		

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

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

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

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

Continue on next page if additional space is needed.

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

School Name			From - To (MM/YY – MM/YY)
CAPUCHINO HIGHSCHOOL			08/89 05/93
Address	**City**	**State**	**Zip**
1501 MAGNOLIA AVE	SAN BRUNO	CA	94066
Diploma/Degree obtained, if any			

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

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

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
			80031
Diploma/Degree obtained, if any			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2017-Present	[redacted]	Erie	Colorado	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

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

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

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

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

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Michael Aymami, **certify that as the MDEG Administrator for**

_____,

that I (initial that you have read and meet the following requirements):

1. Yes Have a high school diploma or its equivalent;
2. Yes Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. Yes Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. Yes Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Aymami
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01 Aug 2024
Date

Board Use Only	Date Received: 8/5/24

Lookup Detail View

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	Public Address
TriSalus Life Sciences, Inc.	Michael Aymami 6272 W 91st Ave Westminster, CO 80031

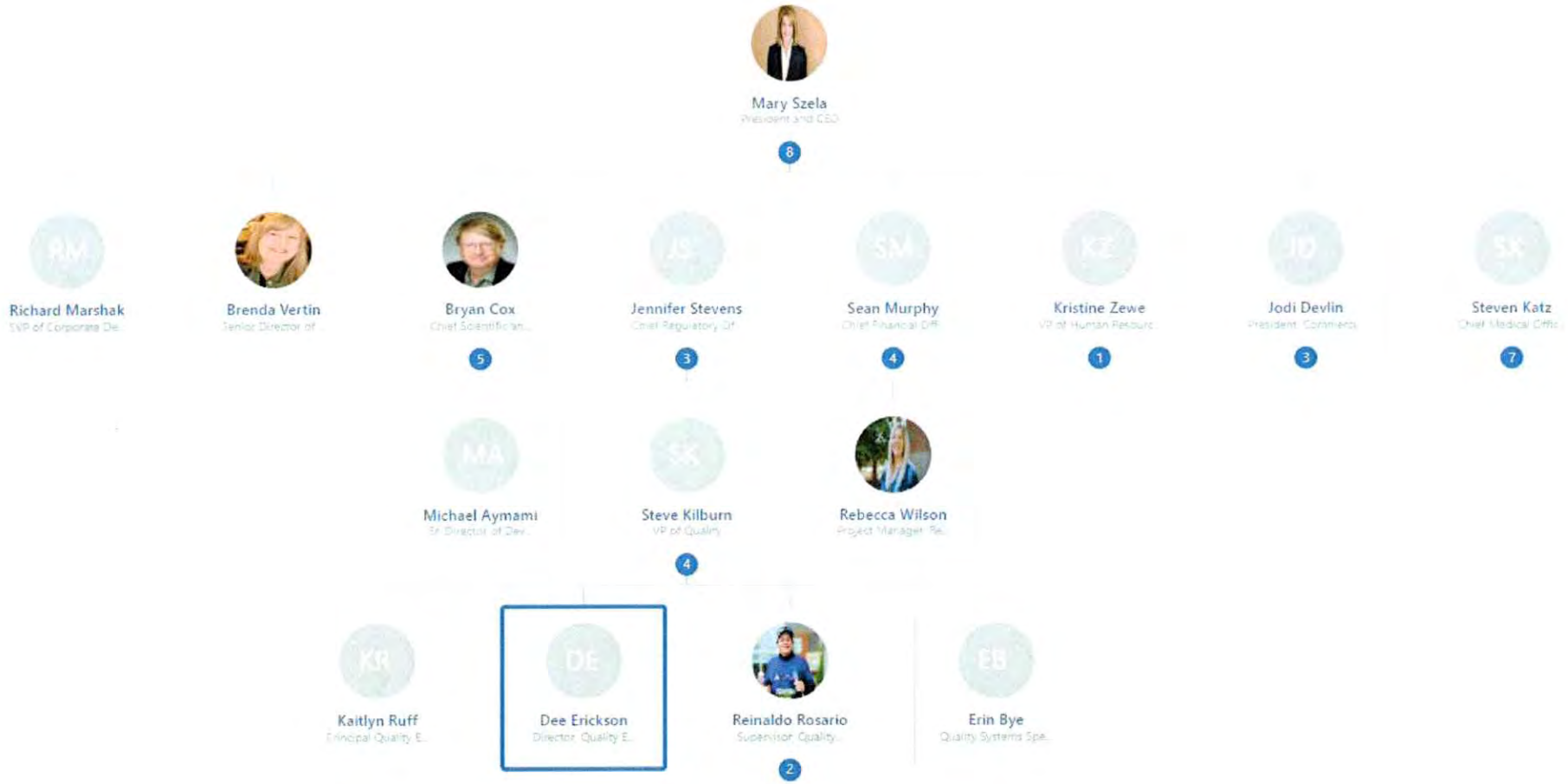
Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
MFR.0001058	Original	Manufacturer	Active	03/31/2023	03/31/2023	10/31/2024

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

Generated on: 4/25/2023 1:19:25 PM


Mary Szela
Richard Marshak
Brenda Vertin
Bryan Cox
Jennifer Stevens
Sean Murphy
Kristine Zewe
Jodi Devlin
Steven Katz
Michael Aymami
Steve Kilburn
Rebecca Wilson
Kaitlyn Ruff
Dee Erickson
Director, Quality E...
Reinaldo Rosario
Erin Bye

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 13, 2024

TRISALUS LIFE SCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-39813	85-3009869
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

6272 W. 91st Ave., Westminster, Colorado	80031
(Address of principal executive offices)	(Zip Code)

(888) 321-5212
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240-13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	TLSI	Nasdaq Global Market
Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of $11.50 per share	TLSIW	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 15, 2024, TriSalus Life Sciences, Inc. (the "Company") issued a press release providing a business update and announcing its financial results for the quarter ended June 30, 2024. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 5.07 Submission of Matters to a Vote of Security Holders.

On August 13, 2024, the Company held its 2024 Annual Meeting of Stockholders (the "Annual Meeting"). As of June 26, 2024, the record date for the Annual Meeting, the aggregate voting power of the outstanding shares of the Company entitled to vote at the Annual Meeting was 31,455,515. A summary of the matters voted upon by stockholders at the Annual Meeting is set forth below. Voting results are, when applicable, reported by rounding fractional share voting down to the nearest whole number.

Proposal 1: Election of Directors

The Company's stockholders elected the four persons listed below as Class I directors, each to serve until the Company's 2027 Annual Meeting of Stockholders, and until his or her successor is duly elected and qualified, or until his or her earlier death, resignation or removal. The final voting results are as follows:

Name of Director Elected	Votes For	Votes Withheld	Broker Non-Votes
Anil Singhal	15,581,603	53,394	2,206,892
Kerry Hicks	15,552,616	82,381	2,206,892
Liselotte Hyveled	15,586,944	48,053	2,206,892
Sean Murphy	15,611,916	23,081	2,206,892

Proposal 2: Ratification of the Appointment of Independent Registered Public Accounting Firm

The Company's stockholders ratified the appointment by the Audit Committee of the Company's Board of Directors of Grant Thornton LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2024. The final voting results are as follows:

Votes For	Votes Against	Abstentions	Broker Non-Votes
17,841,461	427	1	-

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release dated August 15, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 15, 2024

TriSalus Life Sciences, Inc.

By: /s/ Sean Murphy
Name: Sean Murphy
Title: Chief Financial Officer

TriSalus Reports Q2 2024 Financial Results and Business Update

- *Reported revenues of $7.4 million in Q2 2024 and $13.8 million for six months ended June 30, 2024, up 60% and 82%, respectively, compared to prior year periods*
- *Reported gross margin of 88% in Q2 2024 and 86% for six months ended June 30, 2024, compared to 83% and 81%, respectively, in the prior year periods*
- *Announces plan to launch the "DELIVER" Program in Q3 2024, clinical trials leveraging the TriNav® Infusion System (TriNav) in complex patient types and aiming to significantly expand the addressable market*
- *Expects to report data from phase 1 trials of nelitolimod in uveal melanoma liver metastases and locally advanced pancreatic cancer via its pancreatic infusion technology in Q4 2024*
- *Following demonstrated tolerability and efficacy in a limited number of patients in the checkpoint doublet cohort studying nelitolimod in hepatocellular cancer and intrahepatic cholangiocarcinoma (PERIO-2), Company intends to proceed with only investigator-initiated studies in combination with regionally delivered chemotherapy or radiation embolic therapies*
- *Closed up to $50 million of debt financing with OrbiMed to support the TriNav system growth initiatives*
- *Completed warrant exchange offer to simplify capital structure*
- *Management to host earnings conference call on August 15th at 9:00 a.m. EDT*

DENVER – August 15, 2024 - TriSalus Life Sciences Inc., (Nasdaq: TLSI), an oncology company integrating novel delivery technology with immunotherapy to transform treatment for patients with liver and pancreatic tumors, today announced its financial results for the second quarter ended June 30, 2024, and provided a business update.

Mary Szela, President and Chief Executive Officer of TriSalus Life Sciences, stated, "We concluded the second quarter with robust revenue growth and effective execution across our operations. Our sustained revenue growth underscores the critical demand for our Pressure Enabled Drug Delivery™ technology (PEDD ™). We are excited to launch the DELIVER program, which will showcase the advantages of our TriNav system in treating a diverse array of complex patients."

"Additionally, we have successfully advanced development of nelitolimod, having treated 100 patients in four indications and three clinical trials using our PEDD technology. Our progress to date indicates that nelitolimod can be delivered to the liver and pancreas with minimal systemic exposure and shows early promise of benefit in heavily pretreated patients with advanced disease," added Ms. Szela. "We anticipate further growth of our PEDD technology and TriNav system and look forward to presenting our final Phase 1 data for uveal melanoma liver metastases and locally advanced pancreatic cancer in the fourth quarter."

Second Quarter Business Update

DELIVER Program

- TriSalus is excited to unveil the DELIVER program, a series of clinical trials designed to significantly expand the addressable market by evaluating the use of the TriNav system across a diverse range of complex patient populations, with the intent to further validate prior clinical studies that demonstrated the favorable clinical effects of the PEDD technology. This initiative aims to generate comprehensive data and solidify the evidence supporting TriNav's application in patients who might not be suitable candidates for traditional transarterial chemotherapy and radioembolization treatments. A key focus of the DELIVER program is to investigate the potential of combining use of the TriNav system with these therapies to enhance effectiveness and address resistance mechanisms in challenging cancers.
- The Company expects to launch the program with its first clinical study, named "PROTECT" (Pressure Enabled Retrograde Occlusive Therapy with Embolization for Control of Thyroid Disease). The goal of the trial is to highlight the advantages of this novel approach compared to conventional surgical methods.

Nelitolimod Clinical Studies in Uveal Melanoma Liver Metastases, Hepatocellular Carcinoma, Intrahepatic Cholangiocarcinoma, and Locally Advanced Pancreatic Cancer via the Pressure-Enabled Regional Immuno-Oncology (PERIO) Clinical Program

- In November 2023, TriSalus presented initial Phase 1 results for the PERIO-01 and PERIO-03 studies at the Society of Immunotherapy for Cancer annual meeting, and in June 2024, it presented top-line results for PERIO-02 at the American Society of Clinical Oncology (ASCO) annual meeting.
- **PERIO-01** is a Phase 1 trial evaluating hepatic arterial delivery of nelitolimod via the PEDD technology in patients with uveal melanoma liver metastases. The trial includes dose-escalation cohorts with monotherapy and in combination with checkpoint inhibitors. The preliminary data show a tolerable safety profile, evidence of liver metastases myeloid-derived suppressor cells (MDSC) depletion with T cell infiltration, and promising indications of activity, including ctDNA responses, disease control, and survival beyond historical benchmarks in predominantly pre-treated patients. The final results for the PERIO-01 Phase 1 trial are expected in Q4 2024.
- **PERIO-02** focuses on the hepatic arterial delivery of nelitolimod via the PEDD technology for patients with hepatocellular carcinoma or intrahepatic cholangiocarcinoma. The study has been completed, and recent findings presented by investigators from MD Anderson Cancer Center at ASCO demonstrated consistent safety and immunologic effects, along with encouraging survival times in a subset of patients treated with a systemic checkpoint inhibitor doublet. The Company expects further investigation into these indications to continue only through investigator-initiated studies.
- **PERIO-03** is a Phase 1 dose-escalation study of nelitolimod in locally advanced pancreatic cancer. Nelitolimod is administered through outpatient interventional radiology procedures using the Pancreatic TriSalus Infusion System™ PEDD device. Phase 1 results for this study are anticipated in Q4 2024.

Closed up to $50 million of Debt Financing with OrbiMed to support TriNav Growth Initiatives

In April, TriSalus announced the closing of a debt financing facility with OrbiMed, a healthcare investment firm. Under the terms of the credit agreement with OrbiMed, the Company borrowed $25 million at closing. In addition, an aggregate of up to an additional $25 million is available in two tranches at the Company's option, subject to the Company's achievement of certain revenue thresholds.

Cash and cash equivalents on hand totaled $16.5 million at June 30, 2024. Including the Company's Standby Equity Purchase Agreement (SEPA) and other existing sources of liquidity and assuming it achieves the revenue targets and borrow the remaining $25 million of the debt financing, the Company expects to have sufficient cash runway to fund operations through the end of 2025.

Completion of Warrant Exchange Offer

- On May 24, 2024, TriSalus announced an exchange offer of 0.30 shares of Common Stock for each publicly traded and private warrant tendered.
- The offer's purpose was to simplify the Company's capital structure and reduce the potential dilutive impact of the warrants, thereby providing the Company with more flexibility for financing its operations in the future.
- On July 1st, the Company issued 2,110,366 shares of common stock in exchange for 6,529,954 (or 79%) of its publicly traded warrants and 504,685 (or 10%) of its private warrants.

Financial Results for Q2 2024

Revenue, all of which is from the sale of the TriNav system, was $7.4 million and $13.8 million, respectively, for the three and six months ended June 30, 2024, up 60% and 82%, respectively, compared to the same periods in 2023. Revenue growth was driven primarily by increased selling resources and continued market share increases.

Gross margins were 88% and 86% for the three and six months ended June 30, 2024, respectively, compared to 83% and 81%, respectively, for the same periods in 2023. The improvement in the quarter and year-to-date is due to increased factory volumes and improved operational efficiency.

Operating losses were $8.2 million and $19.9 million, respectively, for the three and six months ended June 30, 2024, respectively, compared to losses of $11.4 million and $21.6 million, respectively, for the same periods in 2023. Current year reductions in operating losses are due to increased sales, improved gross margins, and reduced research and development spending associated with the timing of clinical trial spending.

Net losses available to common stockholders were $4.3 million and $17.6 million, respectively, for the three and six months ended June 30, 2024, compared to losses of $14.0 million and $22.2 million, respectively, for the same periods in 2023. Net losses in 2024 include non-cash related losses on change in fair value of the Company's SEPA, warrant and revenue base redemption liabilities of $9.0 million and $6.5 million, respectively for the three and six months ended June 30, 2024, compared to gains of $1.1 million and $3.5 million, respectively, for the same periods in 2023. Net losses in 2023 also include the impact of non-cash related losses on equity issuance of $4.2 million in the three and six months ended June 30, 2023. These amounts are partially offset in 2024 by the impact of non-cash related gains on the change in fair value of contingent earnout liabilities of $13.7 million and $9.7 million, respectively, for the three and six months ended June 30, 2024.

The basic and diluted loss per share for the three and six months ended June 30, 2024, were $0.21 and $0.81, respectively, compared to $35.84 and $59.79 for the three and six months ended June 30, 2023, respectively.

Conference Call

TriSalus will host a webcast to discuss its second quarter 2024 financial results and business highlights on August 15, 2024 at 9:00 a.m. EDT. The webcast can be accessed on the investor relations section of TriSalus' website at https://investors.trisaluslifesci.com/news-events/events-presentations. Following the conclusion of the event, a webcast replay will be available on the website for approximately 90 days. Interested parties participating by phone will need to register using this online form. After registering for the webcast, dial-in details will be provided in an auto-generated e-mail containing a link to the conference phone number and a personal pin.

About TriSalus Life Sciences

TriSalus Life Sciences® is an oncology company integrating novel delivery technology with immunotherapy to transform treatment for patients with liver and pancreatic tumors. The Company's platform includes devices that utilize a proprietary drug delivery technology and a clinical stage investigational immunotherapy. The Company's two FDA-cleared devices use its proprietary Pressure-Enabled Drug Delivery™ (PEDD) approach to deliver a range of therapeutics: the TriNav® Infusion System for hepatic arterial infusion of liver tumors and the Pancreatic Retrograde Venous Infusion System for pancreatic tumors. The PEDD technology is a novel delivery approach designed to address the anatomic limitations of arterial infusion for the pancreas. The PEDD approach modulates pressure and flow in a manner that delivers more therapeutic to the tumor and is designed to reduce undesired delivery to normal tissue, bringing the potential to improve patient outcomes. Nelitolimod, the Company's investigational immunotherapeutic candidate, is designed to improve patient outcomes by treating the immunosuppressive environment created by many tumors and which can make current immunotherapies ineffective in the liver and pancreas. Patient data generated during Pressure-Enabled Regional Immuno-Oncology™ (PERIO) clinical trials support the hypothesis that nelitolimod delivered via the PEDD technology may have favorable immune effects within the liver and systemically. The target for nelitolimod, TLR9, is expressed across cancer types and the mechanical barriers addressed by the PEDD technology are commonly present as well. Nelitolimod delivered by the PEDD technology will be studied across several indications in an effort to address immune dysfunction and overcome drug delivery barriers in the liver and pancreas.

In partnership with leading cancer centers across the country – and by leveraging deep immuno-oncology expertise and inventive technology development – TriSalus is committed to advancing innovation that improves outcomes for patients. Learn more at trisaluslifesci.com and follow us on Twitter and LinkedIn.

Forward Looking Statements

Statements made in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the benefits and potential benefits of the Company's PEDD drug delivery technology, TriNav system and nelitolimod investigational immunotherapy, the expected timing for reporting results from the Company's clinical trials for nelitolimod, the Company's expectation that the development of nelitolimod for the indications covered by PERIO-02 will continue through investigator led trials, the Company's ability to achieve the revenue milestones under the credit facility, the Company's expectations about its casb runway, the Company's expectations about its revenue growth for 2024, the expected benefits from the Company's DELIVER program, the Company's expected timing to launch PROTECT study and any future studies, and the Company's ability to execute on its strategy. Risks that could cause actual results to differ from those expressed in these forward-looking statements include risks associated with clinical development and regulatory approval of drug delivery and pharmaceutical product candidates, including that future clinical results may not be consistent with patient data generated during the Company's clinical trials, the cost and timing of all development activities and clinical trials, unexpected safety and efficacy data observed during clinical studies, the risks associated with the credit facility, including the Company's ability to remain in compliance with all its obligations thereunder to avoid an event of default, the risk that the Company will continue to raise capital through the issuance and sale of its equity securities to fund its operations, the risk that the Company will not be able to achieve the applicable revenue requirements to access additional financing under the credit facility, changes in expected or existing competition or market conditions, changes in the regulatory environment, unexpected litigation or other disputes, unexpected expensed costs, and other risks described in the Company's filings with the Securities and Exchange Commission under the heading "Risk Factors." All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made except as required by law.

Financials

TriSalus Life Sciences

Condensed Consolidated Statement of Operations (unaudited, in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	$ 7,364	$ 4,612	$ 13,821	$ 7,596
Cost of goods sold	912	772	1,883	1,434
Gross Profit	6,452	3,840	11,938	6,162
Operating expenses:				
Research and development	4,666	6,886	10,523	12,504
Sales and marketing	6,004	3,492	12,691	6,741
General and administrative	3,956	4,896	8,583	8,472
Loss from operations	(8,174)	(11,434)	(19,859)	(21,555)
Other income (expense):				
Interest income	97	36	189	71
Interest expense	(877)	(4)	(880)	(9)
Loss on equity issuance		(4,225)		(4,189)
Extinguishment of tranche liability		621		
Change in fair value of SEPA, warrant, and revenue base redemption liabilities	(9,016)	1,070	(6,495)	3,491
Change in fair value of contingent earnout liability	13,689		9,701	
Other expense, net	(44)	(25)	(197)	(43)
Loss before income taxes	(4,325)	(13,961)	(17,541)	(22,234)
Income tax expense	(7)	(13)	(10)	(8)
Net loss available to common stockholders	$ (4,332)	$ (13,974)	$ (17,551)	$ (22,242)
Deemed dividend related to Series B-2 preferred stock down round provision		(2,022)		(2,981)
Undeclared dividends on Series A preferred stock	(801)		(1,602)	
Net loss attributable to common stockholders	$ (5,133)	$ (15,996)	$ (19,153)	$ (25,223)
Net loss per common share, basic and diluted	$ (0.21)	$ (35.84)	$ (0.81)	$ (59.79)
Weighted average common shares outstanding, basic and diluted	23,903,659	446,287	23,613,243	421,861

TriSalus Life Sciences

Condensed Consolidated Balance Sheets (unaudited, in thousands)

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	16,481	11,777
Accounts receivable	4,706	3,554
Inventory, net	3,443	2,545
Prepaid expenses	3,311	2,986
Total current assets	27,941	20,862
Property and equipment, net	1,830	2,091
Right-of-use assets	1,123	1,179
Intangible assets, net	1,113	1,127
Other assets	424	466
Total assets	32,431	25,725
Liabilities and Stockholders' Deficit		
Current liabilities:		
Trade payables	1,976	3,391
Accrued liabilities	9,407	10,556
Short-term lease liabilities	323	351
Other current liabilities	291	389
Total current liabilities	11,997	14,687
Long-term debt, net of unamortized discount and debt issuance costs	21,286	
Revenue base redemption feature	715	
Long-term lease liabilities	1,154	1,244
Contingent earnout liability	8,931	18,632
Warrant and SEPA liabilities	12,497	17,100
Total liabilities	56,580	51,663
Stockholders' deficit:		
Preferred Stock, Series A, $0.0001 par value per share, $10.00 liquidation value per share. Authorized 10,000,000 shares at June 30, 2024, and December 31, 2023, respectively; issued and outstanding, 4,015,002 shares at June 30, 2024 and December 31, 2023, respectively.		
Common stock, $0.0001 par value per share. Authorized 400,000,000 shares at June 30, 2024 and December 31, 2023, respectively; issued and outstanding, 27,159,463 and 26,413,213 shares at June 30, 2024, and December 31, 2024, respectively	2	2
Additional paid-in capital	241,777	222,437
Accumulated deficit	(265,928)	(248,377)
Total stockholders' deficit	(24,149)	(25,938)
Total liabilities and stockholders' deficit	32,431	25,725

Contacts

For Media Inquiries:
Stephanie Jacobson
Argot Partners
610.420.3049
TriSalus@argotpartners.com

For Investor Inquiries:
James Young
SVP-Investor Relations/Treasurer
847.337.0655
james.young@trisaluslifesci.com

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02041	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: American Pharmaceutical Distributors

Physical Address: 6650 Highland Rd Suite 302

City: Waterford State: MI Zip: 48327

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-469-2300 Website: www.AmericanAPD.com

Name of Designated Representative (DR): Antonio Zotti

Licensing Company Email: Compliance@AmericanAPD.com DR Email: TonyZ@AmericanAPD.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

03-26-25

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Braintree Laboratories, INC.
Address: 270 Centre Street City: Holbrook State: MA Zip: 02343

Name: Parmed
Address: 5960 E. Shelby Dr. Ste 100 City: Memphis State: TN Zip: 38141

Name: Mylan Specialty LP
Address: 3711 Ferry Rd. CFS-189 City: Morgantown State: WV Zip: 26505

Name: USWM LLC
Address: 4441 Springdale Rd City: Louisville State: KY Zip: 40241

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Michigan
Parent Company (if any): APD Partners LLC
Corporation/Organization Name: American Pharmaceutical Ingredients LLC
Mailing Address: 6650 Highland Rd Suite 302
City: Waterford State: MI Zip: 48327
Telephone: (855) 469-2300 Email: Compliance@AmericanAPD.com
Contact Person Name: Amen Ramouni

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

American Pharmaceutical Distributors

Facility Name

Amen Ramouni

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3-24-25

Date

Board Use Only	Date Received: 4/23/25	Amount: $1000.00

Accredited Drug Distributors

Find an Accredited Drug Distributor

Facility Name

State (All)

Search Reset

Current list of 18 NABP-Accredited Drug Distributors

Accreditation is valid for three years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

1 2 Next >>

Name	Address	Accreditation Date
American Pharmaceutical Ingredients, LLC dba American Pharmaceutical Distributors	6650 Highland Road, Unit 302 Waterford, MI 48327	10/22/24
AmerisourceBergen Drug Corporation	MI	03/01/25
Auburn Pharmaceutical, LLC dba Auburn	1744 Rochester Industrial Dr Rochester Hills, MI 48309	10/13/24
Bonita Pharmaceuticals LLC dba Bonita Pharmaceuticals	6380 Commerce Drive Westland, MI 48185	10/05/23
Cardinal Health 200, LLC dba Cardinal Health	6000 Rosa Parks Blvd Detroit, MI 48208	05/12/24
Charvi Pharma Services LLC dba Spectrum Pharmaceutical Distributors	1220 Rankin Dr Troy, MI 48083	01/03/24
Concordance Healthcare Solutions, LLC	3625 Park Circle Dr Kalamazoo, MI 49048	Reaccreditation in process
EQ Detroit, Inc dba US Ecology Detroit (South)	1923 Frederick St Detroit, MI 48211	12/12/22

About NABP

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NABP ACCREDITED
DRUG DISTRIBUTOR

American Pharmaceutical Ingredients, LLC
dba American Pharmaceutical Distributors

located at

6650 Highland Road, Unit 302, Waterford, MI 48327

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

0635

APD American Pharmaceutical Distributors®
Human Health Matters®

FDA Registered | BOP Licensed | Dept. of Health Registered | DSCSA Compliant | NABP Accredited Distributor

APD Partners, LLC (EIN: 99-3886917)

Date of Organization in Michigan: 07/09/2024

American Pharmaceutical Ingredients LLC is 100% wholly owned subsidiary of APD Partners LLC

****Members****

Fadi Nuseibeh(Manager)

[redacted]

Amen Ramouni

[redacted]

****ResidentAgent****

USA Records
24530 Ford Rd, Dearborn Heights, MI 48127

****Wholly(100%)Owned Subsidiary****

American Pharmaceutical Ingredients LLC (FEIN: 46-2301708)
dba
American Pharmaceutical Distributors

CEO

Amen Ramouni

[redacted]

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to Certify that the annexed copy has been compared by me with the record on file in this Department and that the same is a true copy thereof.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS ★ Corporations, Securities & Commercial Licensing Bureau ★

In testimony whereof, I have hereunto set my hand, in the City of Lansing, this 19th day of March , 2025.

Linda Clegg

Linda Clegg, Director

Corporations, Securities & Commercial Licensing Bureau

Sent by electronic transmission

Certificate Number: 25030451404

Verify this certificate at: URL to eCertificate Verification Search http://www.michigan.gov/corpverifycertificate.



ID Number: 801683527 Request certificate Return to Results New search

Summary for: AMERICAN PHARMACEUTICAL INGREDIENTS LLC

The name of the DOMESTIC LIMITED LIABILITY COMPANY: AMERICAN PHARMACEUTICAL INGREDIENTS LLC

Entity type: DOMESTIC LIMITED LIABILITY COMPANY

Identification Number: 801683527 **Old ID Number:** E1800F

Date of Organization in Michigan: 03/18/2013

Purpose:

Term: Perpetual

The name and address of the Resident Agent:

Resident Agent Name:	INCORP SERVICES, INC.				
Street Address:	40600 ANN ARBOR ROAD EAST				
Apt/Suite/Other:	STE 200				
City:	PLYMOUTH	State:	MI	Zip Code:	48170

Registered Office Mailing address:

P.O. Box or Street Address:	6650 HIGHLAND ROAD				
Apt/Suite/Other:	UNIT 302				
City:	WATERFORD	State:	MI	Zip Code:	48327

Act Formed Under: 023-1993 Michigan Limited Liability Company Act

Managed By:

Members

View Assumed Names for this Business Entity

View filings for this business entity:

ALL FILINGS
ANNUAL REPORT/ANNUAL STATEMENTS
CERTIFICATE OF CORRECTION
CERTIFICATE OF CHANGE OF REGISTERED OFFICE AND/OR RESIDENT AGENT
RESIGNATION OF RESIDENT AGENT
CERTIFICATE OF ASSUMED NAME

View filings

Comments or notes associated with this business entity:

LARA FOIA Process Transparency State Web Sites

Michigan.gov Home ADA Michigan News Policies

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DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

AMERICAN PHARMACEUTICAL INGREDIENTS
LLC
DBA - AMERICAN PHARMACEUTICAL
DISTRIBUTORS
6650 HIGHLAND ROAD UNIT 302
WATERFORD, MI 48327

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
MANUFACTURER LICENSE

AMERICAN PHARMACEUTICAL INGREDIENTS
LLC
DBA - AMERICAN PHARMACEUTICAL
DISTRIBUTORS
6650 HIGHLAND ROAD UNIT 302
WATERFORD, MI 48327

LICENSE NO.
5306004208

EXPIRATION DATE
08/14/2026

24155100634

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

GRETCHEN WHITMER
GOVERNOR

MARLON I. BROWN, DPA
DIRECTOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

VERIFICATION OF LICENSURE

MICHIGAN BOARD OF PHARMACY

VERIFICATION OF LICENSURE AS OF 03/11/2025

NAME: **American Pharmaceutical Ingredients LLC**
ADDRESS: 6650 Highland Road Unit 302
Waterford, MI 48327

STATUS: Active

LICENSE TYPE: Manufacturer License

LICENSE NUMBER: 5306004208

ORIGINAL DATE: 08/14/2013
EXPIRATION DATE: 08/14/2026
SPECIALTY:
None

EXAM DATE	EXAM TYPE	EXAM RESULTS
	None	

OPEN FORMAL COMPLAINTS

No

DISCIPLINARY ACTION	START DATE	END DATE
No Comments	11/09/2018	11/09/2018
No Comments	11/09/2018	11/09/2018

Brian DeBano, Division Director
Bureau of Professional Licensing
Licensing Division
(517) 241-0199

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100950152

Application/License No. _____

AMERICAN PHARMACEUTICAL INGREDIENTS LLC DBA AMERICAN PHARMACEUTICAL DISTRIBUTORS (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 6650 HIGHLAND RD SUITE 302 WATERFORD, MI, 48327 (Address of Applicant/Principal), as PRINCIPAL, and AMERICAN CONTRACTORS INDEMNITY COMPANY (Surety Company), a corporation organized under the laws of the state of California (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 801 S. Figueroa Street, Suite 700, Los Angeles, CA 90017 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 4/15/2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of April, 2025.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY

AMERICAN CONTRACTORS INDEMNITY COMPANY

Surety Company's Representative

JOSHUA KAYSER, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A Retaliatory
Nevada Resident Agent

TOKIO MARINE HCC

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS:

That American Contractors Indemnity Company of the State of California, a California corporation, does hereby appoint,

JOSHUA KAYSER

its true and lawful Attorney-in-Fact, with full authority to execute on its behalf bond number 100950152, issued in the course of its business and to bind the Company thereby, in an amount not to exceed Twenty-five thousand and 00/100 ($25,000.00).

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the Board of Directors of AMERICAN CONTRACTORS INDEMNITY COMPANY at a meeting duly called and held on the 1st day of September, 2011.

"Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings, including any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts, and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached."

The Attorney-in-Fact named above may be an agent or a broker of the Company. The granting of this Power of Attorney is specific to this bond and does not indicate whether the Attorney-in-Fact is or is not an appointed agent of the Company.

IN WITNESS WHEREOF, American Contractors Indemnity Company has caused its seal to be affixed hereto and executed by its President on this 20th day of November, 2024.

AMERICAN CONTRACTORS INDEMNITY COMPANY

By: _____
Adam S. Pessin, President

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

On this 20th day of November, 2024, before me, D. Littlefield, a notary public, personally appeared Adam S. Pessin, President of American Contractors Indemnity Company, who proved to me on the basis of satisfactory evidence, to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of CALIFORNIA that the foregoing paragraph is true and correct.

D. LITTLEFIELD
Notary Public - California
Los Angeles County
Commission # 2478578
My Comm. Expires Jan 31, 2028

WITNESS my hand and official seal.

Signature _____ (seal)

I, Kio Lo, Assistant Secretary of American Contractors Indemnity Company, do hereby certify that the Power of Attorney and the resolution adopted by the Board of Directors of said Company as set forth above, are true and correct transcripts thereof and that neither the said Power of Attorney nor the resolution have been revoked and they are now in full force and effect.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seals of said Companies at Los Angeles, California this 15th day of April, 2025.

Bond No. 100950152
Agency No. 13266

Kio Lo, Assistant Secretary

Visit tmhcc.com/surety for more information

HCCSOZZPOAACIC12/2023

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: American Pharmaceutical Ingredients LLC dba American Pharmaceutical Distributors

Pharmacy/Wholesaler License # (if applicable): WH02041

Physical Address: 6650 Highland road Suite 302

City: Waterford Township State: MI Zip: 48327-1665

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 734-418-4863 Website: americanapd.com

Licensing Company Email: Compliance@americanapd.com

Section 2: Personal Information

First: Antonio Middle: N/A Last: Zotti

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Rochester Hills State: MI Zip: [redacted]

Telephone: [redacted] Email: tonyz@americanapd.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
William Hingston High School		Graduated in 1975	
Address	**City**	**State**	**Zip**
419 Rue Saint-Roch	Montreal	Quebec	H3N-1K2
Diploma/Degree obtained, if any			
Highschool Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Barry University		Certified in 2013	
Address	**City**	**State**	**Zip**
11300 NE 2nd Ave.	Miami Shores	FL	33161
Diploma/Degree obtained, if any			
Pharmacy Tech Certification			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2022-present	[redacted]	Rochester Hills	MI	[redacted]
11/2021-10/2022		Rochester hills	MI	
06/2021-11/2021		Auburn Hills	MI	
07/2015-06/2021		Boynton Beach	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
American Pharmaceutical Ingredients LLC dba American Pharmaceutical Distributors			09/2015-Present
Business Address	**City**	**State**	**Zip**
6650 Highland Road Suite 302	Waterford Township	MI	48327-1665
Phone	**Title**	**Number of Employed Hours**	
734-418-4863	Warehouse Manager/CDR	16,400	
Description of Duties			
Ordering products, Incoming Product, shipping orders, DSCSA compliance, Inventory counts, Making sure employees comply with SOP's, Opening and closing facility.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03/24/2025
Date

I, Antonio Zotti, **certify that as the designated representative for**

American Pharmaceutical Distributors,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AZ I am at least 21 years of age;
3. AZ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AZ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AZ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AZ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AZ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Antonio Zotti
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/24/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Antonio Zotti

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/24/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Oakland

I, Antonio Zotti, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/24/2025

Date

Subscribed and Sworn to before me this 24th day of March 2025.

HADI HARP
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF WAYNE
My Commission Expires May 3, 2026
Acting In the County of Oakland

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: American Pharmaceutical Distributors

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH03041

Physical Address: 6650 Highland Rd Suite 302

City: Waterford State: MI Zip: 48327

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (855) 469-2300 Website: www.AmericanAPD.com

Licensing Company Email: Compliance@AmericanAPD.com

Section 2: Personal Information

First: Fadi Middle: Mohammed Last: Nuseibeh

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Dearborn State: MI Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wayne State University		09/94 - 05/99	
Address	**City**	**State**	**Zip**
42 Warren Ave	Detroit	MI	48202
Diploma/Degree obtained, if any			
Bachelor of Science Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Fordson High School		09/90 - 06/94	
Address	**City**	**State**	**Zip**
13800 Ford rd	Dearborn	MI	48126
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/23 - present	[redacted]	Dearborn	MI	[redacted]
11/83 - 07/23	[redacted]	Dearborn	MI	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Central Pharmacy			02/09 - present
Business Address	**City**	**State**	**Zip**
3955 Patient Care Drive	Lansing	MI	48911
Phone	**Title**		
517-393-1000	Pharmacy manager		
Description of Duties			
Pharmacist, filling scripts. Managing financials.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6, 7. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
MAY 6 2016	4/26/16	FL	MIAMI	MIAMI-DADE
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
16-016484-CA-01	STATE of FLORIDA, JURISDICTION DISTRICT COURT MIAMI DADE COUNTY			
Reason/Charge				
BUSINESS TORTS / FRAUD				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
FADI NUSEIBEH / REAL ESTATE SALES FORCE HASSIM JABER, BELKIS BERTOT /			LAWSUIT	
Name of Business/Industry/Entity				
REAL ESTATE SALES FORCE / REAL ESTATE /				

Provide explanation below:

I SUED A REAL ESTATE BROKER IN FLORIDA FOR FRAUD. IT WAS SETTLED 2017.

I WAS SEEKING TO PURCHASE TWO CONDO UNITS IN BRICKELL, MIAMI. AMOUNT IN QUESTION WAS $15,000

Original Signature (electronic, copies or stamps not accepted)

3/25/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

FADI NUSEIBEH

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/25/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Wayne

I, FADI NUSEIBEH, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/25/2025

Date

Subscribed and Sworn to before me this 25th day of March 2025.

Notary Public Signature

HADI HARP
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF WAYNE
My Commission Expires May 3, 2026
Acting in the County of _____

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site American Pharmaceutical Distributors

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH02041

Physical Address 6650 Highland Rd Suite 302

City Waterford State MI Zip 48327

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (855) 469-2300 Website www. AmericanAPD.com

Licensing Company Email Compliance@AmericanAPD.com

Section 2: Personal Information

First Amen Middle Ahmed Last Ramouni

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Dearborn State MI Zip [redacted]

Telephone [redacted] Email ARamouni@AmericanAPD.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?'		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wayne State University		09/05 - 09/11	
Address	**City**	**State**	**Zip**
42 W Warren Ave	Detroit	MI	48202
Diploma/Degree obtained, if any			
Bachelors			

School Name		From - To (MM/YY – MM/YY)	
Fordson High School		09/00-06/05	
Address	**City**	**State**	**Zip**
13800 Ford Rd	Dearborn	MI	48126
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/11 - present	[redacted]	Dearborn	MI	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
American Pharmaceutical Distributors			02/25 - present
Business Address	**City**	**State**	**Zip**
6650 Highland Rd Suite 302	Waterford	MI	48327
Phone	**Title**		
(855) 469-2300	CEO		

Description of Duties

Manage and oversee APD and all operations

Business Name			From - To (MM/YY – MM/YY)
Bonita Pharmaceuticals			01/17-01/25
Business Address	**City**	**State**	**Zip**
6380 Commerce Dr	Westland	MI	48185
Phone	**Title**		
(734) 729-7200	VP Sales & Marketing		

Description of Duties

Managed Inside and Outside Sales Reps
Responsible for top line revenue
Optimized Sales Operations

Business Name			From - To (MM/YY – MM/YY)
The Fairlane Club			06/13 - 04/16
Business Address	**City**	**State**	**Zip**
5000 Fairlane Woods Dr	Dearborn	MI	48126
Phone	**Title**		
(313) 336-4400	Athletic Director		

Description of Duties

Handled All club and athletics operations

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03-26-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

AMEN RAMOUNI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-24-25

Date

Please have this section completed in the presence of a Notary Public.

State of MICHIGAN, ss. County of OAKLAND

I, AMEN RAMOUNI, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3-24-25

Date

Subscribed and Sworn to before me this 24th day of March, 2025.

Notary Public Signature

HADI HARP
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF WAYNE
My Commission Expires May 3, 2026
Acting In the County of Oakland

(Seal)

List of employees and contractors

Amen Ramouni - CEO - Employee

Antonio Zotti - Warehouse Manager/CDR - Employee

Albretta Files - Contractor - Compliance consultant

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: The Hilsinger Company Parent, LLC dba Hilco Vision

Physical Address: 9240 Seward Road

City: Fairfield State: OH Zip: 45014

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: 800-955-6544 Website: https://www.hilcovision.com/

Name of Designated Representative (DR): Charles Hicks

Licensing Company Email: licensing@hilcovision.com DR Email: Charles.Hicks@hilcovision.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see Attachment #1 - There is not past, current, or pending disciplinary action for the facility located in Fairfield, OH. The attached discipline has been previously reported to NV BOP. Discipline was taken against facilities which are now closed.

John M.

Original Signature (electronic, copies or stamps not accepted)

4/7/25

Date

HILCO VISION

575 West Street
Suite 120
Mansfield, MA 02048

www.hilcovision.com
T: (800) 955-6544
F: (800) 995-2154

Attachment #1 - Disciplinary Action Summary: Current as of 1/10/2025

All below listed wholesale distributor facilities operate and/or previously operated under the same ownership of The Hilsinger Company Parent, LLC d/b/a Hilco Vision, with Hilsinger Holdings, LLC as the Sole Member. The below listed impacted facilities operated under different officers and directors than the affiliate facilities which are currently operational.

Impacted Facilities
- 33 W Bacon Street, Plainville, MA 02762 (closed)
- 4646 S. Overland Drive, Tucson, AZ 85714 (closed)

Other Affiliate Facilities
- 3908 N 5th Street, North Las Vegas, NV 89032
- 9240 Seward Road, Fairfield, OH 45014

There is no past, current or pending disciplinary sanctions for facilities located in Fairfield, OH, and North Las Vegas, NV. There is disciplinary action against two former locations in Plainville, MA and Tucson, AZ facilities. Please note that Hilco Vision has ceased all operations out of both facilities.

Prior to the Las Vegas and Fairfield facilities opening, the business affiliates had previously operated as a corporation under the name of "The Hilsinger Company d/b/a Hilco." A change of ownership occurred on September 6, 2019. Since then, the applicant has been operating as a limited liability company under the name of "The Hilsinger Company Parent, LLC d/b/a Hilco Vision". All discipline listed below has occurred after the change of ownership. The below sanctions resulted from administrative reporting of the 2019 change of ownership and the reciprocal discipline that compounded thereafter.

Please note this is a summary of all final and resolved discipline. All finalized documentation for each case has previously been submitted. The 101 pages can be provided upon request.

Final: **Plainville, MA** *(building closed 2022)*
- 1. Missouri: Jun 2021; Probation
- 2. Wyoming: Docket No. 2021-17C; Apr 2022; Voluntary Suspension & Fine
- 3. Utah: Case 132158: Citation; Apr 2022; Fine
- 4. New Mexico: Case 2021-046; Apr 2022; Fine
- 5. Alabama: Case 21-L-0184; Aug 2022; Probation & Fine
- 6. Oregon: Case 2021-0832; Aug 2022; Fine
- 7. Colorado: Case 2022-4690; Nov 2022; Letter of Admonition
- 8. Virginia: Case 224254; Dec 2022; Suspension
- 9. Maine: Case 2022-PHA-18402; Jan 2023; Fine
- 10. Idaho: Case BOP-21-145; Dec 2024; Fine

Final: **Tucson, AZ** *(building closed 2023)*
- 11. Utah: Case #132854: Citation; Apr 2022; Fine
- 12. New Mexico: Case 2021-063; Apr 2022; Fine
- 13. Alabama: Case # 22-L-0127: Aug 2022; Probation & Fine
- 14. Virginia: Case # 224253; Dec 2022; Suspension

Summary of Disciplinary Action History – Final

1	State & Jurisdiction	**Missouri Board of Pharmacy**
	Case Name	**Order of the Missouri Board of Pharmacy Issuing The Hilsinger Company Parent, LLC A Drug Distributor License Subject to Probation**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	6/9/2021
	Affected License	MO Drug Distributor license # 2021021107
	Fee/Penalty	Probation
	Description	Order Issuing of a Drug Distributor License Subject to Probation; Plainville, MA facility was issued a license subject to PROBATION for two years for shipping into Missouri without an active drug distributor license during the period of a Change of Ownership.
	Status	Final; License was on probation for two years. Plainville facility is closed. Case is resolved.

2	State & Jurisdiction	**Wyoming State Board of Pharmacy**
	Case Number	**Docket No. 2021-17C**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	4/5/2022
	Affected License	WY Wholesale Distributor License # WD1918
	Fee/Penalty	$60,000
	Description	Settlement Agreement, Stipulation, and Order; $60,000 administrative fine to be issued to Plainville, MA facility and voluntarily SUSPENSION of license until able to provide proof of DDA (formerly VAWD accreditation) with NABP
	Status	Final; License was suspended and fine was paid. Plainville facility is closed. Case is resolved.

3	State & Jurisdiction	**Utah Division of Occupational and Professional Licensing**
	Case Number	**132158** Citation # 101668
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	3/21/2022; Citation Paid 4/19/22
	Affected License	UT Pharmacy-Class C (Distributor) license # 12260272-1710
	Fee/Penalty	$5,000
	Description	Citation; Reciprocal Action Imposed by UT in response to MO disciplinary action; Plainville, MA facility was fined $5,000 for inadvertently shipping prescription drugs to Utah between the dates of the change of ownership and the application of a new Class C Wholesale/Distributor Pharmacy license. During this time, the facility did not hold a required, valid Class C Wholesale/Distributor license.
	Status	Final; Fine was paid. Plainville facility is closed. Case is resolved.

4	State & Jurisdiction	**New Mexico State Board of Pharmacy**
	Case Number	**2021-046**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	4/22/2022
	Affected License	NM Wholesaler Distributor License # WD00013123 issued 4/22/2022 (New application for licensure due to Change of Ownership was pending at time of issuance of settlement agreement)
	Fee/Penalty	$1,350
	Description	Pre-NCA Settlement Agreement; Reciprocal Action Imposed by NM in response to MO disciplinary action; $1,350 administrative fine issued to Plainville, MA facility for shipping prescription drugs into New Mexico during the change of ownership from January 1, 2021, through July 29, 2021.
	Status	Final; Received fully signed agreement on 4/25/2022. Fine was paid. Plainville facility is closed. Case is resolved.

5	State & Jurisdiction	**Alabama Board of Pharmacy**
	Case Number	**21-L-0184**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	8/10/2022
	Affected License	AL Wholesale Distributor License # 195009
	Fee/Penalty	Probation; $6,000 administrative fine (total for both Plainville, MA and Tucson, AZ facilities)
	Description	Consent Order; Reciprocal Action Imposed by AL in response disciplinary action reporting of: • Missouri discipline regarding a license on probation, • Utah citation fine • Wyoming discipline regarding a voluntary suspension of license • New Mexico discipline regarding administrative fine
	Status	Final; Received fully signed Consent Order on 8/10/2022. Fine was paid. Plainville facility is closed. Case is resolved.

6	State & Jurisdiction	**Oregon Board of Pharmacy**
	Case Number	**2021-0832**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	8/17/2022
	Affected License	OR Registration # W1-0004469
	Fee/Penalty	Probation; $1,000 administrative fine
	Description	Consent Order; Reciprocal Action Imposed by OR in response to reporting of MO discipline regarding a license on probation and not reporting MO discipline within required timeframe.
	Status	Final; Received fully executed Consent Order on 8/25/22. Fine was paid. Plainville facility is closed. Case is resolved.

7	State & Jurisdiction	**Colorado Department of Regulatory Agencies - Division of Professions and Occupations**
	Case Number	**2022-4690**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	11/18/2022
	Affected License	CO License # WHO.8119
	Fee/Penalty	Letter of Admonition
	Description	Reciprocal investigation in Colorado from reporting of Wyoming discipline regarding a voluntary suspension of license
	Status	Final; No formal proceedings against wholesale license. However, did receive Letter of Admonition dated 11/18/22. Plainville facility is closed. Case is resolved.

8	State & Jurisdiction	**Virginia Department of Health Professions**
	Case Number	**224254**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	12/12/2022
	Affected License	VA Wholesale Distributor License # 0219001677
	Fee/Penalty	Mandatory Suspension
	Description	Order of Mandatory Suspension; Reciprocal Action Imposed by VA in response to disciplinary action reporting of Alabama discipline. Alabama license was on probation; however, Virginia order stated that the Alabama license was suspended.
	Status	Final; License was suspended. Plainville facility was already closed at the time of suspension. Reinstatement of license not needed. Case is resolved.

9	State & Jurisdiction	**Maine Department of Professional and Financial Regulation-Board of Pharmacy**
	Case Number	**2022-PHA-18402**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	1/13/2023
	Affected License	WH70002458
	Fee/Penalty	$500
	Description	Consent Agreement; Reciprocal discipline imposed by Maine from reporting of Missouri discipline from June 2021. Acceptance of reprimand and $500 civil penalty.
	Status	Final; Fine was paid. Plainville facility is closed. Case is resolved.

10	State & Jurisdiction	**Idaho Board of Pharmacy**
	Case Number	**BOP-21-145**
	Entity Involved	The Hilsinger Company
	Facility	33 W Bacon St, **Plainville, MA** drug distributor facility
	Effective Date	12/11/2024
	Affected License	W56851
	Fee/Penalty	$4,000
	Description	Stipulation and Consent Order; Failure to Properly Submit Change of Ownership and Failure to Fully Cooperate with a Board Investigation in December 2020 through June 2021. A civil fine of $4,000 was paid for Plainville, MA facility.
	Status	Final; Fine was paid. Plainville facility was already closed at the time Order was effective. Case is resolved.

11	State & Jurisdiction	**Utah Division of Occupational and Professional Licensing**
	Case Number	**132854** (Citation # 101669)
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	4646 South Overland Drive, **Tucson, AZ** drug distributor facility
	Effective Date	3/21/2022; Citation Paid 4/19/22
	Affected License	UT Pharmacy-Class C (Distributor) license # 12019303-1710
	Fee/Penalty	$5,000
	Description	Citation; Reciprocal Action Imposed by UT in response to MO disciplinary action; Tucson, AZ facility was fined $5,000 for inadvertently shipping prescription drugs to Utah between the dates of the change of ownership and the application of a new Class C Wholesale/Distributor Pharmacy license. During this time, the facility did not hold a required, valid Class C Wholesale/Distributor license.
	Status	Final; Fine was paid. Tucson facility closed 2/28/23. Case is resolved.

12	State & Jurisdiction	**New Mexico State Board of Pharmacy**
	Case Number	**2021-063**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	4646 South Overland Drive, **Tucson, AZ** drug distributor facility
	Effective Date	4/22/2022
	Affected License	NM Wholesaler Distributor License # WD00013122 issued 4/22/2022 (New application for licensure due to Change of Ownership was pending at time of issuance of settlement agreement)
	Fee/Penalty	$1,350
	Description	Pre-NCA Settlement Agreement; Reciprocal Action Imposed by NM in response to MO disciplinary action; $1,350 administrative fine issued to Tucson, AZ facility for shipping prescription drugs into New Mexico during the change of ownership from January 4, 2021, until September 15, 2021.
	Status	Final; Received fully signed agreement on 4/25/2022. Fine was paid. Tucson facility closed 2/28/23. Case is resolved.

13	State & Jurisdiction	**Alabama Board of Pharmacy**
	Case Number	**22-L-0127**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	4646 South Overland Drive, **Tucson, AZ** drug distributor facility
	Effective Date	8/10/2022
	Affected License	AL Wholesale Distributor License # 194912
	Fee/Penalty	Probation; $6,000 administrative fine (total for both Plainville, MA and Tucson, AZ facilities)
	Description	Consent Order; Reciprocal Action Imposed by AL in response to disciplinary action reporting: • New Mexico discipline regarding administrative fine • Utah citation fine
	Status	Final; Received fully signed Consent Order on 8/10/2022. Fine was paid. Tucson facility closed 2/28/23. Case is resolved.

14	State & Jurisdiction	**Virginia Department of Health Professions**
	Case Number	**224253**
	Entity Involved	The Hilsinger Company Parent, LLC d/b/a Hilco Vision
	Facility	4646 South Overland Drive, **Tucson, AZ** drug distributor facility
	Effective Date	12/12/2022
	Affected License	VA Wholesale Distributor License # 0219001691
	Fee/Penalty	Mandatory Suspension
	Description	Order of Mandatory Suspension; Reciprocal Action Imposed by VA in response to disciplinary action reporting of Alabama discipline. Alabama license was on probation; however, Virginia order stated that the Alabama license was suspended.
	Status	Final; Received Order from VA DOH on 12/19/22 License was suspended and all shipments ceased to Virginia. Tucson facility closed 2/28/23, Reinstatement of license not needed. Case is resolved.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: ALTAIRE PHARMACEUTICALS, INC
Address: 311 West Lane City: Aquebogue State: NY Zip: 11931

Name: BAUSCH & LOMB AMERICAS INC
Address: 400 Somerset Corporate Blvd 8th Fl City: Bridgewater State: NJ Zip: 08807

Name: SANDOZ
Address: 100 College Road West City: Princeton State: NJ Zip: 08540

Name: ALCON LABORATORIES, INC.
Address: 6601 Oak Grove Rd Ste 300 City: Fort Worth State: TX Zip: 76134

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Hilsinger Holdings LLC
Corporation/Organization Name: The Hilsinger Company Parent, LLC dba Hilco Vision
Mailing Address: 575 West Street, Suite 120
City: Mansfield State: MA Zip: 02048
Telephone: (800) 955-6544 Email: licensing@hilcovision.com
Contact Person Name: Williams Sands, Jr.

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** Attachment #2	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** Attachment #2		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** Attachment #3	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Attachment #4		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Attachment #5	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** Attachment #6	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ Attachment #7	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). Attachment #8	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. Attachment #9		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. Attachment #10		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

The Hilsinger Compay Parent, LLC dba Hilco Vision

Facility Name

Girisha Chandraraj

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/13/25

Date

Board Use Only	Date Received: 4/21/25	Amount: $1000 #146046

HILCO Vision

575 West Street
Suite 120
Mansfield, MA 02048

www.hilcovision.com
T: (800) 955-6544
F: (800) 995-2154

The Hilsinger Company Parent, LLC d/b/a Hilco Vision
9240 Seward Road,
Fairfield, OH 45014

Attachment #2 – Drug Distributor Accreditation Certificate

Copy of Drug Distributor Accreditation Certificate



NABP ACCREDITED
DRUG DISTRIBUTOR

The Hilsinger Company Parent LLC
dba Hilco Vision

located at

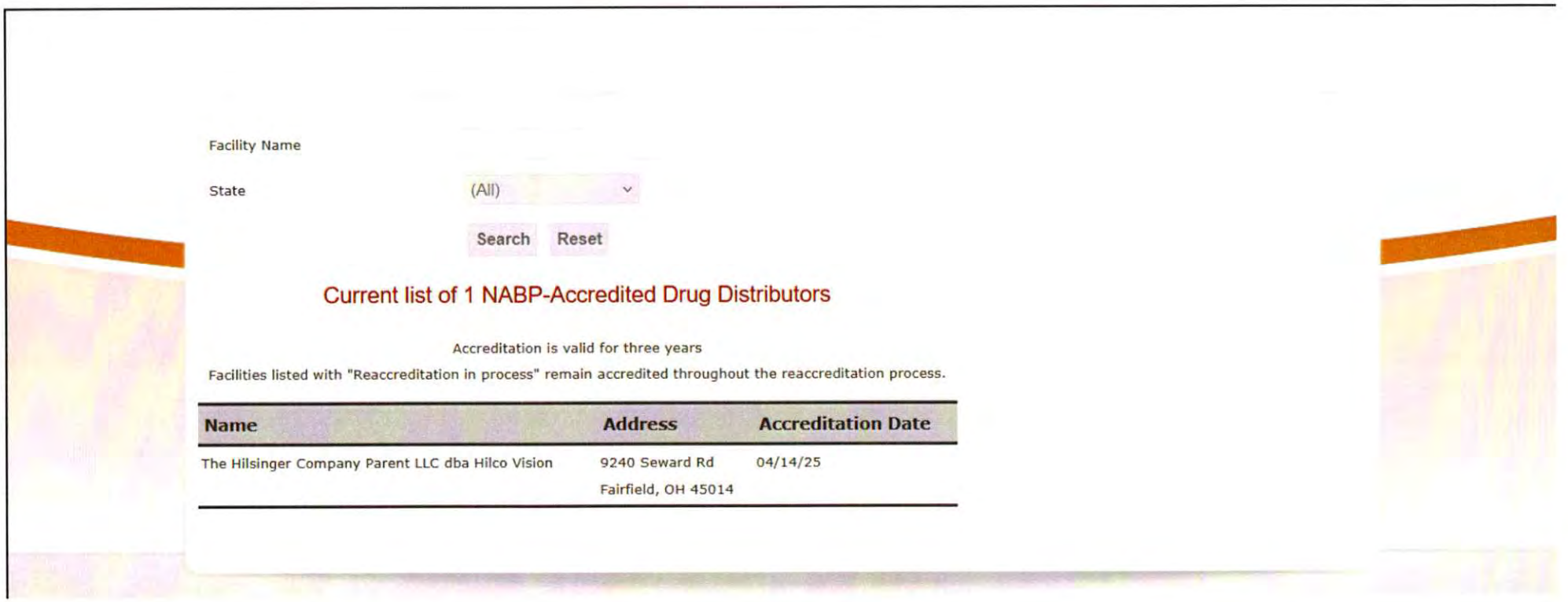
9240 Seward Road, Fairfield, OH 45014

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

Accredited Drug Distributors

Find an Accredited Drug Distributor



Facility Name

State (All)

Search Reset

Current list of 1 NABP-Accredited Drug Distributors

Accreditation is valid for three years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
The Hilsinger Company Parent LLC dba Hilco Vision	9240 Seward Rd Fairfield, OH 45014	04/14/25

HILCO VISION

575 West Street
Suite 120
Mansfield, MA 02048

www.hilcovision.com
T: (800) 955-6544
F: (800) 995-2154

The Hilsinger Company Parent, LLC d/b/a Hilco Vision
9240 Seward Road,
Fairfield, OH 45014

Attachment #4 - Officers List & Organizational Structure

- *List of all Officers and Directors.*
- *List of all corporation shareholders and their percent ownership.*

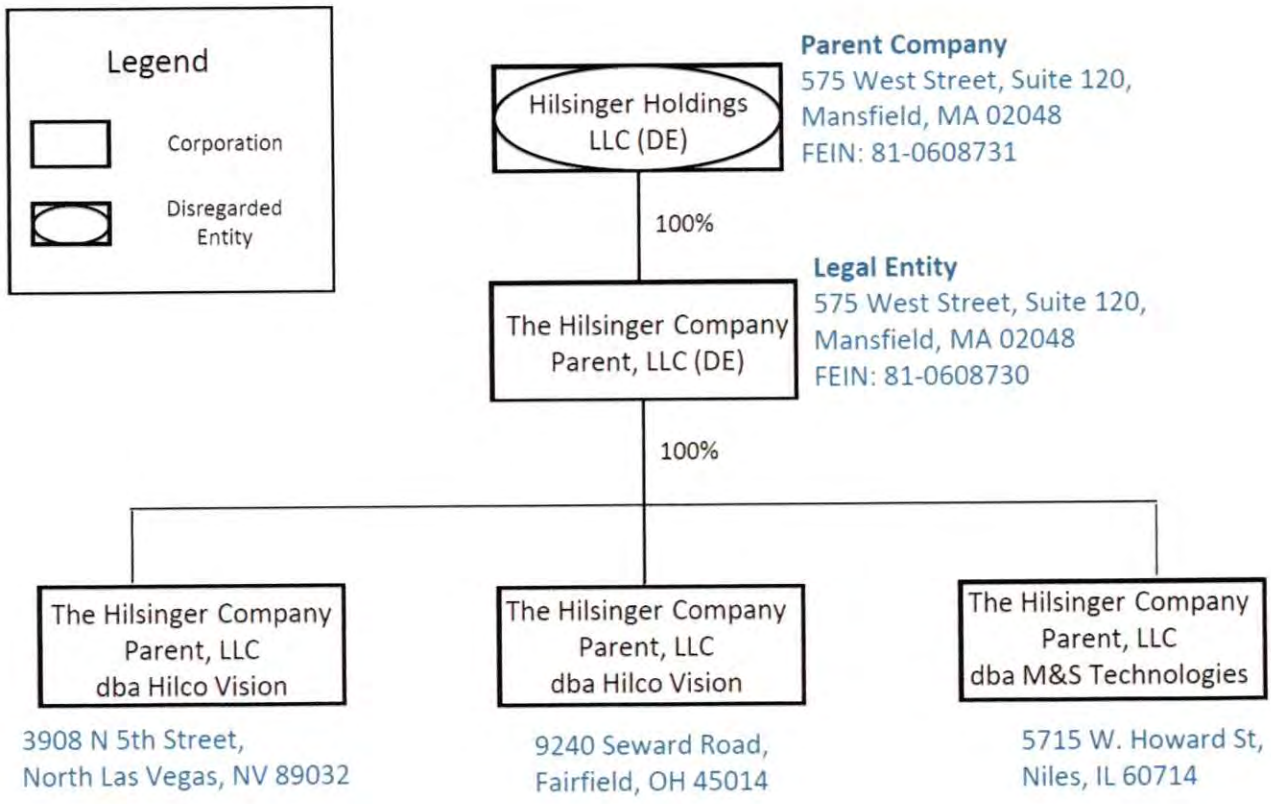
Limited Liability Company – Sole Member (Parent Company)	Percent Ownership
Hilsinger Holdings, LLC 575 West Street, Suite 120 Mansfield, MA 02048	100%
FEIN: 81-0608731	

Legal Entity	Directors	Officers
The Hilsinger Company Parent, LLC 575 West Street, Suite 120 Mansfield, MA 02048 State Incorporated: Delaware Date Incorporated: September 6, 2019	Sole Member: Hilsinger Holdings, LLC	Girisha Chandraraj – CEO & President Sean Bogue – CFO & Treasurer John Lakey – Assistant Secretary William Sands – Chief Operating Officer
FEIN: 81-0608730		

Officer Name	Officer Title	Business Address	Business Phone	Percent Ownership
Girisha Chandraraj	CEO & President	575 West Street, Suite 120 Mansfield, MA 02048	508-699-4406	0%
Sean Bogue	CFO & Treasurer	575 West Street, Suite 120 Mansfield, MA 02048	508-699-4406	0%
John Lakey	Assistant Secretary	575 West Street, Suite 120 Mansfield, MA 02048	508-699-4406	<1%
William Sands	Chief Operating Officer	9240 Seward Road, Fairfield, OH 45014	800-955-6544	0%

Effective 2/17/2025

Organizational Structure



HILCO VISION

575 West Street
Suite 120
Mansfield, MA 02048

www.hilcovision.com
T: (800) 955-6544
F: (800) 995-2154

The Hilsinger Company Parent, LLC d/b/a Hilco Vision
9240 Seward Road,
Fairfield, OH 45014

Attachment #5– Certificate of Good Standing (DE)

Certificate of Corporate Status or Certificate of Good Standing obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last 12 months.

(See attached 1 page of Delaware Secretary of State Certificate of Good Standing for "The Hilsinger Company Parent, LLC" dated on 02/05/2025)

Delaware

The First State

I, CHARUNI P. SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "THE HILSINGER COMPANY PARENT, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF FEBRUARY, A.D. 2025.

C. P. Sanchez

Charuni P. Sanchez, Secretary of State

3630161 8300

5R# 20250375599

Authentication: 202859585

Date: 02-04-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

eLicense Ohio
Professional Licensure

License Look Up

7/30/2025 6:36 PM

THE HILSINGER COMPANY PARENT LLC

License Number	0130000465
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Wholesaler - Category 2
License Issue Date	4/26/22
License Expiration Date	6/30/27
License Effective Date	7/1/25
Street Address	9240 Seward Rd
City	Fairfield
State	OH
Zipcode	45014-5457
Country	United States
Board Action	No

Current date & time: **7/30/2025 6:36 PM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

IAT INSURANCE GROUP Surety

HARCO NATIONAL INSURANCE COMPANY

BOND RIDER

To be attached to and form a part of Bond No TXHNSU 0357822

Dated The 2nd Day of April 2024 By and Between:

The Hilsinger Company Parent, LLC , as Principal, and

_____ as Surety, in favor of State of Nevada

_____ , as Obligee.

It is understood and agreed that the bond is changed or revised in the particulars checked below:

☐ Name of Principal changed to:

_____

_____

☐ Amount of Bond changed from _____
to _____

☑ Other Adding location: 9240 Seward Road, Fairfield, OH 45014
Remove location: 575 West Street, Ste 120, Mansfield, MA 02048

Said bond shall be subject to all its terms, conditions and limitations, except as herein expressly modified. This bond Rider shall become effective as of July 22, 2024

IN WITNESS WHEREOF, has caused its corporate seal to be hereunto affixed this 22nd day of July, 2024.

Principal: The Hilsinger Company Parent, LLC
By: _____

By: _____
Florence McClellan Attorney-in-Fact

POWER OF ATTORNEY

Bond # TXHNSU 0357822

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

TIMOTHY F. KELLY, AARON P. CLARK, TERESA D. KELLY, FLORENCE MCCLELLAN, CRAIG C. PAYNE, RACHEL RICHARDSON, LAURA KNEITZ, ROBERT F. BOBO

Houston, TX

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or egents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, HARCO NATIONAL INSURANCE COMPANY and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2023

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2023 , before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC COMMISSION EXPIRES 4-16-2024 STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2024

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, July 22, 2024

A00717

Irene Martins, Assistant Secretary

HILCO VISION

575 West Street
Suite 120
Mansfield, MA 02048

www.hilcovision.com
T: (800) 955-6544
F: (800) 995-2154

The Hilsinger Company Parent, LLC d/b/a Hilco Vision
9240 Seward Road,
Fairfield, OH 45014

Attachment #3 – Surety Bond

Copy of a bond in an amount of $25,000 made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration.

$100,000 Surety Bond was obtained prior to receiving Drug Distributor Accreditation on 4/15/25, otherwise a $25,000 Bond would have been obtained.

(See attached 5 pages Nonresident Wholesaler Surety Bond and Rider # TXHNSU 0357822)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. TXHNSU 0357822

Application/License No. _____

The Hilsinger Company Parent, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 575 West Street, Suite 120, Mansfield, MA 02048 and 3908 N 5th St., North Las Vegas, NV 89032 (Address of Applicant/Principal), as PRINCIPAL, and Harco National Insurance Company (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 4200 Six Forks Rd., Suite 1400, Raleigh, NC 27609 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 2, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 2nd day of April, 20 24.

APPLICANT/PRINCIPAL

COMPANY
The Hilsinger Company Parent, LLC

Diana Melson
Authorized Representative

SURETY

Harco National Insurance Company

Surety Company's Representative

Florence McClellan, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Tami Jones

Witness Kala Lee

Countersigned by:

N/A
Nevada Resident Agent

POWER OF ATTORNEY

Bond # TXHNSU 0357822

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY,** a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY,** a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

TIMOTHY F. KELLY, AARON P. CLARK, TERESA D. KELLY, FLORENCE MCCLELLAN, CRAIG C. PAYNE, RACHEL RICHARDSON, LAURA KNEITZ, ROBERT F. BOBO

Houston, TX

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY,** as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED,** that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2023

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2023, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY;** that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC STATE OF NEW JERSEY MY COMMISSION EXPIRES 4-16-2024

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2024

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, April 2, 2024

A00717

Irene Martins, Assistant Secretary

CERTIFICATE OF LIABILITY INSURANCE

11/1/2025

DATE (MM/DD/YYYY): 4/7/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	Lockton Companies, LLC DBA as Lockton Insurance Brokers, LLC in CA CA license #0F15767 3657 Briarpark Dr., Ste. 700 Houston TX 77042 (866) 260-3538
CONTACT NAME:	
PHONE (A/C, No, Ext):	FAX (A/C, No):
E-MAIL ADDRESS:	
INSURED	1468893 The Hilsinger Company Parent, LLC DBA Hilco Vision 9240 Seward Road Fairfield OH 45014

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Twin City Fire Insurance Company	29459
INSURER B : Trumbull Insurance Company	27120
INSURER C : --- SEE ATTACHMENT ---	
INSURER D : Arch Specialty Insurance Company	21199
INSURER E :	
INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** 21609319 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT LOC OTHER:	N	N	61CESOF0AWG	12/1/2024	12/1/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 300,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ 2,000,000 $
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS HIRED AUTOS ONLY NON-OWNED AUTOS ONLY	N	N	61UENBB0L89	12/1/2024	12/1/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ XXXXXXX $ XXXXXXX $ XXXXXXX $ XXXXXXX
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $ 10,000	N	N	61XS ON0AAB	12/1/2024	12/1/2025	EACH OCCURRENCE AGGREGATE $	$ 10,000,000 $ 10,000,000 $ XXXXXXX
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) [N] If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	N	61WE BB0L7W	12/1/2024	12/1/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
D	Cyber Liability:	N	N	C-4LPY-051141	11/1/2024	11/1/2025	$5M Agg Limit / $150K Retention	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
THIS CERTIFICATE SUPERSEDES ALL PREVIOUSLY ISSUED CERTIFICATES FOR THIS HOLDER, APPLICABLE TO THE CARRIERS LISTED AND THE POLICY TERM(S) REFERENCED.

CERTIFICATE HOLDER

21609319

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno NV 89521

CANCELLATION See Attachment

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE



ACORD 25 (2016/03)
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The ACORD name and logo are registered marks of ACORD

Workers Compensation Issuing Companies	
State	Company
Arizona	Hartford Casualty Insurance Company
Arkansas	Twin City Fire Insurance Company
California	Sentinel Insurance Company LTD
Colorado	Twin City Fire Insurance Company
Florida	Twin City Fire Insurance Company
Connecticut	Twin City Fire Insurance Company
Georgia	Hartford Underwriters Insurance Company
Illinois	Hartford Underwriters Insurance Company
Indiana	Twin City Fire Insurance Company
Kentucky	Twin City Fire Insurance Company
Maine	Twin City Fire Insurance Company
Massachusetts	Twin City Fire Insurance Company
Missouri	Hartford Underwriters Insurance Company
Montana	Property and Casualty Insurance Company of Hartford
Nevada	Hartford Underwriters Insurance Company
New Jersey	Hartford Underwriters Insurance Company
New York	Twin City Fire Insurance Company
North Carolina	Hartford Underwriters Insurance Company
Ohio	Twin City Fire Insurance Company
Oklahoma	Twin City Fire Insurance Company
Pennsylvania	Twin City Fire Insurance Company
Rhode Island	Hartford Accident and Indemnity Company
South Carolina	Twin City Fire Insurance Company
Texas	Hartford Underwrites Insurance Company
Virginia	Twin City Fire Insurance Company
Washington	Twin City Fire Insurance Company
Wisconsin	Hartford Casualty Insurance Company
Wyoming	Twin City Fire Insurance Company

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG The Hilsinger Company Parent,LLC dba Hilco Vision MDEG License # (if applicable) _____

Physical Address 9240 Seward Road

City Fairfield State OH Zip 45014

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email licensing@hilcovision.com

Section 2: Personal Information

First Charles Middle Roland Last Hicks

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Hamilton State OH Zip [redacted]

Telephone [redacted] Email Charles.Hicks@hilcovision.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Palo Verde High School		08/99-05/03	
Address	**City**	**State**	**Zip**
1302 S Avenida Vega	Tucson	AZ	85710
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/25- Present	[redacted]	Hamilton	OH	[redacted]
04/23 – 02/25		West Chester	OH	
09/18 - 04/23		Tucson	AZ	
04/15 - 08/18		Tucson	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
The Hilsinger Company Parent, LLC dba Hilco Vision			04/23 - Present	
Business Address		**City**	**State**	**Zip**
9240 Seward Road		Fairfield	OH	45014
Phone	**Title**		**Number of Employed Hours**	
800-955-6544	Key Account Lot Manager		19,728	
Description of Duties				
Monitors the integrity of the cold chain process.Trains staff on regulatory processes and procedures. Key participant in defining and implementing processes that align with key facility certifications and programs (e.g., DDA, ISO, cGMP). Leads effort to comply with the drug supply chain security act (DSCSA) including establishing standard operating procedures for identifying product changes and potential counterfeit issues.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6/30/25
Date

I, Charles Hicks, **certify that as the MDEG Administrator for**

The Hilsinger Company Parent, LLC dba Hilco Vision,

that I (initial that you have read and meet the following requirements):

1. CH Have a high school diploma or its equivalent;
2. CH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Charles Hicks
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/27/25
Date

Board Use Only	Date Received: 7/2/25

HILCO VISION

575 West Street
Suite 120
Mansfield, MA 02048

www.hilcovision.com
T: (800) 955-6544
F: (800) 995-2154

The Hilsinger Company Parent, LLC d/b/a Hilco Vision
9240 Seward Road,
Fairfield, OH 45014

Attachment #6– Designated Representative Application

Designated Representative form must be completed by the Designated Representative.

(See attached 9 pages of Nevada Designated Representative Application for Charles Hicks)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: The Hilsinger Company Parent, LLC d/b/a Hilco Vision

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 9240 Seward Road

City: Fairfield State: OH Zip: 45014

Mailing Address (if different from physical address): 9240 Seward Road

City: Fairfield State: OH Zip: 45014

Telephone: 800-955-6544 Website: www.hilcovision.com

Licensing Company Email: licensing@hilcovision.com

Section 2: Personal Information

First: Charles Middle: Roland Last: Hicks

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Hamilton State: OH Zip: [redacted]

Telephone: [redacted] Email: Charles.Hicks@hilcovision.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Palo Verde High School		08/99-05/03	
Address	**City**	**State**	**Zip**
1302 S Avenida Vega	Tucson	AZ	85710
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/25- Present	[redacted]	Hamilton	OH	[redacted]
04/23 – 02/25		West Chester	OH	
09/18 - 04/23		Tucson	AZ	
04/15 - 08/18		Tucson	AZ	
04/14 - 03/15		Tucson	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
The Hilsinger Company Parent, LLC d/b/a Hilco Vision			04/23 - Present
Business Address	**City**	**State**	**Zip**
9240 Seward Road	Fairfield	OH	45014
Phone	**Title**	**Number of Employed Hours**	
800-955-6544	Key Account Lot Manager	4,060	

Description of Duties

Monitors the integrity of the cold chain process.Trains staff on regulatory processes and procedures. Key participant in defining and implementing processes that align with key facility certifications and programs (e.g., DDA, ISO, cGMP). Leads effort to comply with the drug supply chain security act (DSCSA) including establishing standard operating procedures for identifying product changes and potential counterfeit issues.

Business Name			From - To (MM/YY – MM/YY)
The Hilsinger Company Parent, LLC d/b/a Eye Care and Cure, d/b/a Hilco Vision			12/18 - 04/23
Business Address	**City**	**State**	**Zip**
4646 South Overland Drive	Tucson	AZ	85714
Phone	**Title**	**Number of Employed Hours**	
800-955-6544	Distribution Center Manager, Distribution Center Lead	8,690	

Description of Duties

Responsible for management of Tucson wholesale distribution warehouse including managing all warehouse staff. Led inventory control and management, and pharmaceutical recall processes and procedures. Served as distribution lead on key cross-functional projects including cold chain, ERP, WMS, policy and purchasing rationalization. Responsible for DSCSA processes and verification within the receiving process for all pharmaceutical suppliers.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

4/15/25
Date

I, Charles Hicks, **certify that as the designated representative for**

The Hilsinger Company Parent, LLC d/b/a Hilco Vision,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Charles Hicks

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/15/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Charles Hicks

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/15/25

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Butler

I, Charles Hicks, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/15/25

Date

Subscribed and Sworn to before me this 15 day of April 2025.

Danielle Johnson

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

Danielle Johnson
Notary Public, State of Ohio
My Commission Expires:
October 16, 2029 (Seal)

HILCO VISION

575 West Street
Suite 120
Mansfield, MA 02048

www.hilcovision.com
T: (800) 955-6544
F: (800) 995-2154

The Hilsinger Company Parent, LLC d/b/a Hilco Vision
9240 Seward Road,
Fairfield, OH 45014

Attachment #7 - Updated List of Employees

An updated list of each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the wholesaler.

Last Name	First Name	Title	Position	Handles Drugs
Antonio Martin	Gabriela	Distribution Assoc I	Employee	Yes
Carter	Chuck	Inventory Control	Employee	Yes
Chalk	Keith	Pick/pack	Employee	Yes
Companion	Jared	Receiving Supervisor	Employee	Yes
Dhingana	Tika	Distribution Assoc III	Employee	Yes
Guragain	Biren	Distribution Center Lead	Employee	Yes
Hicks	Charles	Inventory Manager / DR	Employee	Yes
Karki	Tulasi	Distribution Assoc I	Employee	Yes
Keith	Kathy	Inventory Control Supv	Employee	Yes
Lamgadey	Tila	Distribution Assoc I	Employee	Yes
Monica	Thomas	Receiver	Employee	Yes
Nunn	Samuel	Distribution Center Lead	Employee	Yes
Perez	Daylor	Material Handler Whse	Employee	Yes
Putman	Sean	Distribution Supervisor	Employee	Yes
Rai	Parbati	Inventory Control	Employee	Yes
Rai	Sony	Distribution Assoc I	Employee	Yes
Sinchuiri	Roshan	Inventory Control Lead	Employee	Yes
Siwakoti	Namita	Distribution Assoc I	Employee	Yes
Barnett	Jerry	Maintenance Supervisor	Employee	No
Bell	Andrew	VP, North American Ops.	Employee	No
Hawkins	Charles	Operations Manager	Employee	No
Hufnagle	David	VP of Global QARA	Employee	No
Johnson	Angela	Wave Planner	Employee	No
Johnson	Danielle	HR Generalist	Employee	No
Jones	Rodney	Janitor	Employee	No
Kratowicz	Tony	Chief Information Officer	Employee	No
Moore	Aaron	Chemical Technician	Employee	No
Obermeyer	Todd	Chemical Technician/Porter	Employee	No
Owens	Blake	Distribution Manager	Employee	No
Sands	Will	Chief Operating Officer	Employee	No
Seksaria	Shivani	Quality Engineer	Employee	No
Stoppelwert	Kyle	IT	Employee	No

Last Name	First Name	Title	Position	Handles Drugs
Tribbey	William	Facilities Maintenance Mg	Employee	No
Vidrio	Virginia	Janitor	Employee	No

Current as of 04/11/2025

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☒ Nevada ☐ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☒ Location Change* (in-state only) * If making a change, provide current license number: WH 03231	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: ACCELERATED CARE PLUS LEASING, INC.

Physical Address: 1170 TRADEMARK DRIVE, SUITE 104

City: RENO State: NV Zip: 89521

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 1.800.350.1100 Website: WWW.ACPLUS.COM

Name of Designated Representative (DR): ZGATKO LARRY HODIN

Licensing Company Email: ACP-CUSTOMERSUPPORT@HANGER.COM DR Email: ZHODIN@HANGER.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☒ Repacker
☒ Hospitals	☒ [a] Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: ACCELERATED CARE PLUS, CORP.
Address: 1170 TRADEMARK DRIVE City: RENO State: NV Zip: 89521

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DELAWARE
Parent Company (if any): HANGER, INC.
Corporation/Organization Name: HANGER, INC.
Mailing Address: 10910 DOMAIN DR., SUITE 300
City: AUSTIN State: TX Zip: 78758
Telephone: 512.777.3800 Email: MEGWILLIAMS@HANGER.COM
Contact Person Name: MEGHAN WILLIAMS - EXTERNAL COMMUNICATIONS MGR.

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

ACCELERATED CARE PLUS LEASING, INC.

Facility Name

ZLATKO L. HODIN

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/1/2025

Date

Board Use Only	Date Received: 7/3/25	Amount: $1000 CK 21027

/help/index.html)

DRLM Home (mainMenu.htm) > View Your Registrations and Listings

View Your Registered Facilities

Owner/Operator:

Clear Sort and Filter

Show 10 per page

Filter:

Registration Number	Registration Status	Registration Status Reason	Facility Name/ Trade Name(s)	Address	Expiration Date	Action
1911273	Active	Legacy Data - Registration activated	ACCELERATED CARE PLUS CORP.	1170 TRADEMARK DR STE 104, RENO, NEVADA 89521 UNITED STATES	2025-12-31	

Showing 1 to 1 of 1 entries

Previous 1 Next

< Previous (drlm.htm?_flowExecutionKey=_c1E8A3F8B-B127-8EB9-0D00-0D05B94F46BB_k97473382-D95B-A366-C283-CCBBA25A5922&_eventId=back)

Hanger Inc
84-0904275
100% Direct owner

Hanger
Empowering Human Potential

INDIRECT Owners

Legal Name	Address	Phone	FEIN	Percentage of Indirect Ownership in Provider	Confirmation of No Adverse Actions
Hero Parent, Inc.	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3548884	100% indirect	None
Hero Intermediate Holdings, Inc.	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3597550	100% indirect	None
PSC Hero Holdings, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3558625	100% indirect	None
PSC Hero Aggregator, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3763319	97.77% indirect	None
PSC Hero Coinvest, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3457821	24.77% indirect	None
Patient Square Equity Partners, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	86-2475113	26.22% indirect	None
Patient Square Equity Partners-A, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	86-2515974	44.72% indirect	None

Accelerated Care Plus Leasing, Inc.

Subsidiary of Hanger, Inc.

Directors

Peter A. Stoy

Thomas E. Kiraly

Officers

Peter A. Stoy	Chief Executive Officer
Spencer D. LeGrand	President
Thomas E. Kiraly	Executive Vice President, Assistant Treasurer an Assistant Secretary
Thomas E. Hartman	Senior Vice President, General Counsel and Secretary
Joseph C. Talley	Treasurer and Assistant Secretary

Accelerated Care Plus Leasing, Inc.

Subsidiary of Hanger, Inc.

List of Shareholders

Name	Percent Ownership
Hanger, Inc.	100%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ACCELERATED CARE PLUS LEASING, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF JUNE, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ACCELERATED CARE PLUS LEASING, INC." WAS INCORPORATED ON THE FIFTH DAY OF DECEMBER, A.D. 2012.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5253538 8300

SR# 20253182578

Authentication: 204050013

Date: 06-26-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Business License from City of Reno is pending new facility inspection and will be provided when issued by the City.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 12/27/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Hanger, Inc. & all its wholly owned subsidiaries 10910 Domain Dr. Ste. 300 Austin TX 78758-7807 USA	INSURER A: Travelers Property Cas Co of America	25674
	INSURER B: The Travelers Indemnity Co.	25658
	INSURER C: Lloyd's Syndicate No. 3623	AA1120055
	INSURER D: ACE Property & Casualty Insurance Co.	20699
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570110072149 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
C	X COMMERCIAL GENERAL LIABILITY			W38C61250101	01/01/2025	01/01/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$50,000
							MED EXP (Any one person)	$5,000
							PERSONAL & ADV INJURY	
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	
	OTHER:							
A	AUTOMOBILE LIABILITY			TJCAP-1R572736-TIL-25	01/01/2025	01/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
D	X UMBRELLA LIAB X OCCUR			G28196842009	01/01/2025	01/01/2026	EACH OCCURRENCE	$5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$5,000,000
	DED X RETENTION $100,000							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			UB2X7193742551K All other states	01/01/2025	01/01/2026	X PER STATUTE OTH-ER	
B	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory in NH)	N/A		UB2X7164642551R For AZ, MA, WI	01/01/2025	01/01/2026	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000
C	Products Liability			W38C61250101 Claims Made SIR applies per policy terms & conditions	01/01/2025	01/01/2026	Each Claim Aggregate	$10,000,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Evidence of Insurance. Product Liability/Completed Operations Retro Date 01/01/2004

CERTIFICATE HOLDER

Hanger, Inc. &
all its wholly owned subsidiaries
10910 Domain Drive #300
Austin TX 78758 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570110072149

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AGENCY CUSTOMER ID: 570000092454
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Hanger, Inc. & all its wholly owned
POLICY NUMBER: See Certificate Number: 570110072149	
CARRIER: See Certificate Number: 570110072149 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
C	Hospital Professional/General Liability			W38C61250101 Claims Made SIR applies per policy terms & conditions	01/01/2025	01/01/2026	Each Claim	$10,000,000
							Aggregate	$10,000,000

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CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 12/27/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Hanger, Inc. & all its wholly owned subsidiaries 10910 Domain Dr. Ste. 300 Austin TX 78758-7807 USA	INSURER A: Travelers Property Cas Co of America	25674
	INSURER B: The Travelers Indemnity Co.	25658
	INSURER C: Lloyd's Syndicate No. 3623	AA1120055
	INSURER D: ACE Property & Casualty Insurance Co.	20699
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570110072149 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
C	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			W38C61250101	01/01/2025	01/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $50,000 $5,000 $2,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			TJCAP-1R572736-TIL-25	01/01/2025	01/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$2,000,000
D	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $100,000			G28196842009	01/01/2025	01/01/2026	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
A B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [N] If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		UB2X7193742551K All other states UB2X7164642551R For AZ, MA, WI	01/01/2025 01/01/2025	01/01/2026 01/01/2026	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $1,000,000 $1,000,000 $1,000,000
C	Products Liability			W38C61250101 Claims Made SIR applies per policy terms & conditions	01/01/2025	01/01/2026	Each Claim Aggregate	$10,000,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Evidence of Insurance. Product Liability/Completed Operations Retro Date 01/01/2004

CERTIFICATE HOLDER

Hanger, Inc. &
all its wholly owned subsidiaries
10910 Domain Drive #300
Austin TX 78758 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast Inc.

Holder Identifier :

Certificate No : 570110072149

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AGENCY CUSTOMER ID: 570000092454
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Hanger, Inc. & all its wholly owned
POLICY NUMBER: See Certificate Number: 570110072149	
CARRIER: See Certificate Number: 570110072149 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
C	Hospital Professional/General Liability			W38C61250101 Claims Made SIR applies per policy terms & conditions	01/01/2025	01/01/2026	Each Claim	$10,000,000
							Aggregate	$10,000,000

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GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	CMS0334100
For	NV Pharmaceutical Wholesaler Bond
Dated effective	01/18/2024 (MONTH, DAY, YEAR)
Executed by	Accelerated Care Plus Leasing, Inc., as Principal, (PRINCIPAL)
And by	RLI Insurance Company, as Surety, (SURETY)
And in favor of	Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Principal Address	4999 Aircenter Circle, Suite 103	1170 Trademark Drive, Suite 104
Principal Zip	89502	89521

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **07/22/2025**

(MONTH, DAY, YEAR)

Signed and Sealed **06/20/2025**

(MONTH, DAY, YEAR)

Accelerated Care Plus Leasing, Inc.
PRINCIPAL

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

BY _____
TITLE

RLI Insurance Company
SURETY

BY Rosalyn D. Hassell
Rosalyn D Hassell, ATTORNEY-IN-FACT

POWER OF ATTORNEY

RLI Insurance Company
Contractors Bonding and Insurance Company

9025 N. Lindbergh Dr. Peoria, IL 61615
Phone: 800-645-2402

Bond No. CMS0334100

Know All Men by These Presents:

That this Power of Attorney is not valid or in effect unless attached to the bond which it authorizes, but may be detached by the approving officer if desired.

That this Power of Attorney may be effective and given to either or both of **RLI Insurance Company** and **Contractors Bonding and Insurance Company**, required for the applicable bond.

That **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, each Illinois corporations (as applicable), each authorized and licensed to do business in all states and the District of Columbia do hereby make, constitute and appoint: **Rosalyn D Hassell** in the City of Spring, State of TX, it's true and lawful Agent and Attorney in Fact, with full power and authority hereby conferred upon him/her to sign, execute, acknowledge and deliver for and on its behalf as Surety, in general, any and all bonds and undertakings in an amount not to exceed Seventy Five Million Dollars ($75,000,000) for any single obligation, and specifically for the following described bond.

Principal: Accelerated Care Plus Leasing, Inc.
Obligee: Nevada State Board of Pharmacy

RLI Insurance Company and **Contractors Bonding and Insurance Company**, as applicable, have each further certified that the following is a true and exact copy of a Resolution adopted by the Board of Directors of each such corporation, and now in force, to-wit:

> **"All bonds, policies, undertakings, Powers of Attorney or other obligations of the Corporation shall be executed in the corporate name of the Corporation by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or Agents who shall have authority to issue bonds, policies or undertakings in the name of the Corporation. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the Corporation. The signature of any such officer and the corporate seal may be printed by facsimile or other electronic image."**

IN WITNESS WHEREOF, **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, as applicable, have caused these presents to be executed by its respective Sr. Vice President with its corporate seal affixed this 24th day of January, 2024.

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

CONTRACTORS BONDING AND INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI Insurance Company
Contractors Bonding and Insurance Company

Eric Raudins — Sr. Vice President

State of Ohio }
County of Cuyahoga } SS

On this 24th day of January, 2024, before me, a Notary Public, personally appeared Eric Raudins, who being by me duly sworn, acknowledged that he signed the above Power of Attorney as the aforesaid officer of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, and acknowledged said instrument to be the voluntary act and deed of said corporation.

By: Jill A. Scott
Jill A. Scott — Notary Public

JILL A SCOTT
Notary Public
State of Ohio
My Comm. Expires
September 22, 2025

CERTIFICATE

I, the undersigned officer of **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, do hereby certify that the attached Power of Attorney is in full force and effect and is irrevocable; and furthermore, that the Resolution of the Company as set forth in the Power of Attorney, is now in force. In testimony whereof, I have hereunto set my hand and the seal of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** this 20th day of June, 2025.

RLI Insurance Company
Contractors Bonding and Insurance Company

By: Jeffrey D Fick
Jeffrey D Fick — Corporate Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

COPY

Bond No. CMS0334101

Application/License No. _____

Innovative Neurotronics, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4999 Aircenter Circle, Suite 103, Reno, NV. 89502 (Address of Applicant/Principal), as PRINCIPAL, and RLI Insurance Company (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 9025 N. Lindbergh Drive , Peoria, IL 61615 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 18, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of eny action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of January, 2024.

APPLICANT/PRINCIPAL

Innovative Neurotronics, Inc.
COMPANY

By: _____
Authorized Representative

SURETY

RLI Insurance Company

By: _____
Surety Company's Representative

Scott D. Chapman, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

Elaine Lewis
Witness Elaine Lewis

Rosalyn Hassell
Witness Rosalyn Hassell

Countersigned by:

_____
Nevada Resident Agent Scott D. Chapman
License No. 746741

Posted February 20, 2020

COPY COPY

POWER OF ATTORNEY

RLI Insurance Company
Contractors Bonding and Insurance Company

9025 N. Lindbergh Dr. Peoria, IL 61615
Phone: 800-645-2402

Know All Men by These Presents:

That this Power of Attorney is not valid or in effect unless attached to the bond which it authorizes executed, but may be detached by the approving officer if desired.

That **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, each an Illinois corporation, (separately and together, the "Company") do hereby make, constitute and appoint:

Scott D. Chapman, Rosalyn D. Hassell, Elaine Lewis, Kevin McQuain, Stacy Owens, Kimberly Stanley, Cheryl Colson, Misty Witt, jointly or severally

in the City of The Woodlands, State of Texas its true and lawful Agent(s) and Attorney(s) in Fact, with full power and authority hereby conferred, to sign, execute, acknowledge and deliver for and on its behalf as Surety, in general, any and all bonds and undertakings in an amount not to exceed **Twenty Five Million** Dollars ($25,000,000.00) for any single obligation.

COPY

The acknowledgment and execution of such bond by the said Attorney in Fact shall be as binding upon the Company as if such bond had been executed and acknowledged by the regularly elected officers of the Company.

RLI Insurance Company and/or **Contractors Bonding and Insurance Company**, as applicable, have each further certified that the following is a true and exact copy of a Resolution adopted by the Board of Directors of each such corporation, and is now in force, to-wit:

"All bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or Agents who shall have authority to issue bonds, policies or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile."

IN WITNESS WHEREOF, the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, as applicable, have caused these presents to be executed by its respective Vice President with its corporate seal affixed this 2nd day of September, 2020.

CONTRACTORS BONDING AND INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI Insurance Company
Contractors Bonding and Insurance Company

By: B. W. D.
Barton W. Davis — Vice President

State of Illinois }
County of Peoria } SS

On this 2nd day of September, 2020, before me, a Notary Public, personally appeared Barton W. Davis, who being by me duly sworn, acknowledged that he signed the above Power of Attorney as the aforesaid officer of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** and acknowledged said instrument to be the voluntary act and deed of said corporation.

By: Catherine D. Glover
Catherine D. Glover — Notary Public

CATHERINE D. GLOVER
OFFICIAL SEAL
Notary Public - State of Illinois
My Commission Expires
March 24, 2024

CERTIFICATE

COPY

I, the undersigned officer of RLI Insurance Company and/or **Contractors Bonding and Insurance Company**, do hereby certify that the attached Power of Attorney is in full force and effect and is irrevocable; and furthermore, that the Resolution of the Company as set forth in the Power of Attorney, is now in force. In testimony whereof, I have hereunto set my hand and the seal of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** this 18th day of January, 2024.

RLI Insurance Company
Contractors Bonding and Insurance Company

By: Jeffrey D. Fick
Jeffrey D. Fick — Corporate Secretary

421n33 H020212

A0058D19

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Accelerated Care Plus Leasing, Inc. MDEG License # (if applicable) _____

Physical Address ~~4999 Aircenter Circle, Suite 103~~ 1170 TRADEMARK DR., SUITE 104

City Reno State NV Zip 89502

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800.350.1100 Website www.ACPLUS.com

Licensing Company Email ACP-CustomerSupport@Hanger.com or ZHodin@Hanger.com

Section 2: Personal Information

First Zlatko Middle Larry Last Hodin

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Reno State NV Zip [redacted]

Telephone [redacted] Email ZHodin@Hanger.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwestern University		09/77 - 06/81	
Address	**City**	**State**	**Zip**
633 Clark St.	Evanston	IL	60208
Diploma/Degree obtained, if any			
BS - Engineering Management			

School Name		From - To (MM/YY – MM/YY)	
William Fremd High School			
Address	**City**	**State**	**Zip**
1000 S. Quentin Rd.	Palatine	IL	60067
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2011 - current	[redacted]	Reno	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7- An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Accelerated Care Plus Leasing, Inc.			-01/2013 - present
Business Address	**City**	**State**	**Zip**
4999 Aircener Circle, Suite 103	Reno	NV	89502
Phone	**Title**	**Number of Employed Hours**	
800.350.1100	Director, Compliance and QA	20,200	
Description of Duties			
Responsible for company regulatory affairs and Quality Assurance activities.			

Business Name			From - To (MM/YY – MM/YY)
Accelerated Care Plus Corp.			01/2001 - 12/2012
Business Address	**City**	**State**	**Zip**
4850 Joule St.	Reno	NV	89502
Phone	**Title**	**Number of Employed Hours**	
7775.485.4000	Vice President, Development Programs	24,000	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, ZLATKO LARRY HODIN, **certify that as the MDEG Administrator for** ACCELERATED CARE PLUS LEASING, INC.,

that I (initial that you have read and meet the following requirements):

1. ZH Have a high school diploma or its equivalent;
2. ZH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ZH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ZH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ZLATKO HODIN
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/1/2025
Date

Board Use Only	Date Received: 7/3/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ACCELERATED CARE PLUS LEASING, INC

Pharmacy/Wholesaler License # (if applicable) WH03231

Physical Address 1170 TRADEMARK DRIVE, SUITE 104

City RENO State NV Zip 89521

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800 350 1100 Website WWW.ACPLUS.COM

Licensing Company Email ACP-CUSTOMER SUPPORT@HANGER.COM

Section 2: Personal Information

First ZLATKO Middle LARRY Last HODIN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City RENO State NV Zip [redacted]

Telephone [redacted] Email ZHODIN@HANGER.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
NORTHWESTERN UNIVERSITY			09/77 - 06/81
Address	**City**	**State**	**Zip**
633 CLARK ST.	EVANSTON	IL	60208
Diploma/Degree obtained, If any			
BS - ENGINEERING MANAGEMENT			

School Name			From - To (MM/YY – MM/YY)
WILLIAM FREMD HIGH SCHOOL			09/73 - 06/77
Address	**City**	**State**	**Zip**
1000 S. QUENTIN ROAD	PALATINE	IL	60067
Diploma/Degree obtained, If any			
HIGH SCHOOL DIPLOMA			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
ACCELERATED CARE PLUS LEASING, INC.			01/13 - CURRENT
Business Address	**City**	**State**	**Zip**
4999 AIRCENTER CIRCLE, SUITE 103	RENO	NV	89502
Phone	**Title**	**Number of Employed Hours**	
800 350 1100	DIRECTOR, COMPLIANCE AND QA	24,800	
Description of Duties			
RESPONSIBLE FOR COMPANY REGULATORY AFFAIRS AND QUALITY ASSURANCE ACTIVITIES.			

Business Name			From - To (MM/YY – MM/YY)
ACCELERATED CARE PLUS, CORP			01/01 - 12/12
Business Address	**City**	**State**	**Zip**
4850 JOULE ST.	RENO	NV	89502
Phone	**Title**	**Number of Employed Hours**	
7756854000	VICE PRESIDENT, DEVELOPMENT	24,000	
Description of Duties			
DEVELOPMENT OF NEW PRODUCTS, EQUIPMENT AND CLINICAL PROGRAMS			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, ZLATKO LANKY HODIN, **certify that as the designated representative for** ACCELERATED CARE PLUS LEASING, INC.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ZH I am at least 21 years of age;
3. ZH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ZH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ZH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ZH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ZH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

ZLATKO HODIN
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

JUNE 24/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Zlatko Hodin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/24/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Zlatko L. Hodin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/24/2025

Date

Subscribed and Sworn to before me this 24th day of June 2025.

Hancy Alexandra Vasquez

Notary Public Signature

HANCY ALEXANDRA VASQUEZ
NOTARY PUBLIC
STATE OF NEVADA
APPT NO. 24-5543-02
APPT EXPIRES JULY 9, 2028

(Seal)

Accelerated Care Plus Leasing, Inc. - Reno Employees

Employee ID	*Last Name*	*First Name*	*Location Name*	*Job Title*
119183	Abeyta	Troy	Reno,NV [Service Center]	Service Technician III
127403	Abid	Erin	Reno,NV [Service Center]	Material Handler II
124081	Aguilar	Jesus	Reno,NV [Service Center]	Material Handler IV
123344	Buckley	Laurie	Reno,NV [Finance]	Accounting Specialist II
103097	Carrell	Nancy	Reno,NV [Service Center]	Material Handler IV
124184	Coville	Tracy	Reno,NV [Customer Support]	Customer Service Rep II
124251	Cranford	James	Reno,NV [Service Center]	Service Technician III
126455	Curby	Luviminia	Reno,NV [Quality Assurance]	QA Analyst-ACP
118111	Diehl	Matthew	Reno,NV [Finance]	ACP Financial Controller
121359	Dukat	Judit	Reno,NV [Finance]	Staff Accountant
118285	Dukes	Jacob	Reno,NV [Service Center]	Mgr, Service Center-ACP
125441	Faillers	Afton	Reno,NV [Finance]	Sr Accountant
123996	Grasseschi	Lee	Reno,NV [Quality Assurance]	Mgr,Compliance and QA
125997	Grohs	Melissa	Reno,NV [Finance]	Accounting Specialist II
117992	Guzman	Theresa	Reno,NV [Finance]	Mgr,Accounting
117926	Hodin	Zlatko	Reno,NV [Quality Assurance]	Dir,Quality & Compl-ACP
126284	Johnson	Kyle	Reno,NV [Service Center]	Service Technician IV
130048	Khan	Aiman	Reno, Nevada H130048	Customer Service Rep II
125481	Lee	Christopher	Reno,NV [Service Center]	Service Technician III
122277	Maley	Lois	Reno,NV [Customer Support]	Customer Service Rep II
117977	Masters	Susan	Reno,NV [Finance]	Sr Accountant
121462	Moore	Karen	Reno,NV [ACP Lease Program]	Administrative Asst II
124179	Nathan	Geraldine	Reno,NV [Clinical Education]	Clinical Education Coord III
126754	Quesada Arias	Andrea	Reno,NV [Finance]	Accounting Specialist II
125360	Retherford	Christian	Reno,NV [Customer Support]	Lease Administrator II
118030	Scheuermann	Dorothy	Reno,NV [Finance]	Accounting Specialist III
123680	Seidman	Lance	Reno,NV [Service Center]	Service Technician II
118097	Thomson	Barry	Reno,NV [Product Development]	Dir,Operations-ACP
121488	Young	Christopher	Reno,NV [Customer Support]	Supv,Customer Service
124318	Young	Gordon	Reno,NV [Customer Support]	Customer Service Rep II

Accelerated Care Plus Leasing, Inc. - All Employees

Employee ID	Last Name	First Name	Location Name	Job Title
119183	Abeyta	Troy	Reno,NV [Service Center]	Service Technician III
127403	Abid	Erin	Reno,NV [Service Center]	Material Handler II
124081	Aguilar	Jesus	Reno,NV [Service Center]	Material Handler IV
118002	Akst	Andree	Cumming, GA H118002	Clinical Ed Consultant IV
118100	Alexander	Danielle	Dryden, MI H118100	Regional Mgr,Ops-ACP
118053	Applegate	William	Edmond, OK 118053	Clinical Program Consultant
118043	Barnes	Tara	Memphis, TN H118043	Clinical Prog Consult- Float
128941	Boger	Toni	Jacksonville, FL H128941	Clinical Program Consultant
118384	Bryant	Alyssa	Birmingham, AL H118384	Clinical Program Consultant
123344	Buckley	Laurie	Reno,NV [Finance]	Accounting Specialist II
113934	Burzynski	Jodi	Coeur d'Alene,ID H113934	Clinical Ed Consultant IV
118710	Calvo	Daniel	St. Augustine, FL H118710	Reg Clinical Prog Consultant
118037	Campbell	John	Phoenixville, PA H118037	ACP Sales & Bus Dev Region Mgr
118079	Capella	Debra	Frederick, MD H118079	Clinical Program Consultant
103097	Carrell	Nancy	Reno,NV [Service Center]	Material Handler IV
128216	Castillo-Ornelas	Janet	Las Vegas, NV H128216	Customer Service Rep II
117958	Chiquito	Juan	Miramar, FL H117958	Clinical Program Consultant
117949	Contreras	Kelly	Tolland, CT H117949	Sr Mgr,Remote Clinical Svcs-AC
129875	Cook	Jamie	Lakewood, WA H129875	Regional Mgr,Ops-ACP
124184	Coville	Tracy	Reno,NV [Customer Support]	Customer Service Rep II
124251	Cranford	James	Reno,NV [Service Center]	Service Technician III
118056	Cullagh	Shannon	Norfolk, MA H118056	Division Business Leader-ACP
126455	Curby	Luviminia	Reno,NV [Quality Assurance]	QA Analyst-ACP
122222	Dankert	Jason	Oak Creek, WI H122222	Clinical Program Consultant
117955	Davis	Karen	Greenwood, IN H117955	Clinical Program Consultant
118111	Diehl	Matthew	Reno,NV [Finance]	ACP Financial Controller
117960	Donaldson	Mark	Saco, ME H117960	Clinical Program Consultant
118003	Dueker	John	Ballwin, MO H118003	Clinical Prog Consult- Float
121359	Dukat	Judit	Reno,NV [Finance]	Staff Accountant
118285	Dukes	Jacob	Reno,NV [Service Center]	Mgr, Service Center-ACP
118039	Dunlap	Jeremy	Chalfont, PA H118039	Market Leader
118065	Dunlay	Edward	Harrison, TN H118065	Dir,Market Development-ACP
117940	Engelmann	Richard	Hickory, NC H117940	Clinical Ed Consultant IV
117945	Escovedo	Ernest	Windsor, CA H117945	Clinical Program Consultant
125441	Faillers	Afton	Reno,NV [Finance]	Sr Accountant
118101	Fiore	Edward	Denver, NC H118101	ACP Sales & Bus Dev Region Mgr
117968	Fortunato	Lawrence	Winter Park, FL H117968	Clinical Program Consultant
118041	Fournie	Lynn	Columbia, IL H118041	Reg Clinical Prog Consultant
118078	Freedman	Joana	Portland, OR H118078	Clinical Prog Consult- Float
117954	Fruits	Angela	Greenwood, IN H117954	Clinical Program Consultant
121226	Gianpetro	Anthony	Plainfield, IL H121226	Clinical Program Consultant
124637	Goggin	Dawn	Flowery Branch, GA H124637	Mgr,Supplier & Inventory Mgmt
124855	Gohel	Sonal	Brooklyn, NY H124855	Clinical Program Consultant
123996	Grasseschi	Lee	Reno,NV [Quality Assurance]	Mgr,Compliance and QA

125997	Grohs	Melissa	Reno,NV [Finance]	Accounting Specialist II
117962	Gurnani	Seema	Chicago, IL H117962	Sr Mgr,Clinical Services
117992	Guzman	Theresa	Reno,NV [Finance]	Mgr,Accounting
118028	Havrilla	Karleen	Canfield, OH H118028	Clinical Program Consultant
118059	Hayes	Ann Marie	Ellington, CT H118059	Clinical Program Consultant
118118	Heimes	Christine	Kansas City, KS H118118	Clinical Program Consultant
117982	Hobbs	Manda	Raleigh, NC H117982	Clinical Program Consultant
117946	Hobbs	Amy	Winston Salem, NC H117946	VP,Clinical Ops-ACP
117926	Hodin	Zlatko	Reno,NV [Quality Assurance]	Dir,Quality & Compl-ACP
118085	Hooks	Darcirae	Delaware, OH H118085	Clinical Program Consultant
121095	Hughes	Robert	Las Vegas, NV H121095	Clinical Program Consultant
117969	Huller	Elizabeth	Lincoln Univ,PA H117969 118073	ACP Sales & Bus Dev Region Mgr
119019	Huntley	Kelly	South Glens Falls, NY H119019	Regional Mgr,Ops-ACP
117947	Jackson	Susan	Bowling Green, KY H117947	Regional Mgr,Ops-ACP
126284	Johnson	Kyle	Reno,NV [Service Center]	Service Technician IV
117967	Jordan	Timothy	Maryville, TN H117967	Clinical Program Consultant
117976	Keck	Jessica	Whitefish,MT [H117976]	Staff Financial Analyst
118264	Kendrick	Rubye	Tyler, TX H118264	Clinical Program Consultant
130048	Khan	Aiman	Reno, Nevada H130048	Customer Service Rep II
117959	Kopp	Donna	Olathe, KS H117959	Division Business Leader-ACP
129821	Kubala	Carrie	Wayne, PA H129821	Clinical Program Consultant
117974	Lang	Lori	Burgaw, NC H117974	Division Business Leader-ACP
119832	Larson	Wendy	Tacoma, WA H119832	Clinical Program Consultant
125481	Lee	Christopher	Reno,NV [Service Center]	Service Technician III
118075	Lindsey	Toni	Irving, TX H11807S	Clinical Program Consultant
118027	Lysons	Dylan	Tulsa, OK H118027	QA Inspector III
122277	Maley	Lois	Reno,NV [Customer Support]	Customer Service Rep II
117956	March	Susan	Winter Park, FL H117956	Regional Mgr,Ops-ACP
117921	Martocci	Lynne	Guilford, CT H117921	Clinical Prog Consult- Float
117977	Masters	Susan	Reno,NV [Finance]	Sr Accountant
117971	McNamara	Debra	Laguna Niguel, CA H117971	Clinical Program Consultant
118894	Meyer	Amy	Marlboro, NJ H118894	Clinical Program Consultant
119235	Micko	Kenneth	Hillsborough, NJ H119235	Clinical Program Consultant
122230	Middleton	Valerie	Jamestown, NC H122230	Clinical Program Consultant
123972	Moore	Tawny	Livingston, TX H123972	Clinical Education Coord III
121462	Moore	Karen	Reno,NV [ACP Lease Program]	Administrative Asst II
121523	Morrow	Dawn	Katy, TX H121523	Clinical Program Consultant
128388	Musselman	Mark	Fort Mill, SC H128388	Clinical Program Consultant
129969	Myers	Elizabeth	Wheeling, WV H129969	Clinical Program Consultant
124624	Nagy	Michelle	Harrisburg, PA H124624	Clinical Program Consultant
124179	Nathan	Geraldine	Reno,NV [Clinical Education]	Clinical Education Coord III
118080	Nitcher	Chad	New Orleans, LA H118080	ACP Sales & Bus Dev Region Mgr
117919	Norton	Tracy	Chatsworth, CA H117919	Clinical Program Consultant
119427	ODonnell	Karin	Chicago, IL H119427	Clinical Program Consultant
118115	OKeeffe	Catherine	Norfolk, MA H118115	Clinical Program Consultant
118088	Oltmans	Jaclyn	Omaha, NE H120206 118088	Clinical Prog Consult- Float
118063	Paddock	Jeffrey	Kenner, LA H118063	Clinical Program Consultant
118055	Panisak	Shannon	Mountain Top, PA H118055	Clinical Program Consultant

117984	Peterson	Janine	Star Prairie, WI H117984	Clinical Program Consultant
126727	Pfeil	Amanda	Rancho Santa Margt, CA H126727	Clinical Program Consultant
129268	Polyak	Marina	Manalapan, NJ H129268	Clinical Program Consultant
117975	Pride	Sherrie	Louisville, KY H117975	Clinical Program Consultant
119812	Purvis	Heather	Wilmington, NC H119812	Market Leader
126754	Quesada Arias	Andrea	Reno,NV [Finance]	Accounting Specialist II
128896	Rainey	Jordan	Lakeland, TN H128896	Clinical Program Consultant
119296	Redublo	Alduaine	Corpus Christi, TX H119296	Clinical Program Consultant
125360	Retherford	Christian	Reno,NV [Customer Support]	Lease Administrator II
129183	Rothstein	Allison	Sayville, New York H129183	Clinical Program Consultant
129240	Rys	Katherine	Lakeland, FL H129240	Clinical Program Consultant
118030	Scheuermann	Dorothy	Reno,NV [Finance]	Accounting Specialist III
119213	Sears	Helena	Austin, TX H119213	Regional Mgr,Ops-ACP
123680	Seidman	Lance	Reno,NV [Service Center]	Service Technician II
129706	South	Laureta	Garden City, NY H129706	Clinical Program Consultant
123359	Steffenilla	Tod	N. Chesterfield, VA H123359	Clinical Program Consultant
129587	Steinmeyer	Julie	Lincoln, NE H129587	Clinical Program Consultant
118050	Stevens	Tera	Pearland, TX H118050	Clinical Program Consultant
129676	Stewart	Jeremy	Remote Work Loc - Texas	Business Dev Associate-ACP
118086	Subramanian	Sharadha	Newburgh, IN H118086	Clinical Program Consultant
117995	Tawfik	John	Schnecksville, PA H117995	Dir,Clinical Services
117973	Thakkar	Hetarthi	Alpharetta, GA H117973	Clinical Program Consultant
118116	Thompson	Karen	Des Moines, IA H118116	Clinical Program Consultant
118097	Thomson	Barry	Reno,NV [Product Development]	Dir,Operations-ACP
118008	Tobin	Susan	Lancaster, OH H118008	Clinical Program Consultant
124783	Verdicchio	Jenna	Portland, OR H124783	Clinical Program Consultant
121940	Vollen	Ronald	Winchester, VA H121940	Clinical Program Consultant
117996	Weinschenk	Karen	Hudson, MA H117996	Clinical Program Consultant
118024	Whittemore	Chara	Friendsville, MD H118024	Clinical Prog Consult- Float
121488	Young	Christopher	Reno,NV [Customer Support]	Supv,Customer Service
124318	Young	Gordon	Reno,NV [Customer Support]	Customer Service Rep II
117993	Zeigler	Diane	Arlington, TX H117993	Clinical Program Consultant

Nevada State Board of Pharmacy

Application for Wholesaler license

Applicant Company: Accelerated Care Plus Leasing, Inc.

- Accelerated Care Plus Leasing, Inc. (ACPL) is a corporation incorporated in the state of Delaware (certificate of good standing included in the application).
- ACPL purchases equipment used in therapy / rehabilitation from affiliated company Accelerated Care Plus, Corp., and sells or leases such equipment to Skilled Nursing Facilities, or other licenses therapy / rehabilitation facilities.
- ACPL is wholly owned by Hanger, Inc. corporation.
- Hanger, Inc. is owned by private equity group, identified on the page attached to this letter as the Indirect Owners.
- No individual person owns more than 10% of ACPL, Hanger, Inc., or any of the equity group companies listed as Indirect Owners.

Application prepared by:

Zlatko L. Hodin
Director of Compliance
775.250.1729

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: SunMed Group Holdings, LLC

Physical Address: 15152 W Camelback Road

City: Litchfield Park State: AZ Zip: 85340

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-443-2797 Website: www.myairlife.com

Name of Designated Representative (DR): Peter Tountas

Licensing Company Email: info@myairlife.com DR Email: ptountas@myairlife.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Distributors		■ Others: Distributor

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6-10-2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): FH Sunrise Purchaser, INC.

Corporation/Organization Name: SunMed Group Holdings, LLC dba AirLife

Mailing Address: 2710 Northridge Dr NW A

City: Walker State: MI Zip: 49544

Telephone: (616) 259-8400 Email: info@myairlife.com

Contact Person Name: Rob Yamashita

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

SunMed Group Holdings, LLC

Facility Name

Peter Tountas

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6-10-2025

Date

Board Use Only	Date Received: 6/18/25	Amount: $1,000-cc

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing
New Search

Back To Search Results

Establishment:
SUNMED GROUP HOLDINGS, LLC Dba AirLife
15152 W. Camelback Rd.
Litchfield Park, AZ 85340
Registration Number: 3030308442
FEI Number*: 3030308442
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further information.
Date Of Registration Status: 2025

Owner/Operator:
SunMed Group Holdings, LLC Dba AirLife[6]
2710 Northridge Drive NW, Suite A
Grand Rapids, MI US 49544
Owner/Operator Number: 10044795[7]

Official Correspondent:
Rob Yamashita
2710 Northridge Drive NW, Suite A
Grand Rapids, MI 49544
Phone: 01-616-2598373

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified 10/27/25 M.H

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Page Last Updated: 03/10/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SUNMED GROUP HOLDINGS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTEENTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SUNMED GROUP HOLDINGS, LLC" WAS FORMED ON THE TWENTY-FIRST DAY OF AUGUST, A.D. 2019.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7571375 8300

SR# 20250553466

Authentication: 202946082

Date: 02-16-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

5306007997APP24

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

SUNMED GROUP HOLDINGS, LLC
2710 NORTHRIDGE DR NW
SUITE C-3
GRAND RAPIDS, MI 49544

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

SUNMED GROUP HOLDINGS, LLC
2710 NORTHRIDGE DR NW
SUITE C-3
GRAND RAPIDS, MI 49544

LICENSE NO.
5306007997

EXPIRATION DATE
03/07/2027

25066070306

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

Nevada State Board of Pharmacy

For licensing inquires please send an email to, pharmacylicensing@pharmacy.nv.gov (mailto:pharmacylicensing@pharmacy.nv.gov).

For current information on **disciplinary actions taken against licensees**, please send an email to teambc@pharmacy.nv.gov (mailto:teambc@pharmacy.nv.gov).

VERIFY LICENSE

Facility Name	License Number#	License Status	License Expiration Date	City	State	Discipline	Action
AirLife	WH03510	Active	10/31/2026	Grand Rapids	MI	N	

Facility Name	License Number#	License Status	License Expiration Date	City	State	Discipline	Action

License Number : WH03510

Name : AirLife

License Type : Wholesaler

License Status : Active

License Date : 09/26/2023

Discipline : None

Expiration Date : 10/31/2026



Drop file(s) here to upload or click here to browse and select file(s) to upload. ()

Complete Upload Reset

Document Type	Upload Date	Name	Other Name	Is Public?	Status	Uploaded By	Link	Actions

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CERTIFICATE OF LIABILITY INSURANCE

12/31/2025

DATE (MM/DD/YYYY) 12/18/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Lockton Companies, LLC 3280 Peachtree Road NE, Suite #1000 Atlanta GA 30305 (404) 460-3600	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED 1493635 SunMed Group Holdings LLC DBA Airlife 2710 Northridge Dr NW, Grand Rapids MI 49544	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Federal Insurance Company — 20281 INSURER B : Great Northern Insurance Company — 20303 INSURER C : Chubb Indemnity Insurance Company — 12777 INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 19909424 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR X STOP GAP X $1,000,000 GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:	N	N	36057113	12/31/2024	12/31/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG 	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ XXXXXXX $
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY	N	N	73618786	12/31/2024	12/31/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) 	$ 1,000,000 $ XXXXXXX $ XXXXXXX $ XXXXXXX $ XXXXXXX
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $	N	N	78181821	12/31/2024	12/31/2025	EACH OCCURRENCE AGGREGATE 	$ 15,000,000 $ 15,000,000 $ XXXXXXX
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [N] N/A If yes, describe under DESCRIPTION OF OPERATIONS below		N	71776686	12/31/2024	12/31/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
A	Products/E&O-Claims Made	N	N	99497228	12/31/2024	12/31/2025	Occurrence Limit: $10,000,000 Aggregate: $10,000,000 Deductible: $250,000	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

19909424
Evidence of Coverage

CANCELLATION See Attachments

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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Named Insureds

FH Sunrise Holdings, Inc.
Sunmed Group Holdings, LLC
Sunmed Holdings, LLC
Omega Medical Products, LLC
Blue Jay Holdings, LLC
Sunmed, LLC
Bay Medical Products, LLC
Mainline Medical Products, LLC
Ventlab, LLC
VL International Limited
Sunmed AP, Ltd
Salter Labs, LLC
Salter Labs Texas, LLC
Ethox Medical, LLC
Salter Labs de Mexico S.A. de C.V.
Salter Labs UK Limited
Parker Medical LLC
Westmed Holding Company
Westmed, Inc.
VBT, LLC
Westmed de Mexico S.A. de C.V.
FH Sunrise Intermediate, Inc.
FH Sunrise Purchaser, Inc.
FH Sunrise Parent, LP
Airlife US, Inc.
Airlife Finland OY
Airlife Japan G.K.
Airlife France SAS
Airlife Spain, S.L.U.
Airlife Canada ULC
Airlife Hong Kong Limited
Shenzhen Vital Signs – KTL Medical Instrument Co., LTD.
Airlife MX LLC
Productos Urologos De Mexico S.A. DE C.V.
Airlife Ciel, Inc.
Sunmed Australia Holdings Pty Ltd.
Sunmed Canada Holdings, In
Sunmed Germany Holdings, GMBH
Sunmed India Holdings, Private Limited
Sunmed Italy Holdings S.R.L.
Sunmed Netherlands Holdings, B.V.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 101536807

Application/License No. _____

SunMed Group Holdings, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 15152 West Camelback Road Glendale, AZ 85340 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 11, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of June, 2025.

APPLICANT/PRINCIPAL

SunMed Group Holdings, LLC

Authorized Representative

CAITLIN ANDERSON
Chief Administrative Officer
General Counsel

SURETY COMPANY

Merchants Bonding Company (Mutual)

Surety Company's Representative

Ryan Norman, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Cait Cullimore

Witness Danielle Stauder

SIGNED and SEALED in the presence of:

Witness Emma J Bryant

Witness Ashley Burns

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED 1933

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

MERCHANTS BONDING COMPANY™

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, and MERCHANTS NATIONAL INDEMNITY COMPANY , an assumed name of Merchants National Bonding, Inc., (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Ryan Norman

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the By-Laws adopted by the Board of Directors of the Companies.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship o obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner - Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 11th day of June , 2025 .

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS NATIONAL INDEMNITY COMPANY CALIFORNIA

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor

President

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 11th day of June 2025 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL), MERCHANTS NATIONAL BONDING, INC., and MERCHANTS NATIONAL INDEMNITY COMPANY; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA

Penni Miller
Commission Number 787952
My Commission Expires
January 20, 2027

Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, Elisabeth Sandersfeld, Secretary of MERCHANTS BONDING COMPANY (MUTUAL), MERCHANTS NATIONAL BONDING, INC., and MERCHANTS NATIONAL INDEMNITY COMPANY do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 11th day of June , 2025 .

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS NATIONAL INDEMNITY COMPANY CALIFORNIA

Secretary

POA 0018 (5/25)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG SunMed Group Holdings LLC MDEG License # (if applicable) _____

Physical Address 15152 West Camelback

City Litchfield State AZ Zip 85340

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 00-443-2797 Website www.myairlife.com

Licensing Company Email info@myairlife.com

Section 2: Personal Information

First Peter Middle Michael Last Tountas

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 15152 West Camelback

City Litchfield State az Zip 85340

Telephone 800-443-2797 Email ptountas@myairlife.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Brookline College		01/15-03/16	
Address	**City**	**State**	**Zip**
300 S Craycroft Rd	Tucson	AZ	85711
Diploma/Degree obtained, if any			
ssociates in Buisness Administration			

School Name		From - To (MM/YY – MM/YY)	
Brookline College		06/13-02/14	
Address	**City**	**State**	**Zip**
300 S Craycroft Rd	Tucson	AZ	85711
Diploma/Degree obtained, if any			
Diploma- Pharamcy Technician			

School Name		From - To (MM/YY – MM/YY)	
Palo Verde Highschool		08/08- 05/12	
Address	**City**	**State**	**Zip**
1302 S Avenida Vega	Tucson	AZ	85710
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/24-Present	[redacted]	Tucson	AZ	[redacted]
02/24-11/24		Tucson	AZ	
02/23-01/24		Tucson	AZ	
2/21-02/23		Tucson	AZ	
02/20-02/21		Tucson	AZ	
02/18-02/20		Tucson	AZ	
02/15-02/18		Tucson	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
SunMed LLC dba AirLife			10/17-Present	
Business Address		**City**	**State**	**Zip**
2710 Northridge Dr NW		Grand Rapids	MI	49544
Phone	**Title**		**Number of Employed Hours**	
800-433-2797	Senior Regulatory Specialist		16,640	
Description of Duties				
Regulatory Affairs Quality Assurance				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6-17-2025
Date

I, Peter Tountas, **certify that as the MDEG Administrator for**

SunMed Group Holdings LLC,

that I (initial that you have read and meet the following requirements):

1. PT Have a high school diploma or its equivalent;
2. PT Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. PT Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. PT Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Tountas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-10-2025

Date

Board Use Only	Date Received: 6/18/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler SunMed Group Holdings LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 15152 West Camelback

City Litchfield State AZ Zip 85340

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-443-2797 Website www.myairlife.com

Licensing Company Email info@myairlife.com

Section 2: Personal Information

First Peter Middle Michael Last Tountas

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 15152 West Camelback

City tchfield State AZ Zip 85340

Telephone 800-443-2797 Email ptountas@myairlife.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Brookline College		01/15-03/16	
Address	**City**	**State**	**Zip**
300 S Craycroft Rd	Tucson	AZ	85711
Diploma/Degree obtained, if any			
Associates in Buisness Administration			

School Name		From - To (MM/YY – MM/YY)	
Brookline College		06/13-02/14	
Address	**City**	**State**	**Zip**
300 S Craycroft Rd	Tucson	AZ	85711
Diploma/Degree obtained, if any			
Diploma- Pharamcy Technician			

School Name		From - To (MM/YY – MM/YY)	
Palo Verde Highschool		08/08- 05/12	
Address	**City**	**State**	**Zip**
1302 S Avenida Vega	Tucson	AZ	85710
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/24-Present	[redacted]	Tucson	AZ	[redacted]
02/24-11/24		Tucson	AZ	
02/23-01/24		Tucson	AZ	
02/21-02/23		Tucson	AZ	
02/20-02/21		Tucson	AZ	
02/18-02/20		Tucson	AZ	
02/15-02/18		Tucson	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
SunMed LLC dba AirLife			10/17-Present	
Business Address		**City**	**State**	**Zip**
2710 Northridge Dr NW		Grand Rapids	MI	49544
Phone	**Title**		**Number of Employed Hours**	
800-433-2797	Senior Regulatory Specialist		16,640	
Description of Duties				
Regulatory Affairs Quality Assurance				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6-17-2025
Date

I, Peter Tountas, **certify that as the designated representative for**

SunMed Group Holdings LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PT I am at least 21 years of age;
3. PT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Peter Tountas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-10-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Tountas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-10-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Pima

I, Peter Tountas, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-17-2025

Date

Subscribed and Sworn to before me this 17TH day of June, 2025

Notary Public Signature

JOSE MINUER HUACUJA
Notary Public - Arizona
Pima County
Commission # 626999
My Comm. Expires Apr 20, 2026
(Seal)

Payroll Name	Job Title Description
Ayala, Javier	Inventory Control Lead
Griffin, Maria	Quality Control Inspector
Rogel, Esperanza	Senior Quality Control Lead
Angulo, Monica	Returns Clerk
Contreras, Luz	Warehouse Associate
Majette, Voshon	Warehouse Associate
Cortez Burgos, Diego	Shipping and Receiving Lead
Burruel, Rudy	Warehouse Associate
LeBlue, Kameron	Warehouse Associate
Lopez Gonzalez, Angie	International Clerk
Seitz, Brandon	Inventory Control Coordinator
Wright, Raneka Elizabeth	Receiving Clerk
Pacheco, Kerlly	Shipping Clerk
Arzate, Roberto	Shipping Coordinator
Martinez, Monique	Warehouse Associate
Valencia, Michael	Warehouse Associate
Rosalez, Michael	Warehouse Associate
Holiday, Jerime	Shipping Coordinator
Phillips, Jamar	Maintenance Tech I
King, Wayne William	Receiving Associate
Zaragoza, Victor	Warehouse Associate
Mejia, Sergio	Warehouse Associate
Cordova Nunez, Yesenia	Warehouse Associate
Amaya, Juan	Warehouse Associate
Garcia, Alejandro	Warehouse Associate
Cruz Corona, Jose	Warehouse Associate
Gunsch, Zachare	Warehouse Associate
Jeffery, Malcom	Receiving Clerk
Gomez, Barbara	Warehouse Associate
Floyd, Randal	Warehouse Associate
Okamura, Mike	Receiving Associate
Santiago, Edwin	Warehouse Associate
Garcia, Jose	Warehouse Associate
Aranda, Marcos	Warehouse Associate
Grijalva, Kevin	Shipping and Receiving Lead
Perrotte, Glynda	Warehouse Associate
Gebhart, Rachael	Warehouse Associate
Ciotola, Rosario	Warehouse Associate
Villegas Lira, Manuel	Warehouse Associate
Banderas, Roberto	Warehouse Associate
Garcia Moctezuma, Olany	Warehouse Associate
Gutierrez, Andrea	Warehouse Associate
Ortiz, Alejandro	Warehouse Associate
Bouldin, Anthony	Yard Driver
Ortiz, Samuel	Picking Lead
Barraza, Carlos	Replenishment Lead
Ochoa, Victor	Warehouse Associate
Chagollan, Cesar	Warehouse Associate
Alfaro, Alejandro	Warehouse Associate
Torres, Samuel	Inventory Control Coordinator
Leon, Felix	Warehouse Associate
Newman, Orlando	Warehouse Associate
Cano, Ned	Warehouse Associate
Sadiq, Sohail	Inventory Associate
Juarez, Nelbin	Warehouse Associate
Nino, Oscar	Warehouse Associate
Perez Jr, Johnny	Warehouse Associate
Cardenas, Monica	Warehouse Associate

Payroll Name	Job Title Description
Garcia Sanchez, Luis /	Warehouse Associate
Rogers, Robert	Warehouse Associate
Cuevas Guerrero, Selene	Finisher
Ramsey, Brian	Warehouse Associate
Nevarez, Alejandra	International Clerk
Rubalcaba, Felipe	Warehouse Associate
Hernandez, Nancy	Customer Service Clerk
Gomez, Alex	Warehouse Associate
Ortiz, Maynor	Warehouse Associate
Johnson, Nicholas	Warehouse Associate
Allen, Joshua	Warehouse Associate
Moss, Christopher	Warehouse Associate
Payne, Christopher	Warehouse Associate
Carvallo, Daniel	Wave Clerk
Fuentes, Mario	Warehouse Associate
Niyazov, Nison	Warehouse Associate
Ramirez, Yesenia	Warehouse Associate
Montiel-Rincon, Maria	Warehouse Associate
Martinelli, Christopher	Warehouse Associate
Lopez, Alexander	Systems Analyst
Rodgers, Lori	Operational Excellence Manager
Paramore, Jennings	EHS Warehouse Manager
Harbeck, Karen	Inventory Control Supervisor
Berkenbile, Bradley	Distribution Director
Trujillo, Leticia	Human Resources Supervisor
Lang, Clifton	Manager, EHS & Maintenance
Dalrymple, Paul	Operations Shift Supervisor
Benoit, Devon	Operations Shift Supervisor
Herndon, Ashleigh	Shipping Supervisor
Errico, Kenneth	Human Resources Manager
Lopez, Michael	Warehouse Associate
Nieto, Angel	Warehouse Associate
Sanchez, Jorge	Warehouse Associate
Payan, Ismael	Warehouse Associate

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Arteriocyte Medical Systems, Inc.

Physical Address: 45 South Street, Suite F

City: Hopkinton State: MA Zip: 01748

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 8887054786 Website: www.istobiologics.com

Name of Designated Representative (DR): Jerry Keefe

Licensing Company Email: istocorporate@istobiologics.com DR Email: jkeefe@istobiologics.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

6/16/2025

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Antron Engineering & Machine Co., Inc
Address: 170 Mechanic St. City: Bellingham State: MA Zip: 02019

Name: Micromedics
Address: 1270 Eagan Industrial Road City: Eagan State: MN Zip: 55121

Name: Midstate Mold & Engineering
Address: 20 Liberty Way D City: Franklin State: MA Zip: 02038

Name: Terumo BCT Ltd
Address: 10810 West Collins Avenue City: Lakewood State: CO Zip: 80215

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Isto Group, Inc.
Corporation/Organization Name: Arteriocyte Medical Systems, Inc.
Mailing Address: 7676 Forsythe Blvd, Suite 2700
City: St. Louis State: MO Zip: 63105
Telephone: 5084357489 Email: istocorporate@istobiologics.com
Contact Person Name: Kenneth Galbraith

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Arteriocyte Medical Systems, Inc.

Facility Name

Ganfeng Wu

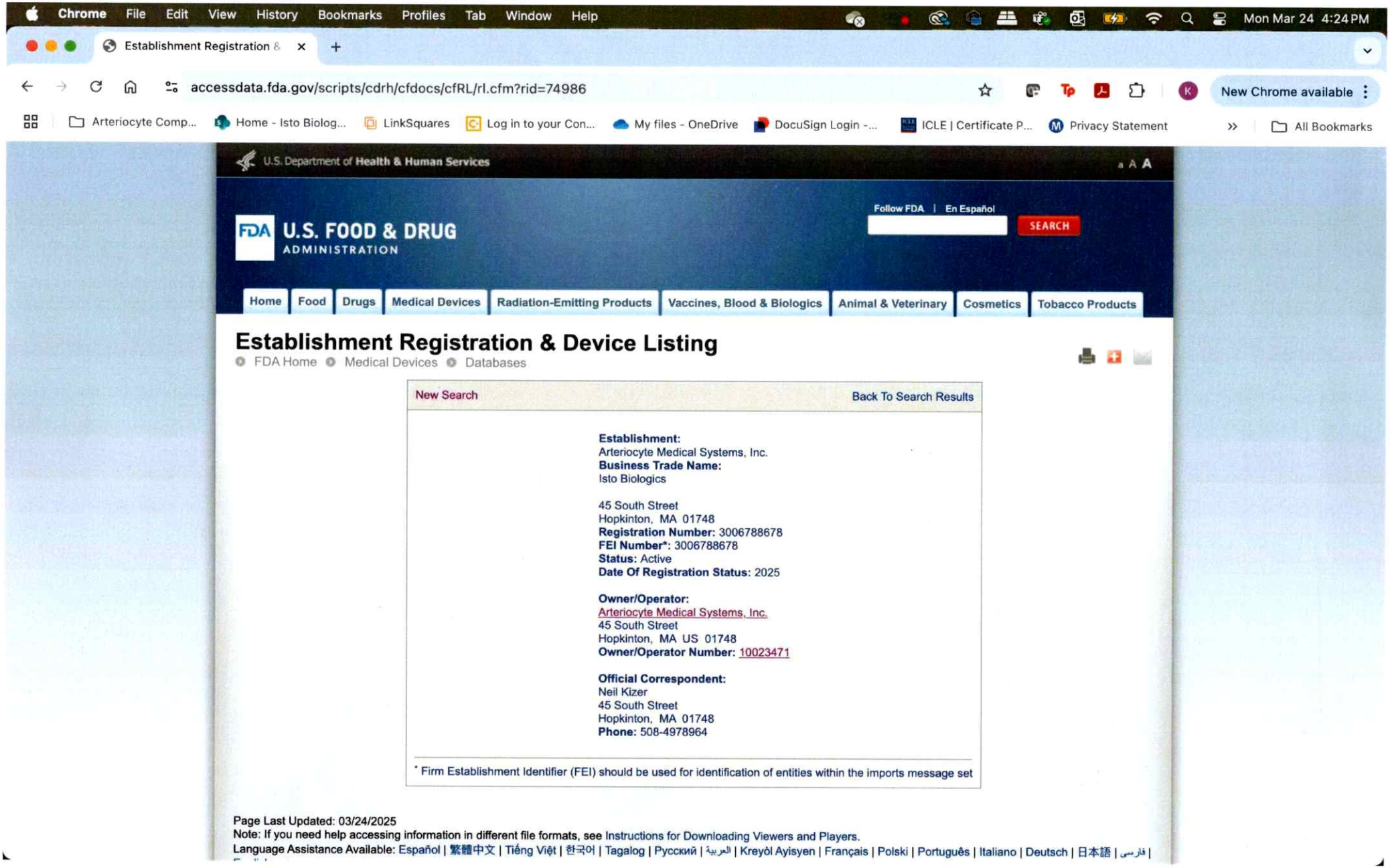
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/16/2025

Date

Board Use Only	Date Received: 6/18/25	Amount: $1,000 CK 31767


Chrome File Edit View History Bookmarks Profiles Tab Window Help
Mon Mar 24 4:24 PM
Establishment Registration &
accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=74986
New Chrome available
Arteriocyte Comp...
Home - Isto Biolog...
LinkSquares
Log in to your Con...
My files - OneDrive
DocuSign Login -...
ICLE | Certificate P...
Privacy Statement
All Bookmarks
U.S. Department of Health & Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION
Follow FDA | En Español
SEARCH
Home
Food
Drugs
Medical Devices
Radiation-Emitting Products
Vaccines, Blood & Biologics
Animal & Veterinary
Cosmetics
Tobacco Products
Establishment Registration & Device Listing
FDA Home
Medical Devices
Databases
New Search
Back To Search Results
Establishment:
Arteriocyte Medical Systems, Inc.
Business Trade Name:
Isto Biologics
45 South Street
Hopkinton, MA 01748
Registration Number: 3006788678
FEI Number*: 3006788678
Status: Active
Date Of Registration Status: 2025
Owner/Operator:
Arteriocyte Medical Systems, Inc.
45 South Street
Hopkinton, MA US 01748
Owner/Operator Number: 10023471
Official Correspondent:
Neil Kizer
45 South Street
Hopkinton, MA 01748
Phone: 508-4978964
* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set
Page Last Updated: 03/24/2025
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی |

Arteriocyte Medical Systems, Inc.

Board of Directors:
Harry Holiday
Jesse Klein
Joseph St. Geme

Officers:
Harry Holiday – Chairman/Secretary
Donald Brown – CEO
Brian Barnes – President
Jesse Klein – Vice-President
Elizabeth Borow – Vice-President
Ganfeng Wu – Vice-President, Chief Financial Officer
Joseph St. Geme – Vice-President
Nathan Taylor – Vice-President of Sales & Marketing

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ARTERIOCYTE MEDICAL SYSTEMS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTIETH DAY OF MAY, A.D. 2025.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

4443121 8300

SR# 20252475731

Authentication: 203744387

Date: 05-20-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Drug Manufacturer or Drug Distributor Controlled Substance Registration to:

ARTERIOCYTE MEDICAL SYSTEMS, INC.
45 SOUTH STREET, Suite 3
HOPKINTON, MA 01748

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: MA0087355

Type: Manufacture, Distribute

Schedules: VI

Issue Date: 01/22/2025

Expiration Date: 04/16/2026

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
05/30/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. St. Louis MO Office 4220 Duncan Ave, Suite 401 St Louis MO 63110 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Isto Biologics 45 South Street Hopkinton MA 01748 USA	INSURER A: Atlantic Specialty Insurance Company	27154
	INSURER B: OBI National INsurance Company	34452
	INSURER C: Homeland Insurance Company of New York	14190
	INSURER D:	

COVERAGES **CERTIFICATE NUMBER:** 570066694036 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [X] LOC OTHER:			711-01-52-74-0009	06/03/2025	06/03/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $10,000 $1,000,000 $2,000,000 Excluded
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY [ ] SCHEDULED AUTOS X HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			390-00-16-81-0003	06/03/2025	06/03/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
A	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED RETENTION			711-01-52-74-0009	06/03/2025	06/03/2026	EACH OCCURRENCE AGGREGATE	$4,000,000 $4,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [Y] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			4060439640009	06/03/2025	06/03/2026	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $1,000,000 $1,000,000 $1,000,000
C	Products Liability			850-00-03-04-0000 Claims Made	06/03/2025	06/03/2026	Aggregate Limit Retention Prod. Work Haz.Cvg.	$10,000,000 $150,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Isto Biologics
45 South Street
Hopkinton MA 01748 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc

Holder Identifier :

Certificate No : 570066694036

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AGENCY CUSTOMER ID: 570000068889
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Isto Biologics
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER Evanston Insurance Company	35378
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER Misc Med Prof			MKLV3PSM003127 Medical Professional	06/03/2025	06/03/2026	Each Incident	$1,000,000
	Cyber			MKLV1PCY000193	06/03/2025	06/03/2026	Each Event	$5,000,000

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBJJ1121

Application/License No. _____

ARTERIOCYTE MEDICAL SYSTEMS INC. DBA ISTO BIOLOGICS (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 45 South St Hopkinton, MA 01748 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 11, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of June, 20 25.

APPLICANT/PRINCIPAL
ARTERIOCYTE MEDICAL SYSTEMS INC. DBA ISTO BIOLOGICS

Authorized Representative

SURETY COMPANY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Patrick Breene, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ann Breene

Witness Joanne Wagner

Countersigned by:

NA
Nevada Resident Agent

Posted February 20, 2020

HARTFORD FIRE INSURANCE COMPANY

Hartford, Connecticut

Financial Statement, December 31, 2024

Statutory Basis

ASSETS

U.S. Government Bonds	$	548,689,389
Bonds of Other Governments		176,613,593
State, County and Municipal Bonds		1,086,274,087
Miscellaneous Bonds		6,611,928,546
Stocks		5,985,304,899
Short Term Investments		54,038,852
	$	**14,462,849,366**
Real Estate	$	283,466,249
Cash		68,685,525
Agents' Balances (Under 90 Day)		4,015,475,979
Other Invested Assets		4,887,481,789
Miscellaneous		4,495,822,980
Total Admitted Assets	$	**28,213,781,888**

LIABILITIES

Reserve for Claims and Claim Expense		$	11,735,400,585
Reserve for Unearned Premiums			2,853,522,077
Reserve for Taxes, License and Fees			46,650,892
Miscellaneous Liabilities			1,078,283,636
Total Liabilities		$	**15,713,857,190**
Capital Paid In	$ 55,320,000		
Surplus	12,444,604,698		
Surplus as regards Policyholders		$	**12,499,924,698**
Total Liabilities, Capital and Surplus		$	**28,213,781,888**

STATE OF FLORIDA
SEMINOLE COUNTY } SS.
CITY OF LAKE MARY

Joelle L. LaPierre, Assistant Vice President and Phyllis A. Clark, Assistant Secretary of the Hartford Fire Insurance Company, being duly sworn, each deposes and say that the foregoing is a true and correct statement of the said company's financial condition as of December 31, 2024.

Subscribed and sworn to before me this
11th day of March, 2025.

Marilez Arce
Notary Public

MARILUZ ARCE
Notary Public - State of Florida
Commission # HH 287363
My Comm. Expires Jul 13, 2026
Bonded through National Notary Assn.

Joelle L. LaPierre
Joelle L. LaPierre, Assistant Vice President

Phyllis A. Clark
Phyllis A. Clark, Assistant Secretary

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK SERVICES CENTRAL INC
Agency Code: 39-421678

- ☒ **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- ☒ **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- ☒ **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- ☐ **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :
Mary L. Yohnke of Los Angeles CA, Patrick Breene, Annmarie Breene, Dana Donahue, Patricia Dorsaneo, Cathy H. Ho , Wayne G. McVaugh, Sara Owens , Patricia A. Rambo, Lori S. Shelton, Kimberly G. Sherrod, Joanne C. Wagner , Babette Ward of PHILADELPHIA, Pennsylvania
their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of June 11, 2025.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Arteriocyte Medical Systems, Inc. MDEG License # (if applicable): _____

Physical Address: 45 South Street, Suite F

City: Hopkinton State: MA Zip: 01748

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-705-4786 Website: www.istobiologics.com

Licensing Company Email: istocorporate@istobiologics.com

Section 2: Personal Information

First: Jerry Middle: _____ Last: Keefe

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 45 South Street, Suite F

City: Hopkinton State: MA Zip: 01748

Telephone: [redacted] Email: jkeefe@istobiologics.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Framingham State University		08/88-05/94	
Address	City	State	Zip
100 State St	Framingham	MA	01701
Diploma/Degree obtained, if any			
Masters, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Massachusetts College of Liberal Arts		08/80-05/84	
Address	City	State	Zip
375 Church St.	North Adams	MA	01247
Diploma/Degree obtained, if any			
Bachelors, Computer Science			

School Name		From - To (MM/YY – MM/YY)	
Framingham South High School		08/77-05/80	
Address	City	State	Zip
Winch Park, 115 A St.	Framingham	MA	01701
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/91-Present	[redacted]	Hopkinton	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Arteriocyte Medical Systems, Inc.			03/10- Present	
Business Address		**City**	**State**	**Zip**
45 South Street, Suite F		Hopkinton	MA	01748
Phone	**Title**		**Number of Employed Hours**	
508-435-7407	Vice President of Operations		31,200	
Description of Duties				
- Lead operations teams in Hopkinton facilities including Supply Chain, Manufacturing, Kitting and Finished Goods, Information Technology.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/16/2025
Date

I, Jerry Keefe, **certify that as the MDEG Administrator for**

Arteriocyte Medical Systems, Inc.,

that I (initial that you have read and meet the following requirements):

1. ____ Have a high school diploma or its equivalent;
2. ____ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ____ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ____ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jerry Keefe
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/16/2025
Date

Board Use Only	Date Received: 6/18/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Arteriocyte Medical Systems, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 45 South Street Suite F

City Hopkinton State MA Zip 01748

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-705-4786 Website www.istobiologics.com

Licensing Company Email istocorporate@istobiologics.com

Section 2: Personal Information

First Jerry Middle _____ Last Keefe

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 45 South Street Suite F

City Hopkinton State MA Zip 01748

Telephone [redacted] Email jkeefe@istobiologics.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Framingham State University		08/88-05/94	
Address	**City**	**State**	**Zip**
100 State St	Framingham	MA	01701
Diploma/Degree obtained, if any			
Masters, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Massachusetts College of Liberal Arts		08/80-05/84	
Address	**City**	**State**	**Zip**
375 Church St.	North Adams	MA	01247
Diploma/Degree obtained, if any			
Bachelors, Computer Science			

School Name		From - To (MM/YY – MM/YY)	
Framingham South High School		08/77-05/80	
Address	**City**	**State**	**Zip**
Winch Park, 115 A St.	Framingham	MA	01701
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/91-Present	[redacted]	Hopkinton	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Arteriocyte Medical Systems, Inc.			03/10 - Present	
Business Address		**City**	**State**	**Zip**
45 South Street, Suite F		Hopkinton	MA	01748
Phone	**Title**		**Number of Employed Hours**	
5084357407	Vice President of Operations		31,200	
Description of Duties				
Lead operations teams in Hopkinton facilities including Supply Chain, Manufacturing, Kitting and Finished Goods, Information Technology.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/16/2025
Date

I, Jerry Keefe, **certify that as the designated representative for**

Arteriocyte Medical Systems, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jerry Keefe

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/16/2005

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jerry Keefe

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/16/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of middlesex

I, Jerry Keefe, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/16/2025

Date

Subscribed and Sworn to before me this 16 day of June.

Kathleen M Carl

Notary Public Signature

KATHLEEN M. CARL
MY COMMISSION EXPIRES ON
05-17-2030
COMMONWEALTH OF MASSACHUSETTS
NOTARY PUBLIC

(Seal)

Employee	State of Employment	Title
Adawag, Jesse M	CA	Dir of QA/RA
Addam, Nora	CA	Sales & Cust. Serv Representative
Addy (Ryan), Erin	FL	Regional SaLes Manager
Aispuro, Rebecca	CA	QA Specialist
Aouane, Mebrouk	MA	Kitting Supervisor
Baker, Linda	MA	Mfg. Assembler-Kitting
Barge, Rose	MO	Sr. Accountant
Barnes, Brian	MA	President
Barnes, Dawn	MA	Marketing Specialist
Barr, Mason	MA	Sales & Cust. Serv Representative
Barrett, Kevin	MA	Senior Accountant
Belleville (Ostiguy), Lindse	MA	Human Resources Manager
Black, Hailey	CA	Research Associate
Broadaway, Charles E	CA	Dir of Clinical Operations
Brown, Donald	TX	CEO
Brown, Paula	ID	Clinical Specialist I
Carl, Kathy	MA	Sr. Executive Asst.
Camacho, Jason	MA	Warehouse Associate
Castillo, Sydney	CA	Process Development Engineer
Chandler, Mitchell	MA	IT Support Specialist
Charon, Alexis	MA	Senior Quality Associate
Chime, Tenzin	MA	Regulatory Affairs Associate
Choezom, Tenzin	MA	Regulatory Affairs Manager
Choi, Bryan J	CA	Sr. Director of R&D
Coffey, Kendall	OH	Territory Manager
Coffman, Emilia	OR	Clinical Specialist II
Collins, Troy	MA	Senior Quality Associate
Craig, James (JD)	MA	Regional Sales Manager
Curry, Karen	MA	Senior Director of Revenue Operations
DeMello, Luke	TX	Territory Manager
DeVigil, Mirian	MA	Mfg. Assembler/ECR
Diegmueller, Jared	OH	Senior Director of Field Operations
Dlugolecki, Kathy	MA	V.P. of Human Resources
Doucette, Joshua	MA	Sr. Magellan Svc.& Repair Technician
Doucette, Joy	MA	Sr. Supervisor Magellan Svc & Repair
Duncan, David W	CA	Director of Operations
Epstein, Rachel	MA	Operations Specialist
Ferrick, Joe	VA	Regional Sales Manager
Fortner (Purkey), Melissa	CA	Sales Support Specialist
Fyrer, Kathryn	MA	Director of Project Management
Galbraith, Kenneth	MI	General Counsel
Gatley, Maria	MA	Senior Supervisor ECR

Giovanetti, Thomas (Neill)	SC	Senior Account Specialist
Glass, Kelly	IL	Regional Sales Manager
Govil, Amit P	CA	Chief Technology Officer
Govil, Virginia	CA	Data Entry Operator
Guerrero, Marie	CA	Operations Specialist
Haase, Jeff	CA	Controller
Hamby, Clayton	GA	Territory Manager
Hand, Raquel	CA	Senior Quality Specialist
Hanlon, Morgan	MA	Marketing Manager
Harpole, Mallory	TX	Senior Account Specialist
Hart, Christina	CT	Territory Sales Director
Hatjes, Taylor	OH	Territory Sales Director
Herrera, Letisia	CA	QC Specialist
Heuer, Alexandra	NY	Senior Account Specialist
Hinojosa, Rhea	CA	Senior Engineer of Quality
Holt, Kelly	CA	Operations & Purchasing Specialist
Humphrey, John	TN	Director of Business Development
Igoe, Sara	MA	Senior Accountant
Jacobs, Lisa	MA	Manufacturing Assembler/ECR
Kang, Rui	MA	Director Supply Chain & Mfg
Kasler, Antolette	CA	Research Associate
Keefe, Jerry	MA	VP, Operations
Keesara, Harini	MA	Sr. Regulatory Affairs Specialist
Kemp, Jessica	MA	Marketing Director
Kersey, Samantha	TX	Regional Sales Manager
King, Quinn	NY	Territory Manager
Kizer, Neil	MO	VP, Quality Assurance & Regulatory Affairs
Kropfelder, Christiane	VA	Regional Sales Manager
Le, Thi "Thao"	MA	Mfg. Assembler/ECR
Leacy, Taylor	MA	Finance Analyst
Lechtenberg, Kim	WA	Clinical Specialist II
Lewis, David	SC	Territory Manager
Li, Fuyan	MA	Product Manager
Li, Yiming	CA	Scientist
Liguori, Kristi	NY	Regional Sales Manager
MacDonald, Robert	MA	Controller
Marquez, Abraham	CA	Lead Operations Specialist
Martin, Mason	CA	Senior Research Associate
Martinez, Anthony	MA	Warehouse Associate
Massey, Matt	MA	Engineering Manager
McCarthy, Lavender	MA	Sr. Operations & Purchasing Specialist
McGrath, Haley	MA	Contract Specialist
McGrath, Sandra	MA	Customer Service Manager
McLain, Lauren	OR	Regional Sales Manager

Meek, Susan	OH	Regional Sales Manager
Mendez, Mathew	MA	Accounts Receivable Associate
Mikulak, John R.	MN	Area V.P. OUS
Mills, Tanner	MO	Senior Regional Sales Mgr.
Mitchell, Sean	MA	Business Analyst
Monahan, Kyle	CA	Territory Sales Director
Mulvehill, Kelly	MA	Sales Support Specialist
Murphy, Lindsay E.	OH	Area Vice President-East
Nuernberger, Kevin T	CA	Project Manager
Onofre, Dionisio	CA	Operations Supervisor
Ortiz, Marco	CA	Operations Specialist
Parker, Aline	MA	Quality Assurance Associate
Pazo, Alexandra	OH	Senior Account Specialist
Perryman, Ashley	MA	Customer Service Team Lead
Pierce, Omar	CA	Warehouse Associate
Rankin, Jared	TN	Regional Sales Manager
Rash, Jeremy	WA	Clinical Manager, ATS
Rena, Gabrielle	CA	Research Associate
Rigsby, Jeffery	WA	Sr. Clinical Specialist II
Rizalado, Julian	CA	Quality/Process Engineer
Rodriquez, Haley	MA	Sales & Cust. Serv Representative
Roland, Emma	AZ	Sr. Account Specialist
Roland, Erica	AZ	Sr. Account Specialist
Rose, Abby	MA	Associate Project Manager
Rose, Lisa	MA	Accts Receivable Manager
Samberg, Joshua	CA	G.M. of Engineering & Tissue Operations
Sanabria, Denise	MA	Sales & Cust. Serv Representative
Santos, Alcimar	MA	Quality System Manager
Scarborough, Nelson	MA	Bone Technology Coach
Schroeder, Anna	MO	Clinical Field Specialist
Schroeder, Christine	MO	Associate V.P. of Clinical Affairs
Scougal, Fiona	MA	Sales & Cust. Serv Representative
Silva, Caroline	MA	Tissue & Warehouse Associate
Slade, Jason	TX	Area Vice President-West
Smith, Ashleigh	MA	Manufacturing Assembler/ECR
Smith, Jennifer	FL	Director of Clinical Affairs
Smith, Karissa	MA	Lead Warehouse Associate
Sturgis, Stanton	GA	Regional Sales Manager
Swail, Grace	MN	Senior Account Specialist
Taylor, Nathan	OH	Chief Revenue Officer
Torres, Abel	MA	Warehouse Associate
Valente, Jose	MA	Manufacturing Assembler/ECR
VanDerVort, Anthony	CA	Facilities & Safety Manager
Villagrana, Sara	MA	Manufacturing Assembler/ECR

Ward, Jacquelyn R	IL	Territory Manager
Willette, Kellie	MA	Senior Manufacturing & Materials Manager
Wong, Dylan	MA	Research & Development Bioengineer
Wu, Ganfeng	MA	Chief Financial Officer
Part Time/Per Diem		
Avalos, Isaac	WA	Clinical Specialist II
Eddy, Gianna	MA	Customer Service Assistant
Edmerson, Exodus	OR	Clinical Specialist I
Goswamy, Ananya	MA	Lab Intern
Hand, Andrew	OR	Clinical Specialist I
Ignatovich, Dmitriy	OR	Clinical Specialist I
Larson, Maddox	MN	Sales Support Intern
Nesterovich, Wilhelm	OR	Clinical Specialist I
Salazar, Berenis	WA	Clinical Specialist II
Streight, Kelsey	OR	Clinical Specialist I
Tareen, Haaris	CA	Radiology Data Specialist
VanSlate, Simone	ID	Clinical Specialist I
Wu, Jacob	MA	Lab Intern
Young, Madisyn	AZ	Account Specialist

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:17 PM 07/18/2018
FILED 05:17 PM 07/18/2018
SR 20185730999 - File Number 4443121

AMENDED AND RESTATED

CERTIFICATE OF INCORPORATION

OF

ARTERIOCYTE MEDICAL SYSTEMS, INC.

(Pursuant to Sections 242 and 245 of the
General Corporation Law of the State of Delaware)

Arteriocyte Medical Systems, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "**General Corporation Law**")

DOES HEREBY CERTIFY:

1. That the name of this corporation is Arteriocyte Medical Systems, Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law on October 18, 2007.

2. That the Board of Directors duly adopted resolutions proposing to amend and restate the Certificate of Incorporation of this corporation, declaring said amendment and restatement to be advisable and in the best interests of this corporation and its stockholders, and authorizing the appropriate officers of this corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

ARTICLE 1 - NAME

The name of the corporation (the "**Corporation**") is: Arteriocyte Medical Systems, Inc.

ARTICLE 2 - REGISTERED OFFICE AND REGISTERED AGENT

The address, including street, number, city, and county, of the registered office of the Corporation in the State of Delaware is: 160 Greentree Drive, Suite 101, Dover, County of Kent, Delaware 19904. The name of the Corporation's resident agent at such address is: National Registered Agents, Inc.

ARTICLE 3 - NATURE OF BUSINESS

The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which a corporation may be incorporated under the General Corporation Law.

In addition to the powers and privileges conferred upon the Corporation by law and those incidental thereto, the Corporation shall possess and may exercise all the powers and privileges which are necessary or convenient to the conduct, promotion or attainment of the business or purposes of the Corporation.

ARTICLE 4 - CAPITAL STOCK

The total number of shares of stock which the Corporation shall have authority to issue is Ten Thousand (10,000) shares of common stock, of the par value of $0.01 per share. The Corporation shall have authority to issue fractions of shares.

ARTICLE 5 - EXISTENCE

The Corporation is to have perpetual existence.

ARTICLE 6 - BOARD OF DIRECTORS

The management of the business and the conduct of the affairs of the Corporation shall be vested in its Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed by, or in the manner provided in, the Bylaws. The phrase "whole Board" and the phrase "total number of directors" shall each mean the total number of directors which the Corporation would have if there were no vacancies.

ARTICLE 7 - BYLAWS

Except as otherwise provided in this Certificate of Incorporation or in any stockholder agreement between the Company and any holders of capital stock of the Corporation, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws of the Corporation.

ARTICLE 8 - INDEMNIFICATION AND LIABILITY LIMITATION

(a) The Corporation shall indemnify and protect any director, officer, employee or agent of the Corporation, or any person who serves at the request of the Corporation as a director, officer, employee, member, manager or agent of another corporation, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise, to the fullest extent permitted by the laws of the State of Delaware.

(b) The stockholders, officers, directors, employees and agents of the Corporation shall not be personally liable for the payment or performance of the debts or other obligations of the Corporation.

(c) Without limiting the generality of the foregoing provisions of this Article 9, to the fullest extent permitted or authorized by the laws of the State of Delaware, including, without limitation, the provisions of § 102(b)(7) of Title 8 of the Delaware Code as now in effect and as it may from time to time hereafter be amended, no director of the Corporation shall be personally liable to the Corporation or to its stockholders for monetary damages for breach of fiduciary duty as a director. Any repeal or modification of the limitation of liability provided by the immediately preceding sentence shall not adversely affect any right or protection of a director of the Corporation existing hereunder with respect to any act or omission occurring prior to or at the time of such repeal or modification. If the General Corporation Law is amended after the effective date of this Certificate of Incorporation to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation automatically shall be eliminated or limited to the fullest extent permitted by the General Corporation Law, as so amended.

ARTICLE 9 - STOCKHOLDERS OF RECORD

Except as may be otherwise provided by statute, the Corporation shall be entitled to treat the registered holder of any shares of the Corporation as the owner of such shares and of all rights derived from such shares for all purposes, and the Corporation shall not be obligated to recognize any equitable or other claim to or interest in such shares on the part of any other person, including, but without limiting the generality of the term "person", a purchaser, pledgee, assignee or transferee of such shares, unless and until such person becomes the registered holder of such shares. The foregoing shall apply whether or not the Corporation shall have either actual or constructive notice of the claim by or the interest of such person.

ARTICLE 10 - BOOKS AND RECORDS

The books and records of the Corporation may be kept (subject to any provision contained in the statutes of the State of Delaware) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

ARTICLE 11 - AMENDMENTS

From time to time any of the provisions of this Certificate of Incorporation may be amended, altered, changed or repealed, and other provisions authorized or permitted by the General Corporation Law at the time in force may be added or inserted in the manner and at the time prescribed by the General Corporation Law, and all rights at any time conferred upon the stockholders of the Corporation by this Certificate of Incorporation are granted subject to the provisions of this Article.

Any person, upon becoming the owner or holder of any shares of stock or other securities issued by the Corporation, does thereby consent and agree that (i) all rights, powers, privileges,

obligations or restrictions pertaining to such person or such shares or securities in any way may be altered, amended, restricted, enlarged or repealed by legislative enactments of the State of Delaware or of the United States hereinafter adopted which have reference to or affect corporations, such shares, securities, or persons and (ii) the Corporation reserves the right to transact any business of the Corporation, to alter, amend or repeal this Certificate of Incorporation, or to do any other acts or things as authorized, permitted or allowed by such legislative enactments.

ARTICLE 12 - COMPROMISE WITH CREDITORS

Whenever a compromise or arrangement is proposed between this Corporation and its creditors or any class of them or between this Corporation and its stockholders or any class of them, any court of equitable jurisdiction within the State of Delaware may, on the application in a summary way of this Corporation or of any creditor or stockholder thereof or on the application of any receiver or receivers appointed for this Corporation under § 291 of Title 8 of the Delaware Code or on the application of trustees in dissolution or of any receiver or receivers appointed for this Corporation under § 279 of Title 8 of the Delaware Code, order a meeting of the creditors or class of creditors, or of the stockholders or class of stockholders of this Corporation, as the case may be, to be summoned in such manner as the said court directs. If a majority in number representing three-fourths (¾) in value of the creditors or class of creditors, or of the stockholders or class of stockholders of this Corporation, as the case may be, agree to any compromise or arrangement and to any reorganization of this Corporation as consequence of such compromise or arrangement, the said compromise or arrangement and the said reorganization shall, if sanctioned by the court to which the said application has been made, be binding on all the creditors or class of creditors, or on all the stockholders or class of stockholders, of this Corporation, as the case may be, and also on this Corporation.

* * * *

3. That the foregoing amendment and restatement was approved by the holders of the requisite number of shares of this corporation in accordance with Section 228 of the General Corporation Law.

4. That this Amended and Restated Certificate of Incorporation, which restates and integrates and further amends the provisions of this Corporation's Certificate of Incorporation, has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned has executed this Amended and Restated Certificate of Incorporation as of July 11, 2018.

ARTERIOCYTE MEDICAL SYSTEMS, INC.

By: _____
Name: Jesse Klein
Title: Vice President

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH01287	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Bayer HealthCare LLC

Physical Address: 800 Dwight Way

City: Berkeley State: CA Zip: 94710

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.bayerhealthcare.com

Name of Designated Representative (DR): Todd Anthony Goulart

Licensing Company Email: BHL@slsny.com DR Email: todd.goulart@bayer.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: Drugs (Biologics)	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Distributors, Distribution sites within organization		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/03/2009		CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2009-3367	Colorado State Board of Pharmacy

Reason/Charge
Discipline

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Bayer HealthCare LLC	N/A

Name of Business/Industry/Entity
Bayer HealthCare LLC

Provide explanation below:

See attached supporting documents.

Michael J McDonald

Original Signature (electronic, copies or stamps not accepted)

9/26/2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
09/19/2019		KS	Topeka	Shawnee
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
19-444		Kansas Board of Pharmacy		
Reason/Charge				
Discipline				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Bayer HealthCare LLC		N/A		
Name of Business/Industry/Entity				
Bayer HealthCare LLC				

Provide explanation below:

See attached supporting documents.

Michael J McDonald
Original Signature (electronic, copies or stamps not accepted)

9/26/2024
Date

Discipline - CO 06/03/09
Case #: 2009-3367
Resolved

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

Bill Ritter, Jr.
Governor

D. Rico Munn
Executive
Director

June 3, 2009

Bayer HealthCare LLC
Attn: Gerald Stonebarger, Designated Representative
747 Grayson Road
Berkley, CA 94701

RECEIVED
JUN 0 8 2009
BY:----------

RE: Stipulation and Final Agency Order
Case #2009-3367

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF **BAYER HEALTHCARE, LLC**,

Dear Mr. Stonebarger:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) in the above mentioned matter, which became effective June 3, 2009.

Accordingly, and pursuant to Item 8 – Conditional Registration of the Stip/FAO, Bayer HealthCare LLC, at the above listed location, has been issued out-of-state prescription drug wholesaler registration #7612, effective June 3, 2009.

If you have any questions, or require additional information, please contact the Board's office.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson
Complaint Analyst

Enclosure

cc: Robert J. Haydu, Associate Director, Regulatory Affairs CMC
Bayer HealthCare Pharmaceuticals
Jazell Carter, Licensing Specialist, Office of Licensing
File

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case No. 2009-3367

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF **BAYER HEALTH CARE LLC,**

Wholesaler Applicant.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Bayer Health Care, LLC ("Wholesaler Applicant") to resolve all matters pertaining to Board Case Number 2009-3367 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Wholesaler Applicant, its application for registration as an out-of-state wholesaler and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Wholesaler Applicant admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

3. On February 4, 2009, Wholesaler Applicant distributed prescription drugs into Colorado without having first registered as an out-of-state wholesaler in the State of Colorado.

4. On March 16, 2009, the Board issued Wholesaler Applicant a Cease and Desist Order for engaging in unregistered wholesale distribution of drugs into the State of Colorado.

5. Wholesaler Applicant's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes:

Colorado Revised Statutes

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in

accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

12-22-125.2. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

* * *

12-22-802. Wholesaler license requirements. (1) A wholesaler that resides in this state shall be licensed by the board. A wholesaler that does not reside in this state shall be licensed in this state prior to engaging in the wholesale distribution of prescription drugs in this state...

* * *

6. On March 11, 2009, Wholesaler Applicant submitted an out-of-state wholesaler application, which application was denied by the Board.

7. The Board finds and concludes, and Wholesaler Applicant agrees, that based upon Wholesaler Applicant's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances as a condition of its registration as an out-of-state wholesaler.

DISPOSITION
Conditional Registration;
$5,000.00 Fine Plus 15% Surcharge and Terms
Agreement to Comply with §§12-22-801, *et seq.* C.R.S.
Release from Cease and Desist Order

8. **Conditional Registration.** Wholesaler Applicant shall be granted a registration as an out-of-state wholesaler upon execution of this Final Agency Order and satisfaction of the terms and conditions set forth herein.

9. **Fine with Surcharge.** Wholesaler Applicant accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S., Wholesaler Applicant shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Wholesaler Applicant understands and acknowledges, pursuant to §24-34-108, C.R.S., that the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 15% of this fine. Wholesaler Applicant shall therefore pay a total amount of **Five Thousand, Seven Hundred Fifty Dollars and No Cents ($5,750.00).** The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Wholesaler Applicant submits this signed Final Agency Order to the Board.

10. **Compliance.** Wholesaler Applicant shall at all times remain in compliance with §§12-22-801, *et seq.* C.R.S. and shall not at any time distribute prescription drugs into Colorado without being registered as an out-of-state wholesaler in the State of Colorado at the time of distribution.

11. **Release from Cease & Desist Order.** Upon execution of this Final Agency Order, payment of the required fine as required above in paragraph 9, and issuance of Wholesaler Applicant's registration as an out-of-state wholesaler in the state of Colorado as set forth above in paragraph 8, the terms of the Cease and Desist Order entered on March 16, 2009 no longer apply and Wholesaler Applicant is hereby RELEASED from the Cease and Desist Order. The Cease and Desist Order shall remain a public record published in accordance with the Colorado Open Records Act and Board policy along with this Final Agency Order, as set forth below in paragraph 16.

12. **Advisements and Waivers.** Wholesaler Applicant enters into this Final Agency Order freely and voluntarily, whether or not Wholesaler Applicant has consulted with legal counsel. Wholesaler Applicant acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;
    b. To respond to said formal notice of charges;
    c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
    d. To appeal this Board order.

    Wholesaler Applicant freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

13. **Acknowledgments.** The undersigned authorized agent of Wholesaler Applicant has read this Final Agency Order in its entirety and acknowledges, whether or not Wholesaler Applicant has consulted with legal counsel, that Wholesaler Applicant understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable.

14. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Wholesaler Applicant to take all appropriate steps to comply fully with this Final Agency Order. Wholesaler Applicant acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Wholesaler Applicant to comply with all terms and conditions of this Final Agency Order.

15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Reviewed
Legal:
Finance:

Robert T. Hayden
Authorized Agent of Wholesaler Applicant

Dated: 5/28/2009

Subscribed and sworn to by Robert T. Hayden, in his/her capacity as an authorized agent of Bayer HealthCare Pharmaceuticals, before me in the County of Morris, State of NJ, this 28th day of May, 2009.

Laura Simonelli
Notary Public

My commission expires:
October 31, 2010

LAURA SIMONELLI
Notary Public of New Jersey
My Commission Expires
October 31, 2010

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 3RD day of June, 2009.

State Board of Pharmacy

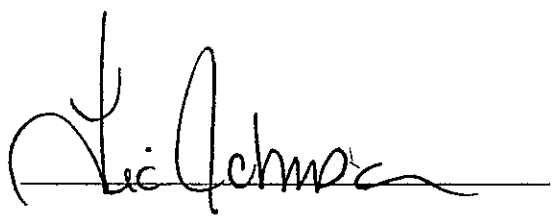
BY: Wendy J Anderson

Wendy Anderson
Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 3rd day of June 2009, addressed as follows:

Bayer Health Care, LLC
Attn: Gerald Stonebarger
747 Grayson Road
Berkeley, CA 94710



800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Discipline - KS 09/19/19
Case #: 19-444
Resolved
Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

September 19, 2019

BAYER HEALTHCARE LLC
800 DWIGHT WAY
BERKELEY, CA 94710

RE: Case No. 19-444

To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $500. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

Filed By

BEFORE THE KANSAS BOARD OF PHARMACY SEP 19 2019

KANSAS STATE BOARD OF PHARMACY

In the Matter of	Case No. 19-444
Bayer HealthCare LLC	
Registration No. 5-109760	

SUMMARY ORDER

NOW, on this 19th day of September 2019, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of Bayer HealthCare LLC. ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 5-00739 which entitles Respondent to operate as a wholesale distributor in the State of Kansas ("Respondent's Registration").

2. On January 1, 2019, Respondent's facility experienced a change in ownership.

3. On May 29, 2019, the Board received Form BA-05 Distributor Registration Application from Respondent, notifying the Board of the change in ownership.

4. On July 11, 2019, the Board approved Respondent's Distributor Application.

5. Subsequently, Respondent's previous registration number 5-00739 was cancelled, effective January 1, 2019, and Respondent was issued new registration number 5-109760, effective May 29, 2019.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1643, it shall be unlawful for any person to distribute at wholesale any drugs without first obtaining a registration as a wholesale distributor from the Board.

3. Respondent's application documents indicated Respondent had functioned as a wholesale distributor in the state of Kansas between the January 1, 2019 ownership change and the May 29, 2019 effective new registration.

4. By operating as a wholesale distributor in the state of Kansas prior to its Wholesale Distributor Application approval by the Board, Respondent violated K.S.A. 65-1643(c).

ORDER

The Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $500.00. Respondent has 30 days from the date of this order to pay the full $500.00.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

9/19/19
Date

Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 19th day of September 2019, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

BAYER HEALTHCARE LLC
800 DWIGHT WAY
BERKELEY, CA 94710

Kansas Board of Pharmacy Staff

9471083242S8 C034

Pat LEGAL

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year:

Name: Cardinal Health SPD
Address: 6640 Echo Ave, Ste J City: Reno State: NV Zip: 89506
Name: Hemostasis and Thrombosis Ctr of NV
Address: 8352 W Warm Springs Rd, Ste 200 City: Las Vegas State: NV Zip: 89113
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

N/A

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Bayer Essure Inc. (11.5%), Bayer Medical Care, Inc. (51.6%), Bayer West Coast Corporation (26.5%), Bayer HealthCare US Funding LLC (5.33%)
Corporation/Organization Name: Bayer HealthCare LLC
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: BHL@slsny.com
Contact Person Name: Christine Cannon

N/A

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA #: 2910913	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Bayer HealthCare LLC

Facility Name

Michael J McDonald

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9/26/2024

Date

Board Use Only	Date Received: 3/17/25	Amount: CK $1000 6660

Bayer HealthCare LLC

Corporate Address: 100 Bayer Boulevard, Whippany, NJ 07981 USA
FEIN: 06-1653795
www.bayerhealthcare.com

Drug Labeler Code: 0026, 0280, 11523 please see notes
Incorporation State: DE

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
BRK	800 Dwight Way Berkeley, CA 94710 County: Alameda	2910913		127769128	No	(510) 705-5000	(510) 705-5553

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Todd Anthony Goulart	[redacted]	Designated Representative	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Bayer Medical Care Inc.	1 Bayer Drive Indianola, PA 15051	N/A	51.6%	N/A	25-1151038	N/A	N/A
Bayer West Coast Corporation	100 Bayer Boulevard Whippany, NJ 07981	N/A	26.5%	N/A	45-3945391	N/A	N/A
Bayer Essure Inc.	100 Bayer Boulevard Whippany, NJ 07981	N/A	11.5%	N/A	94-3170244	N/A	N/A
Other Owners owning less than 4%		N/A		N/A		N/A	N/A
Bayer HealthCare US Funding LLC	800 North Lindbergh Blvd. St. Louis, MO 63167	N/A	5.33%	N/A	36-4813010	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
William B Dodero	[redacted]	Secretary	No	[redacted]		
Priyal P Patel		Treasurer	No			
Gurumurthy Ramamurthy		President	No			
Michael J McDonald		Assistant Secretary	No			
Keith Robert Abrams		Assistant Secretary				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Corporation Service Company			

Bayer HealthCare LLC

3PLS Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Exel Inc. dba DHL Supply Chain	84 Zions View Road Manchester, PA 17345					

Disciplinary History: CO 2009, KS 2019

FDA

An official website of the United States government Here's how you know

FDA

Home > Drug Database > DECRS > Search Result

Share Tweet LinkedIn Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *Bayer HealthCare LLC*

Showing 1 to 3 of 3 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Bayer HealthCare LLC	2243252	785159372	MANUFACTURE	36 Columbia Rd, Morristown, New Jersey (NJ) 07960, United States (USA)	12/31/2025
BAYER HEALTHCARE LLC	2510692	072827066	ANALYSIS; LABEL; MANUFACTURE; PACK; REPACK	400 W Stoever Ave, Myerstown, Pennsylvania (PA) 17067-1418, United States (USA)	12/31/2025
Bayer HealthCare LLC	2910913	127769128	ANALYSIS; API MANUFACTURE; LABEL; MANUFACTURE; PACK	800 Dwight Way, Berkeley, California (CA) 94710, United States (USA)	12/31/2025

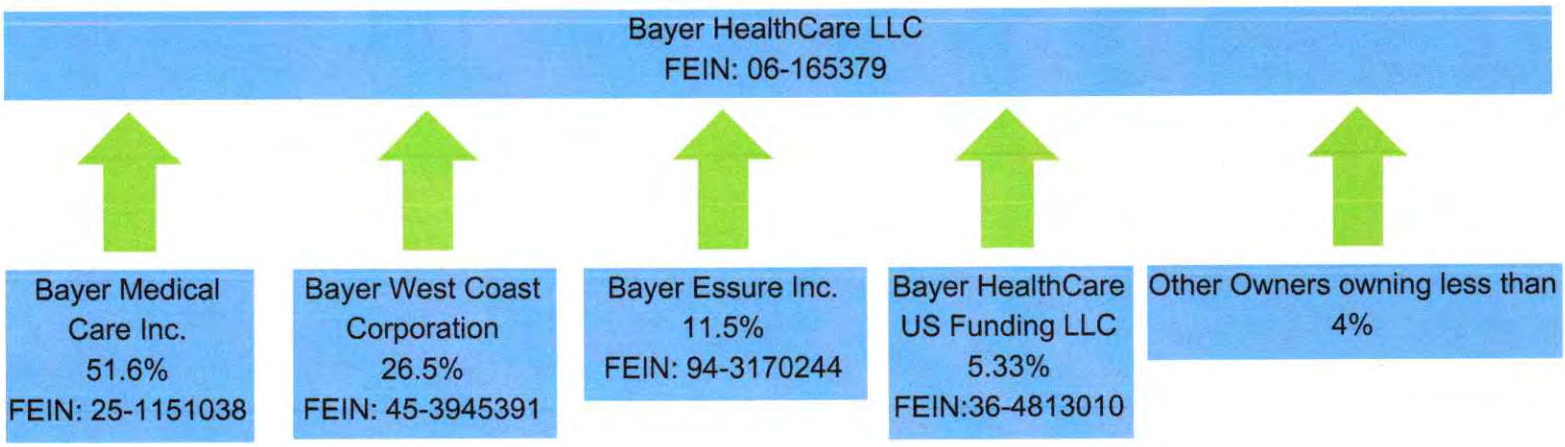
Previous 1 Next

Data Current Through: Wednesday, Mar 12, 2025

New Search

Org Chart

POST-Common Ownership Org. Chart for Bayer HealthCare LLC
After April 1, 2024



Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BAYER HEALTHCARE LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BAYER HEALTHCARE LLC" WAS FORMED ON THE SIXTEENTH DAY OF OCTOBER, A.D. 2002.

Jeffrey W. Bullock, Secretary of State

3536270 8300

SR# 20243732407

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204439341

Date: 09-19-24

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

DRUG MANUFACTURING LICENSE

Bayer Healthcare LLC
800 Dwight Way
Berkeley, CA 94710

LICENSE NUMBER: 105358
EXPIRATION DATE: 11/15/2026

The person named herein is licensed to manufacture drugs through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

OSP 07 102308

Printed: 11/20/2024

Home State License

CONTINUATION CERTIFICATE

Liberty Mutual Insurance Company , Surety upon

a certain Bond No. 674212375

dated effective September 4, 2020
(MONTH-DAY-YEAR)

on behalf of Bayer HealthCare LLC
(PRINCIPAL)

and in favor of Nevada State Board of Pharmacy
(OBLIGEE)

does hereby continue said bond in force for the further period

beginning on September 4, 2024
(MONTH-DAY-YEAR)

and ending on September 4, 2025
(MONTH-DAY-YEAR)

Amount of bond $ 25,000.00

Description of bond Pharmaceutical Wholesaler

PROVIDED: That this continuation certificate does not create a new obligation and is executed upon the express condition and provision that the Surety's liability under said bond and this and all Continuation Certificates issued in connection therewith shall not be cumulative and that the said Surety's aggregate liability under said bond and this and all such Continuation Certificates on account of all defaults committed during the period (regardless of the number of years) said bond had been and shall be in force, shall not in any event exceed the amount of said bond as hereinbefore set forth.

Signed and dated on August 28, 2024
(MONTH-DAY-YEAR)

Liberty Mutual Insurance Company

By _____
Kathleen K. Freund , **Attorney-In-Fact**

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

S-0157/GEEF 11/99

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint,

Kathleen K. Freund

all of the city of Denver, state of Colorado each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 28th day of August, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Marsh MSurety POA LMIC OCIC WAIC Multi Co_082024

Bond w/ Rider

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 674212375

Application/License No. _____

Bayer Healthcare LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 800 Dwight Way, Berkeley, CA 94710 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 4, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 4th day of September, 2020.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Kathleen K. Freund, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8201188

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Stacy Killebrew, Kathleen K. Freund

all of the city of Denver state of CO each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 2nd day of May, 2019.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: David M. Carey
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 2nd day of May, 2019 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Teresa Pastella, Notary Public
Upper Merion Twp., Montgomery County
My Commission Expires March 28, 2021
Member, Pennsylvania Association of Notaries

By: Teresa Pastella
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
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ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 4th day of September, 2020.

By: Renee C. Llewellyn
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

To confirm the validity of this Power of Attorney call 1-610-832-8240 between 9:00 am and 4:30 pm EST on any business day.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 07/07/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA, LLC.
800 Market Street, Suite 1800
St. Louis, MO 63101-2500

CN102140943--GAW5-25-26

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 **FAX (A/C, No):**
E-MAIL ADDRESS: StLouis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : HDI Global Insurance Co.	41343
INSURER B : Old Republic Insurance Company	24147
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Bayer HealthCare Pharmaceuticals Inc.
c/o Bayer Corporation
800 N. Lindbergh Blvd.
St. Louis, MO 63167

COVERAGES **CERTIFICATE NUMBER:** CHI-010958727-01 **REVISION NUMBER:** 1

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			GLD1136616	04/01/2025	04/01/2026	EACH OCCURRENCE	$ 5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 5,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 5,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			MWTB 319159 25	04/01/2025	04/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$ 2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			MWC 319158 25	04/01/2025	04/01/2026	X PER STATUTE ☐ OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N / A					E.L. EACH ACCIDENT	$ 2,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 2,000,000
							ASE - POLICY LIMIT	$ 2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule,
Evidence of Insurance

- Not Needed but it was Provided

CERTIFICATE HOLDER

Bayer Healthcare LLC
800 Dwight Way

Berkeley, CA 94710

CANC

SHOU[illegible]BOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE [illegible]ATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Bayer HealthCare LLC

Pharmacy/Wholesaler License # (if applicable): WH01287

Physical Address: 800 Dwight Way

City: Berkeley State: CA Zip: 94710

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.bayerhealthcare.com

Licensing Company Email: BHL@slsny.com

Section 2: Personal Information

First: Todd Middle: Anthony Last: Goulart

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Brentwood State: CA Zip: [redacted]

Telephone: [redacted] Email: todd.goulart@bayer.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Antioch High School			09/82-06/84	
Address		City	State	Zip
700 W 18th Street		Antioch	CA	94509
Diploma/Degree obtained, if any				
Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19-current	[redacted]	Brentwood	CA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
04/15-05-19		Oakley	CA	
From - To (MM/YY – MM/YY)		City	State	
03/02-04/15		Antioch	CA	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Bayer HealthCare LLC			10/2008 - Present	
Business Address		**City**	**State**	**Zip**
800 Dwight Way		Berkeley	CA	94710
Phone	**Title**		**Number of Employed Hours**	
(510) 705-5000	Associate Manager Shipping / Designated Representative		~ 33,280 hours	
Description of Duties				
Coordinate logistics with customer service on over 50 International destinations, review shipping documents, manage/supervise the shipping personnel that performs the packing and screening of products for shipment, involved with the planning for the materials used in packing the Domestic and International shipments.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Todd Anthony Goulart, **certify that as the designated representative for**

Bayer HealthCare LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TG I am at least 21 years of age;
3. TG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Todd Anthony Goulart

Print Name (First, Last)

Todd Anthony Goulart

Original Signature (electronic, copies or stamps not accepted)

2024-09-23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Todd Anthony Goulart

Print Name (First, Last)

Todd Anthony Goulart

Original Signature (electronic, copies or stamps not accepted)

2024-09-23

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of ALAMEDA

I, Todd Anthony Goulart, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Todd Anthony Goulart

Original Signature Todd Anthony Goulart

2024-09-23

Date

Subscribed and Sworn to before me this 23rd day of September, 2024

Notary Public Signature

PETER TAN
COMM # 2364991
NOTARY PUBLIC • CALIFORNIA
ALAMEDA COUNTY
Commission Expires July 10, 2025

(Seal)

Berkeley Facility Employee List

- Armando Rodriguez-Assistant Supervisor Shipping
- David Hernandez-Shipping Clerk
- Isaia Ofoia-Shipping Clerk
- Gonzalo Rodriguez-Shipping Clerk
- Jose Mendoza-Shipping Clerk

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Bright Uro Inc

Physical Address: 3 Goddard

City: Irvine State: CA Zip: 92618

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 949-216-0873 Website: www.brighturo.com

Name of Designated Representative (DR): Tracy Maahs

Licensing Company Email: info@brighturo.com DR Email: Tracy@brighturo.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

18 JULY 2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: This is a medical device - so no pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): _____

Corporation/Organization Name: Bright Uro Inc

Mailing Address: 3 Goddard

City: Irvine State: CA Zip: 92618

Telephone: 949-216-0873 Email: info@brighturo.com

Contact Person Name: Tracy Maahs

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Bright Uro Inc

Facility Name

Derek Herrera

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

18 JULY 2025

Date

Board Use Only	Date Received: _____	Amount: _____

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
BRIGHT URO, INC.
3 Goddard
Irvine, CA 92618
Registration Number: 3029753827
FEI Number*: 3029753827
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
Bright Uro, Inc.[6]
3 Goddard
Irvine, CA US 92618
Owner/Operator Number: 10093586[7]

Official Correspondent:
Suranjan Roychowdhury
3 Goddard
Irvine, CA 92618
Phone: 01-949-2160873

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10093586&OwnerOperatc

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10093586&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10093586&OwnerOperatc

0870

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
BRIGHT URO, INC.
3 Goddard
Irvine, CA 92618
Status: Active; Awaiting Assignment Of Registration Number
Date Of Registration Status: 2025

Owner/Operator:
Bright Uro, Inc.[6]
3 Goddard
Irvine, CA US 92618
Owner/Operator Number: 10093586[7]

Official Correspondent:
Suranjan Roychowdhury
3 Goddard
Irvine, CA 92618
Phone: 01-949-2160873

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10093586&OwnerOperato
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10093586&OwnerOperato

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FDA

U.S. Food and Drug Administration
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Silver Spring, MD 20993
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U.S. Department of **Health & Human Services**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10093586&OwnerOperato
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10093586&OwnerOperato

Kristy Langston

From: Kevin Hershberger <kevin@brighturo.com>
Sent: Tuesday, August 5, 2025 3:56 AM
To: Kristy Langston; h.herrera@pharmacy.nv.gov
Cc: Tracy Maahs
Subject: RE: Nevada Wholesaler Application - Bright Uro Inc.
Attachments: Bright Uro - Cap Table - 06162025.xlsx; Bright Uro Inc._State of NV LC Draft V1.docx

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello Kristy,
Thank you for confirming receipt of our application and providing the follow-up requests. Please see our responses to each item below:

- **A list of officers:** *Derek Herrera is the only officer named in Bright Uro's corporate documents. We provided his name and additional required information in the application.*
- **A list of corporate shareholders and their percent ownership:** *Please see the attached table for the shareholder information as requested.*
- **A Certificate of Good Standing from the Secretary of State's Office in the State where the business was domiciled, in this case Delaware:** *The state in which Bright Uro, Inc. is domiciled is California (Bright Uro is incorporated, but not domiciled, in Delaware). We provided a copy of California's Certificate of Good Standing as part of the application supplement. Please confirm if that was not received. Thank you.*
- **A Personal History Record Application (see attached) for each shareholder/stockholder/partner/owner with 10% or more ownership of the company:** *There are no individual shareholder/stockholder/partner/owners with 10% or more ownership of the company.*
- **A $100,000 Surety Bond (see attached):** *Per Nevada law , when a bond is required for the protection of the state, typically a letter of credit can be provided instead (see NRS 100.065). We also noted that the application instructions indicate that a $100,000 bond is only required if not FDA registered. Bright Uro, Inc. is FDA registered, and therefore we understand the bond requirement of $25,000 applies instead (per page 5 of the Wholesaler Application which contains these instructions). We have attached a copy of a proposed letter of credit in that amount. Please let us know if this is satisfactory and we will issue the letter accordingly.*

Thank you for your assistance and please advise if you have any additional questions.

Sincerely,
Kevin

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	BRIGHT URO, INC.
Entity No.:	4710920
Registration Date:	03/01/2021
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of June 16, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 338115627

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Bright Uro, Inc.
3 Goddard
Irvine, CA 92618

LICENSE NUMBER: 124996
EXPIRATION DATE: 2/25/2027

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

OSP 07 102308

Printed: 3/5/2025

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 2/25/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER ARCON Insurance Brokers 301 Bayview Circle STE 104 SMB 5126 Newport Beach CA 92660	CONTACT NAME: Arcon Service PHONE (A/C, No, Ext): (866) 661-2345 FAX (A/C, No): E-MAIL ADDRESS: contact@arconinsurance.com
INSURED Bright Uro, Inc. 3 Goddard Irvine CA 92618	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Hartford Underwriters Ins. Co. — 30104 INSURER B: ProAssurance Specialty Ins. Co. — 17400 INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** 2025 Master Cert **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			72 SBA BS1HPL	04/19/2025	04/19/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ EXCLUDED $
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] ALL OWNED AUTOS [ ] SCHEDULED AUTOS [X] HIRED AUTOS [X] NON-OWNED AUTOS [ ]			72 SBA BS1HPL	04/19/2025	04/19/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ 1,000,000 $ $ $ $
A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [X] RETENTION $ 10,000			72 SBA BS1HPL	04/19/2025	04/19/2026	EACH OCCURRENCE AGGREGATE [ ]	$ 4,000,000 $ 4,000,000 $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [ ] N/A If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $
B	PRODUCTS LIABILITY			N24CA38008B	7/24/2024	7/24/2025	EACH OCCURRENCE AGGREGATE	$3,000,000 $3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

PROOF ONLY DOCUMENT

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Graham Harvey/H001

© 1988-2014 ACORD CORPORATION. All rights reserved.

L/C DRAFT LANGUAGE

IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER _____

ISSUE DATE: _____

ISSUING BANK:
FIRST-CITIZENS BANK & TRUST COMPANY
2625 AUGUSTINE DRIVE, SUITE 301
SANTA CLARA, CALIFORNIA 95054

BENEFICIARY:
STATE OF NEVADA
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

APPLICANT:
BRIGHT URO, INC.
3 GODDARD
IRVINE, CA 92618

AMOUNT: US$ 25,000 (Twenty five thousand AND 00~~XX~~/100 U.S. DOLLARS)

EXPIRATION DATE: ONE YEAR FROM ISSUANCE

PLACE OF EXPIRATION: ISSUING BANK'S COUNTERS AT ITS ABOVE ADDRESS

DEAR SIR/MADAM:

WE HEREBY ESTABLISH OUR IRREVOCABLE STANDBY LETTER OF CREDIT NO. _____ IN YOUR FAVOR AVAILABLE BY PAYMENT AGAINST YOUR PRESENTATION TO US OF THE FOLLOWING DOCUMENTS:

1.THE ORIGINAL OF THIS LETTER OF CREDIT AND ORIGINALS OR COPIES OF ALL AMENDMENTS, IF ANY, TO THIS LETTER OF CREDIT.

2.BENEFICIARY'S SIGNED AND DATED STATEMENT STATING AS FOLLOWS:

"THE APPLICANT HAS FAILED TO PAY AS PER THAT CERTAIN AGREEMENT DATED _____. THE AMOUNT HEREBY DRAWN UNDER THE LETTER OF CREDIT IS US$_____, WITH PAYMENT TO BE MADE TO THE FOLLOWING ACCOUNT: [INSERT WIRE INSTRUCTIONS (TO INCLUDE NAME AND ACCOUNT NUMBER OF THE BENEFICIARY)]."

PARTIAL DRAWS AND MULTIPLE PRESENTATIONS ARE ALLOWED.

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND FIRST-CITIZENS BANK & TRUST COMPANY, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____
APPLICANT'S SIGNATURE(S) DATE

THIS LETTER OF CREDIT SHALL BE AUTOMATICALLY EXTENDED FOR AN ADDITIONAL PERIOD OF ONE YEAR, WITHOUT AMENDMENT, FROM THE PRESENT OR EACH FUTURE EXPIRATION DATE UNLESS AT LEAST 60 DAYS PRIOR TO THE THEN CURRENT EXPIRATION DATE WE SEND TO YOU A NOTICE BY REGISTERED OR CERTIFIED MAIL OR OVERNIGHT COURIER SERVICE AT THE ABOVE ADDRESS THAT THIS LETTER OF CREDIT WILL NOT BE EXTENDED BEYOND THE THEN CURRENT EXPIRATION DATE. IN THE EVENT WE SEND SUCH NOTICE OF NON-EXTENSION, YOU MAY DRAW HEREUNDER BY YOUR PRESENTATION TO US OF (1) THE ORIGINAL LETTER OF CREDIT AND ORIGINALS OR COPIES OF ALL AMENDMENTS, IF ANY, TO THIS LETTER OF CREDIT AND (2) YOUR SIGNED AND DATED STATEMENT STATING THAT YOU HAVE RECEIVED A NON-EXTENSION NOTICE FROM SILICON VALLEY BANK IN RESPECT OF LETTER OF CREDIT NO. _____, YOU ARE DRAWING ON SUCH LETTER OF CREDIT FOR US$_____, AND YOU HAVE NOT RECEIVED A REPLACEMENT LETTER OF CREDIT ACCEPTABLE TO YOU.

ALL DEMANDS FOR PAYMENT SHALL BE MADE BY PRESENTATION OF THE REQUIRED DOCUMENTS ON A BUSINESS DAY AT OUR OFFICE (THE "BANK'S OFFICE") AT: FIRST CITIZENS BANK & TRUST COMPANY, 2625 AUGUSTINE DRIVE, 301, SANTA CLARA, CA 95054, ATTENTION: GLOBAL TRADE FINANCE.

IF ANY INSTRUCTIONS ACCOMPANYING A DRAWING UNDER THIS LETTER OF CREDIT REQUEST THAT PAYMENT IS TO BE MADE BY TRANSFER TO YOUR ACCOUNT WITH ANOTHER BANK, WE WILL ONLY EFFECT SUCH PAYMENT BY FED WIRE TO A U.S. REGULATED BANK, AND WE AND/OR SUCH OTHER BANK MAY RELY ON AN ACCOUNT NUMBER SPECIFIED IN SUCH INSTRUCTIONS EVEN IF THE NUMBER IDENTIFIES A PERSON OR ENTITY DIFFERENT FROM THE INTENDED PAYEE.

THIS LETTER OF CREDIT IS SUBJECT TO THE INTERNATIONAL STANDBY PRACTICES (ISP98), INTERNATIONAL CHAMBER OF COMMERCE, PUBLICATION NO. 590.

FIRST-CITIZENS BANK & TRUST COMPANY

_____
AUTHORIZED SIGNATURE

ALL THE DETAILS SET FORTH HEREIN IN THIS LETTER OF CREDIT DRAFT IS APPROVED BY APPLICANT. IF THERE IS ANY DISCREPANCY BETWEEN THE DETAILS OF THIS LETTER OF CREDIT DRAFT AND THE LETTER OF CREDIT APPLICATION, BETWEEN APPLICANT AND FIRST-CITIZENS BANK & TRUST COMPANY, THE DETAILS HEREOF SHALL PREVAIL.

_____ _____
APPLICANT'S SIGNATURE(S) DATE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Bright Uro, Inc. MDEG License # (if applicable) _____

Physical Address 3 Goddard

City Irvine State CA Zip 92618

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 310-650-8138 Website www.brighturo.com

Licensing Company Email info@brighturo.com

Section 2: Personal Information

First Tracy Middle Dwane Last Maahs

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Lake Forest State CA Zip [redacted]

Telephone [redacted] Email tracy@brighturo.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
GMI Engineering and Management Institute (now Kettering University)		07/87 - 12/91	
Address	**City**	**State**	**Zip**
1700 University Ave.	Flint	MI	48504
Diploma/Degree obtained, if any			
Bachelor of Science Mechanical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Colorado School of Mines		08/85 - 12/86	
Address	**City**	**State**	**Zip**
1500 Illinois St	Golden	CO	80401
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Julesburg High School			
Address	**City**	**State**	**Zip**
102 W. 6th St.	Julesburg	CO	80737
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/24-Current	[redacted]	Canyon Lake	CA	[redacted]
08/20-Present		Lake Forest	CA	
03/15-08/20		Lake Forest	CA	
05/11 - 06/15		Yorba Linda	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Bright Uro, Inc			11/23 - Current	
Business Address	**City**		**State**	**Zip**
3 Goddard				
Phone	**Title**		**Number of Employed Hours**	
310-650-8138	COO		3200	
Description of Duties				
I am responsible for assisting in the develop of devices and leading the operation department building and shipping product to customers				

Business Name			From - To (MM/YY – MM/YY)	
USGI Medical			08/03-07/20	
Business Address	**City**		**State**	**Zip**
1140 Calle Cordillera	San Clemente		CA	92673
Phone	**Title**		**Number of Employed Hours**	
(949) 369-3890	COO		35000	
Description of Duties				
I was responsible for product development and product manufacturing for components coming into the company and finished goods going out to customers				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Tracy D. Maahs, **certify that as the MDEG Administrator for**

Bright Uro, Inc.,

that I (initial that you have read and meet the following requirements):

1. TDM Have a high school diploma or its equivalent;
2. TDM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. TDM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. TDM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tracy Maahs
Print Name (First, Last)

Tracy D Maahs
Original Signature (electronic, copies or stamps not accepted)

7.7.2025
Date

Board Use Only	Date Received: 7/22/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Bright Uro Inc

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 3 Goddard

City Irvine State CA Zip 92618

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 310-650-8138 Website www.brighturo.com

Licensing Company Email info@brighturo.com

Section 2: Personal Information

First Tracy Middle D Last Maahs

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Lake Forest State CA Zip [redacted]

Telephon[redacted] Email tracy@brighturo.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
GMI Engineering and Management Institute (now Kettering University)		07/87 - 12/91	
Address	**City**	**State**	**Zip**
1700 University Ave.	Flint	MI	48504
Diploma/Degree obtained, if any			
Bachelor of Science Mechanical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Colorado School of Mines		08/85 - 12/86	
Address	**City**	**State**	**Zip**
1500 Illinois St	Golden	CO	80401
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Julesburg High School		08/81-05/85	
Address	**City**	**State**	**Zip**
102 W. 6th St.	Julesburg	CO	80737
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/24-Current	[redacted]	Canyon Lake	CA	[redacted]
08/20-Present		Lake Forest	CA	
03/15-08/20		Lake Forest	CA	
05/11 - 06/15		Yorba Linda	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Bright Uro, Inc			11/23 - Current	
Business Address		**City**	**State**	**Zip**
3 Goddard		Irvine	CA	92618
Phone	**Title**		**Number of Employed Hours**	
310-650-8138	COO		3200	
Description of Duties				
I am responsible for assisting in the develop of devices and leading the operation department building and shipping product to customers				

Business Name			From - To (MM/YY – MM/YY)	
USGI Medical			08/03-07/20	
Business Address		**City**	**State**	**Zip**
1140 Calle Cordillera		San Clemente	CA	92673
Phone	**Title**		**Number of Employed Hours**	
(949) 369-3890	COO		35000	
Description of Duties				
I was responsible for product development and product manufacturing for components coming into the company and finished goods going out to customers				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Tracy D. Maahs, **certify that as the designated representative for**

Bright Uro, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TDM I am at least 21 years of age;
3. TDM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TDM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TDM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TDM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TDM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

TRACY MAAHS
Print Name (First, Last)

Tracy D Maahs
Original Signature (electronic, copies or stamps not accepted)

7.7.2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tracy Maahs

Print Name (First, Last)

Tracy D Maahs

Original Signature (electronic, copies or stamps not accepted)

7.7.2025

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of ORANGE

I, TRACY D. MAAHS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Tracy Maahs

Original Signature

7.7.2025

Date

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of the document.

Subscribed and Sworn to before me this 07 day of July 2025.

Sean Hashemi

Notary Public Signature

SEAN HASHEMI
Notary Public - California
Orange County
Commission # 2522195
My Comm. Expires Jun 30, 2029

(Seal)

Bright Uro Inc.

Employee Listing

16-Jun-25

Employee	Primary job title
Benjamin Abramowitz	Sales Director, West
Edward Balcos	Director, Quality & Regulatory Affairs
Elinor Banai	Grants Manager
Brittany Carter	Senior Director, Clinical Affairs
Kristen Comstock	Vice President, Marketing
Julie Damo-Gilliam	Document Control Specialist
Ali Daneshkhah	R&D Engineer
Guillermina Esparza	Sr. Manufacturing Technician/Sr. Quality Technician
Diego Flores	Manufacturing Engineer
Jesse Flores	Warehouse Supervisor
Lizeth Flores	Manufacturing Tech I
Arshin Gharibi	Senior Manufacturing Engineer
Betty Hall	Clinical Specialist
Gideon Hamson	Principal R&D Engineer
Derek Herrera	CEO
Kevin Hershberger	Chief Financial Officer
Casey Kanel	Chief Commercial Officer
Tim Kelp	Sales Director
Douglas Ly	Principal Manufacturing Engineer
Tracy Maahs	COO
Angelo Mastrio II	Sales Director
James Monacelli	Sales Director
Yoselyn Moreno Orellana	Manufacturing Tech I
Sabrina Nash	Sales & Marketing Operations Specialist
Bryan Nowroozi	CSO
William Ospina	Director of Manufacturing
James Pak	Director, Systems Engineering
Alexander Poulsen	R&D Engineer
Srinivas Pullabhotla	Software Test Engineer
Oscar Quinteros	Manufacturing Tech II
Silvia Reyes Trejo	Production Supervisor
Aracely Rodriguez	Manufacturing Tech II
Suranjan Roychowdhury	Chief Product Development Officer
Christopher Runkle	Vice President, Sales
Rachel Snyder	Executive Assistant
Taylor Takayoshi	Clinical Research Associate I (CRA I)
Itzel Ticante Nicolas	Manufacturing Tech II
Henky Wibowo	CTO
David Sussman MD	Consultant
Eric S. Rovner, MD	Consultant
Jason Kim MD	Consultant
Jeffrey Dann MD	Consultant
Jen Fontanilla	Consultant
Jim Monacelli	Consultant
Joseph Scolieri	Consultant
Richard Cohn	Consultant
Scott A. MacDiarmid, MD	Consultant
Dr. Howard Goldman	Consultant
Mike Gaynes	Consultant
Natalie Hay Williams	Consultant
Dr. John G. Lee	Consultant
Aiden Johnson	Consultant
Andres Escobedo	Consultant
Victoria Maahs	Consultant

Bright Uro, Inc. Detailed Cap Table

As of 6/16/2025 • Generated by Kevin Hershberger (kevin@brighturo.com) at 06/16/2025 09:00:

Name	Outstanding Ownership
10579670, Canada Inc.	0.895%
1294590 Ontario Inc.	0.045%
2011 Wong Family Trust, dated November 22, 2011	0.090%
Abe Rutman	0.090%
Abner Trust, dated March 30, 2023	8.947%
Adam G. Kaplan	0.045%
Adam T. Hill	0.090%
Advanta IRA Services, LLC FBO James C. Pittman IRA #8013439	0.091%
Advanta IRA Services, LLC FBO James D. Pittman IRA #8013520	0.090%
AIN SPV SERIES LLC – BRIGHT URO LLC	0.185%
AIN Ventures Fund I, LP	0.739%
Akhil Das	0.179%
Alex Poulsen	0.000%
Ali Daneshkhah	0.000%
Alireza Bozorgi	0.027%
Allen E. Austin	0.090%
Alpesh Amin	0.448%
Andrew Ellenbogen	0.313%
Antoine Khoury	0.179%
Ariannejad and Ghoniem Family Trust	0.036%
Arshin Gharibi	0.000%
Arthur Mourtzinos	0.090%
Bagel Boy Equity Group II, LLC	0.448%
Barbara Ann Cohen Trust	0.314%
Ben Abramowitz	0.072%
Bilal Chughtai	0.045%

BJK Family Trust	0.045%
Brent Burrows	0.090%
Brittany Carter	0.112%
Bryan Nowroozi	1.678%
Casey Kanel	0.045%
Cheryl Sullivan	0.179%
Chong Choe And Leah Nakamura	0.090%
Chris Klecher	0.090%
Chris Runkle	0.000%
Christian Stone	0.090%
Christopher D. & Karen W. Jennings JTWROS	0.269%
Christopher Kelly	0.045%
Community National Bank Cust FBO: Porter Travis Roth IRA 3075494	0.045%
Cooper 5 Ventures V LLC - Series 1	0.301%
Craig Comiter	0.090%
Daniel C. Jaffee	0.061%
Darrin O'Leary	0.090%
David & Janet Polak Foundation	0.448%
David Abramowitz	0.090%
David F. Monahan	0.179%
David Gloth	0.448%
David J. Garcia Revocable Living Trust	0.179%
David Perry	0.112%
David Sussman	0.045%
Dazzle Investor, LLC	13.009%
Dean Elterman	0.761%
Derek Herrera	4.473%
Derek Sham	0.022%
Device of Tomorrow Capital II LLC	0.358%
Diane Lynn Cohen Trust	0.314%
Diego Flores	0.000%
DJ Investments LLC	0.941%
Doug Madsen	0.179%

Dr. Dean Elterman Medicine Professional Corporation	1.672%
Dustin Kern	0.090%
Ed Balcos	0.000%
Elinor Banai	0.045%
Equity Trust Company Custodian FBO Benjamin M. Abramowitz Traditiona	0.358%
Equity Trust Company Custodian FBO Christopher A. Runkle IRA	0.358%
Equity Trust Company Custodian FBO Joel Gelman IRA	1.433%
Equity Trust Company Custodian FBO Joel Gelman Roth IRA	0.716%
Equity Trust company Custodian FBO Martha Aronson Roth IRA	0.179%
Eric Burner	0.627%
Eric Burner and Pamela Landman	0.597%
Ernest Agatstein	0.090%
Executive Medical Investments LLC	1.254%
Faysal Yafi	0.269%
FCG Partners I, LLC	0.895%
Frank Lin	0.045%
Frederic Moll	2.060%
Gamal Ghoniem	0.224%
Gideon Hamson	0.000%
Gordon Brown	0.313%
Guillermina Esparza	0.000%
Guillermo Patino Patino Urology PLLC	0.045%
Gutentag Revocable Trust dated June 4, 2019	0.314%
Hamed Shamkhalichenar	0.112%
Henky Wibowo	0.000%
Holley Family Trust	0.045%
Howard Goldman	0.067%
Jaime Landman	1.342%
Jake Rommel	0.042%
James and Susan Cramer Living Trust	0.721%
James Yerkes	0.063%
Jeff Rosino	0.056%
Jeffrey Current self Directed IRA	0.448%

Jeffrey Markowitz	0.358%
Jennifer Blackley	0.179%
Jennifer Schultz	0.179%
Jim Kazmierkoski	0.134%
Jim Monacelli	0.000%
Jim Pak	0.000%
John Gross	0.627%
John P Ramirez and Elise A Ramirez Revocable Trust	0.125%
Joint Revocable Trust of Jeffrey Glen Proctor and Vivian Claire Proctor	0.045%
Jonathan Schupp	0.054%
JVP Holdings, Inc.	0.269%
Karen Noblett	0.034%
Karen Noblett & Pamela Jacobson Family TST DTD 1/27/17	0.179%
Kathleen Kobashi	0.134%
Keith Xavier	0.090%
Kevin Arnal	0.056%
Kohrs Family LLLP	0.492%
Kristen Comstock	0.358%
Kurt Azarbarzin	0.112%
Kyle Blackley and Bailey Blackley	0.072%
Laura Landman	0.627%
Laura Sue Cohen Trust	0.314%
Laurelin Investors, LLC	3.582%
Lee Chitiz	0.045%
Lemonade LP	0.627%
Leslie Abramson 2012 Trust	1.254%
Lizeth Flores	0.000%
Mark Kirsch	0.090%
Martha Goldberg Aronson	0.000%
Matt Zamani	0.179%
Matthew Gialich	0.063%
Matthew P. Rutman	0.090%
Matthew Rutman	0.045%

Michael D. Fabrizio	0.090%
Michael Daneshvar	0.054%
Michael Hendricks and Kelly Hendricks	0.018%
Michael Plymack	0.179%
Michael Starr	0.045%
Mitchell Chitiz	0.045%
Mitchell O'Leary	0.552%
Morteza Sadeghi	0.027%
Neal Cohen	0.336%
Neal Cohen Trust	1.568%
NextGen Ventures 2 LLC	0.054%
Nitin Bhatia	1.568%
North Point Trust Company, LLC, as Trustee of the LL South Dakota Trust	3.020%
Oscar Quinteros	0.000%
Paul S. Jaffee	0.059%
Peman Montazemi	0.909%
Peter J Matton	0.045%
Peter Vermette	0.209%
Porter Travis	1.173%
Preservation Trust Company, Inc., as Trustee of the Hamshir Trust dated A	1.254%
Preservation Trust Company, Inc., as Trustee of the JL Nevada Trust, date	2.349%
Primal Core LLC	0.715%
Rachel Snyder	0.036%
Ralph & Carol Clayman	0.627%
Ralph and Lori McPherson	0.045%
Re Venture Inc	0.131%
Richard I. Jaffee	0.059%
RM Management LLC	0.627%
RMOH Holdings LLC	0.090%
Roger Dmochowski	0.045%
Roshan Patel	0.179%
Ross Tsugita	0.090%
Sandeep Lad	0.104%

Sandy Siegel, MD	0.000%
Sck Investment Trust	0.179%
Scott MacDiarmid, MD	0.000%
Sew-Wah Tay	0.022%
Shaggy Trust, dated March 30, 2023	8.947%
Shahrad Aynehchi	0.314%
Sherman Williams	0.000%
Silvia Reyes	0.000%
Simone Blankstein	0.045%
Skye Holdings LLC	3.702%
Sovrin Shah	0.090%
Sri Sivalingam	0.090%
Stanford Johnson	0.090%
Steven Novenson	0.090%
Stuart Chalfin	0.090%
Sunflower Family Ltd Partnership	0.090%
Suranjan Roychowdhury	0.000%
Suzette E. Sutherland, MD	0.045%
Taylor Takayoshi	0.000%
Taylor Vaughan	0.000%
Teresa Nguyen	0.015%
The Monroe Peak Legacy Trust	0.179%
The Regents of the University of California	3.582%
The Te Family 2012 Trust	0.045%
The Zive Trust Established April 1, 2011	0.358%
Thomas Nicholson	0.314%
Toblesky family trust dated 9-14-2002	0.314%
Tracy Cannon-Smith	0.090%
Tracy Maahs	0.000%
Twiss Holdings, LLC	0.618%
Udi Blankstein	0.090%
Urn and Litho LLC	0.179%
Victor Nitti	0.045%

William A Klauer	0.134%
William Ospina	0.000%
Xuehai Yan	0.179%
Yoselyn Moreno	0.000%
Youderian Family Trust	0.470%
Options and RSU's issued and outstanding	
Shares available for issuance under the plan	
Fully diluted shares	
Fully diluted ownership	
Total Shares outstanding	**0.000%**
Percentage outstanding	
Share Class Original Issue Price	

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Flexicare, Inc. - Irvine

Physical Address: 15281 Barranca Parkway, Unit D

City: Irvine State: CA Zip: 92618

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 949-450-9999 Website: https://flexicare.com/en-us/

Name of Designated Representative (DR): Jesus Lopez

Licensing Company Email: Peter.Sauer@flexicare.com DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Rx only medical devices	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year:

Name: See attached.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Flexicare (Group) Limited

Corporation/Organization Name: Flexicare, Inc.

Mailing Address: 15281 Barranca Parkway, Unit D

City: Irvine State: CA Zip: 92618

Telephone: 949-450-0000 Email: inquiries@flexicare.com

Contact Person Name: Ashley Motamedi

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Flexicare, Inc. - Irvine

Facility Name

Michael Devine

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4/17/25

Date

Board Use Only	Date Received: 4/21/25	Amount: $1000 ck 3830

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
FLEXICARE INC.
15281 Barranca Pkwy.
Unit D
Irvine, CA 92618
Registration Number: 3005919257
FEI Number*: 3005919257
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
FLEXICARE MEDICAL LTD.[6]
CYNON VALLEY BUSINESS PARK
MOUNTAIN ASH, Rhondda Cynon Taff GB CF45 4ER
Owner/Operator Number: 8021995[7]

Official Correspondent:
Khashayar Poormand
CYNON VALLEY BUSINESS PARK
MOUNTAIN ASH, Rhondda Cynon Taff GB CF45 4ER
Phone: 044-144-474647

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8021995&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8021995&OwnerOperator

Page Last Updated: 04/21/2025

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8021995&OwnerOperator

7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8021995&OwnerOperator

Registration Information

Facility

Registration Number	3005919257
FEI Number	3005919257
Registration Status	Active
Registration Status Reason	Legacy Data - Registration activated
Initial Importer	Y
Facility Name	FLEXICARE INC.
Legal Name	
Facility Address	15281 BARRANCA PKWY., UNIT D IRVINE, CALIFORNIA, 92618, UNITED STATES
DUNS Number	
Foreign Trade Zone	N
Facility URL	
Other Business Trade Name(s)	
Establishment located on a campus	

Owner/Operator

Owner/Operator Number	8021995
Contact Name	KHASHAYAR - POORMAND
Business Name	FLEXICARE MEDICAL LTD.
Address	CYNON VALLEY BUSINESS PARK MOUNTAIN ASH, RHONDDA CYNON TAFF, CF45 4ER, UNITED KINGDOM
Phone Number	044 - 144 - 474647
Fax Number	044 - 144 - 3474222
E-mail	regulatory@flexicare.com
DUNS Number	

Official Correspondent

Contact Name	KHASHAYAR - POORMAND
Business Name	FLEXICARE MEDICAL LTD.
Address	CYNON VALLEY BUSINESS PARK MOUNTAIN ASH, RHONDDA CYNON TAFF, CF45 4ER, UNITEO KINGDOM
Phone Number	044 - 144 - 474647
Fax Number	044 - 144 - 3474222
E-mail	regulatory@flexicare.com
DUNS Number	

Registration Status

Expiration Date	2025-12-31
PIN - PCN	50458619 - 25640166

Flexicare, Inc.'s Medical Device Wholesaler Application - Responses to Section 3

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Flexicare's top four suppliers of prescription only medical devices are as follows.

1. Flexicare Medical (Dongguean) Ltd., No. B-15 Xicheng Industrial Zone, Hengli Town, Dongguan City, Guangdong, China 523460. FDA Registration Number 3006061749.
2. Flexicare Lanka (Pvt) Ltd., 382/x, Kumbuka Road, Raigama, Bandaragama Western, Sri Lanka 12530. FDA Registration Number: 3017202422.
3. Axess Vision Technology S.A.S. (dba TSC Life) - Zone de la Liodiere, 6 Rue De La Flottiere, Joue Les Tours Indre-et-Loire, France 37300. FDA Registration Number 3017859830.
4. Allied Medical LLC, 1720 Sublette Ave., Saint Louis, Missouri 63110. FDA Registration Number: 1924066

Flexicare, Inc.'s Medical Device Wholesaler Application - Responses to Questions in Section 9

I. **List of all Officers and Directors**
   a. Ghassem Poormand (CEO/CFO)
   b. Michael Devine (President)
   c. Shaz Poole (Secretary and Vice President)
   d. Ashley Motamedi (Vice President)

II. **List of all corporation shareholders and their percent ownership** - Flexicare Inc. is owned 100% by Flexicare (Group) Limited, a United Kingdom Company located at Cynon Valley Business Park, Mountain Ash, CF45 4ER, United Kingdom.

III. **Certificate of Corporate Standing** - attached as Exhibit 1.

IV. **Designated Representative form** – attached as Exhibit 2.

V. **Copy of DEA certificate if handling controlled substances** – N/A as Flexicare does not handle controlled substances.

VI. **Personal History Record Application** - Flexicare Inc. is 100% owned by Flexicare (Group) Limited. There are no natural people who own more than 10% of Flexicare Inc. stock or shares.

VII. **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender, or holder of indebtedness of the applicant** – attached as Exhibit 3.

VIII. **Copy of your license, certification, permit or registration issued to your wholesaler business.** Attached as Exhibit 4 (California Department of Public Health Medical Device Manufacturer's License), Exhibit 5 (California Board of Pharmacy Wholesaler License), and Exhibit 6 (FDA registration).

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	FLEXICARE INCORPORATED
Entity No.:	2890587
Registration Date:	07/25/2006
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of April 07, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 314980733

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Flexicare, Inc.
15281 Barranca Pkwy Unit D
Irvine, CA 92618

LICENSE NUMBER: 120354
EXPIRATION DATE: 4/30/2026

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 8519

ISSUE DATE 3/17/2025

FLEXICARE INC
15281 BARRANCA PKWY STE D
IRVINE, CA 92618-2202

The above is licensed with the State Board of Pharmacy as a Corporation

SHUMAN ABIGAIL MARIE — EXEMPTEE IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov.

PLACE RENEWAL LICENSE HERE

VALID UNTIL 3/1/2026

RECEIPT NUMBER 00771628

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

OPHWS1 09/30/19 WLS

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 6/9/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Alliant Insurance Services, Inc. 101 Park Ave 14th Fl New York NY 10178 License#: 0C36861	CONTACT NAME: Jennifer Giannone PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS: Jennifer.Giannone@alliant.com
INSURED Flexicare Inc. 15281 & 15291 Barranca Pkway Unit D Irvine CA 92618 FLEXICA-01	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Federal Insurance Company — 20281 INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 240730609 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE / X OCCUR X Products/Comp Oper-Claims Made GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY / PRO-JECT / LOC OTHER:	Y	Y	36053583	6/1/2025	6/1/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Prod CompOps Ea Occ	$ 2,000,000 $ 2,000,000 $ 10,000 $ 2,000,000 $ 2,000,000 $ 5,000,000 $ $5,000,000
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY / SCHEDULED AUTOS X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY	Y	Y	2373633739	6/1/2025	6/1/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A	UMBRELLA LIAB / X OCCUR X EXCESS LIAB / CLAIMS-MADE DED / RETENTION $	Y	Y	78189557	6/1/2025	6/1/2026	EACH OCCURRENCE AGGREGATE	$ 3,000,000 $ 3,000,000 $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N / N/A If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE / OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Preview

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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BANK OF AMERICA

DATE: APRIL 29, 2025
IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER: 68204043

APPLICANT
FLEXICARE INCORPORATED
15281 BARRANCA PARKWAY #D
IRVINE, CA 92618

BENEFICIARY
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

ISSUING BANK
BANK OF AMERICA, N.A.
ONE FLEET WAY
PA6-580-02-30
SCRANTON, PA 18507-1999

AMOUNT
NOT EXCEEDING USD 25,000.00
NOT EXCEEDING TWENTY FIVE THOUSAND AND 00/100'S US DOLLARS

EXPIRATION
APRIL 30, 2026 AT OUR COUNTERS

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF FLEXICARE INCORPORATED, BANK OF AMERICA, N.A. HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT (CREDIT) IN THE PRINCIPAL SUM OF $25,000.00.

2. WE ARE ADVISED BY THE APPLICANT THAT THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE APPLICANT/LICENSEE.

3. WE ARE FURTHER ADVISED BY THE APPLICANT THAT THIS CREDIT IS INTENDED BY THE PARTIES TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY APPLICANT/LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAW REGARDING APPLICANT/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. PURSUANT TO NRS 639.515(4), UPON THE IMPOSITION OF ANY FINES OR COSTS BY THE BOARD AGAINST THE APPLICANT/LICENSEE, THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN SUBSTANTIALLY THE SAME FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT THE ADDRESS ABOVE.

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE IN PERSON OR BY REGISTERED MAIL, RETURN RECEIPT REQUESTED OR OVERNIGHT COURIER SERVICE.

ORIGINAL

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED PAYMENT SHALL BE MADE TO THE BOARD, OR TO AN ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, AT SUCH TIME AND PLACE AS THE BOARD SHALL SPECIFY.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THIS CREDIT, WE SHALL GIVE THE BOARD NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFORE, AND AWAIT FURTHER INSTRUCTIONS.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT WITHIN THE EXPIRATION DATE.

10. ALL DRAWINGS UNDER THIS CREDIT SHALL BE PAID WITH OUR FUNDS. EACH DRAWING HONORED BY US HEREUNDER SHALL REDUCE, PRO TANTO, THE PRINCIPAL SUM. BY PAYING TO THE BOARD AN AMOUNT DEMANDED IN ACCORDANCE HEREWITH, WE MAKE NO REPRESENTATIONS AS TO THE CORRECTNESS OF THE AMOUNT DEMANDED.

11. THIS CREDIT WILL BE CANCELLED IN WHOLE UPON RECEIPT BY USE OF A CERTIFICATE OF CANCELLATION, WHICH (I) SHALL BE IN THE FORM OF ATTACHMENT B ATTACHED HERETO, AND SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY OF THE BOARD.

12. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT AT THE ADDRESS ABOVE AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

13. THIS CREDIT MAY NOT BE TRANSFERRED, EITHER IN WHOLE OR IN PART.

14. THIS CREDIT SHALL BE DEEMED A CONTRACT MADE UNDER THE LAWS OF STATE OF NEVADA, AND ANY ACTION RELATED TO THIS CREDIT SHALL BE FILED IN THE STATE OF NEVADA AND SHALL BE SUBJECT TO THE LAWS OF THE OF THE STATE OF NEVADA.

15. THIS CREDIT SHALL, IF NOT CANCELED AS PROVIDED HEREIN, EXPIRE ON APRIL 30, 2026.

THIS LETTER OF CREDIT IS SUBJECT TO THE INTERNATIONAL STANDBY PRACTICES (ISP98), INTERNATIONAL CHAMBER OF COMMERCE PUBLICATION NO. 590.

IF YOU REQUIRE ANY ASSISTANCE OR HAVE ANY QUESTIONS REGARDING THIS TRANSACTION, PLEASE CALL 800-370-7519.

Jessica Walsh

ORIGINAL

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

AUTHORIZED SIGNATURE

ORIGINAL

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

ATTACHMENT A
CERTIFICATE FOR DRAWING

DATE: _____

ISSUING BANK:
BANK OF AMERICA, N.A.
1 FLEET WAY,
SCRANTON, PA 18507

APPLICANT:
FLEXICARE INCORPORATED
15281 BARRANCA PARKWAY #D
IRVINE, CA 92618

IRREVOCABLE LETTER OF CREDIT NUMBER _____

BENEFICIARY:
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY OF THE NEVADA STATE BOARD OF PHARMACY (BOARD) (AS DEFINED IN THE ABOVE REFERENCED CREDIT), HEREBY CERTIFIES TO THE ISSUER THAT:

1. A LAWFUL ORDER IMPOSING FINES AND/OR COST AGAINST THE APPLICANT/LICENSEE HAS BEEN ENTERED THAT ENTITLES THE BOARD TO DRAW AGAINST IRREVOCABLE STANDBY LETTER OF CREDIT NO. _____ (CREDIT).

2. THE UNDERSIGNED IS AUTHORIZED UNDER THE TERMS OF THE CREDIT TO PRESENT THIS CERTIFICATE OF DRAWING AS THE SOLE MEANS FOR DEMANDING PAYMENT ON THE CREDIT.

3. THE BOARD IS THEREFORE MAKING A DRAWING UNDER THE CREDIT IN THE AMOUNT OF $_____.

4. THE AMOUNT DEMANDED DOES NOT EXCEED THE PRINCIPAL SUM.

5. SUMS RECEIVED SHALL BE USED BY THE BOARD IN ACCORDANCE WITH THE TERMS OF THE CREDIT.

6. THE AMOUNT OF DRAWING REQUESTED SHALL BE PAYABLE TO THE BOARD IN LAWFUL, IMMEDIATELY AVAILABLE FUNDS TO BE RECEIVED BY THE BOARD AT THE ABOVE ADDRESS NO LATER THAN 5:00 PM EASTERN TIME ON THE _____ DAY OF _____ 20_____

ORIGINAL

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE AS OF THE __DAY OF_____, 20__.

NEVADA STATE BOARD OF PHARMACY
BY

_____
(INSERT NAME)
EXECUTIVE SECRETARY

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

ATTACHMENT B
CERTIFICATE FOR CANCELLATION

DATE: _____

ISSUING BANK:
BANK OF AMERICA, N.A.
PA6-580-02-30
1 FLEET WAY
SCRANTON, PA 18507

APPLICANT:
FLEXICARE INCORPORATED
15281 BARRANCA PARKWAY #D
IRVINE, CA 92618

IRREVOCABLE LETTER OF CREDIT NUMBER _____

BENEFICIARY:
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. THE LICENSE FOR WHICH THE CREDIT WAS ISSUED HAS EXPIRED, BEEN REVOKED, BEEN CANCELLED OR OTHERWISE IS NO LONGER IN EFFECT, THEREBY MAKING THE CANCELLATION OF THE CREDIT APPROPIATE.

2. THE BOARD THEREFORE REQUESTS THE CANCELLATION OF THE ABOVE-REFERENCED CREDIT AND RETURNS THE ATTACHED ORIGINAL LETTER OF CREDIT AND AMENDMENT(S), IF ANY.

THEREFORE, THE UNDERSINGED HAS EXECUTED AND DELIVERED THIS CANCELLATION AS OF THE ___DAY OF _____, 20__.

NEVADA STATE BOARD OF PHARMACY

BY

_____ (INSERT NAME)
EXECUTIVE SECRETARY

ORIGINAL

BANK OF AMERICA

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

ATTACHMENT B
CERTIFICATE FOR CANCELLATION

DATE: _____

ISSUING BANK:
BANK OF AMERICA, N.A.
PA6-580-02-30
1 FLEET WAY
SCRANTON, PA 18507

APPLICANT:
FLEXICARE INCORPORATED
15281 BARRANCA PARKWAY #D
IRVINE, CA 92618

IRREVOCABLE LETTER OF CREDIT NUMBER _____

BENEFICIARY:
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

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2. THE BOARD THEREFORE REQUESTS THE CANCELLATION OF THE ABOVE-REFERENCED CREDIT AND RETURNS THE ATTACHED ORIGINAL LETTER OF CREDIT AND AMENDMENT(S), IF ANY.

THEREFORE, THE UNDERSINGED HAS EXECUTED AND DELIVERED THIS CANCELLATION AS OF THE ___DAY OF _____, 20__.

NEVADA STATE BOARD OF PHARMACY

BY

_____ (INSERT NAME)
EXECUTIVE SECRETARY

ORIGINAL

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE AS OF THE __DAY OF_____, 20__.

NEVADA STATE BOARD OF PHARMACY
BY

_____
(INSERT NAME)
EXECUTIVE SECRETARY

ORIGINAL

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

ATTACHMENT A
CERTIFICATE FOR DRAWING

DATE: _____

ISSUING BANK:
BANK OF AMERICA, N.A.
1 FLEET WAY,
SCRANTON, PA 18507

APPLICANT:
FLEXICARE INCORPORATED
15281 BARRANCA PARKWAY #D
IRVINE, CA 92618

IRREVOCABLE LETTER OF CREDIT NUMBER _____

BENEFICIARY:
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY OF THE NEVADA STATE BOARD OF PHARMACY (BOARD) (AS DEFINED IN THE ABOVE REFERENCED CREDIT), HEREBY CERTIFIES TO THE ISSUER THAT:

1. A LAWFUL ORDER IMPOSING FINES AND/OR COST AGAINST THE APPLICANT/LICENSEE HAS BEEN ENTERED THAT ENTITLES THE BOARD TO DRAW AGAINST IRREVOCABLE STANDBY LETTER OF CREDIT NO. _____ (CREDIT).

2. THE UNDERSIGNED IS AUTHORIZED UNDER THE TERMS OF THE CREDIT TO PRESENT THIS CERTIFICATE OF DRAWING AS THE SOLE MEANS FOR DEMANDING PAYMENT ON THE CREDIT.

3. THE BOARD IS THEREFORE MAKING A DRAWING UNDER THE CREDIT IN THE AMOUNT OF $_____.

4. THE AMOUNT DEMANDED DOES NOT EXCEED THE PRINCIPAL SUM.

5. SUMS RECEIVED SHALL BE USED BY THE BOARD IN ACCORDANCE WITH THE TERMS OF THE CREDIT.

6. THE AMOUNT OF DRAWING REQUESTED SHALL BE PAYABLE TO THE BOARD IN LAWFUL, IMMEDIATELY AVAILABLE FUNDS TO BE RECEIVED BY THE BOARD AT THE ABOVE ADDRESS NO LATER THAN 5:00 PM EASTERN TIME ON THE _____ DAY OF _____ 20_____

ORIGINAL

BANK OF AMERICA

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

AUTHORIZED SIGNATURE

ORIGINAL

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68204043

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED PAYMENT SHALL BE MADE TO THE BOARD, OR TO AN ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, AT SUCH TIME AND PLACE AS THE BOARD SHALL SPECIFY.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THIS CREDIT, WE SHALL GIVE THE BOARD NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFORE, AND AWAIT FURTHER INSTRUCTIONS.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT WITHIN THE EXPIRATION DATE.

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12. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT AT THE ADDRESS ABOVE AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

13. THIS CREDIT MAY NOT BE TRANSFERRED, EITHER IN WHOLE OR IN PART.

14. THIS CREDIT SHALL BE DEEMED A CONTRACT MADE UNDER THE LAWS OF STATE OF NEVADA, AND ANY ACTION RELATED TO THIS CREDIT SHALL BE FILED IN THE STATE OF NEVADA AND SHALL BE SUBJECT TO THE LAWS OF THE OF THE STATE OF NEVADA.

15. THIS CREDIT SHALL, IF NOT CANCELED AS PROVIDED HEREIN, EXPIRE ON APRIL 30, 2026.

THIS LETTER OF CREDIT IS SUBJECT TO THE INTERNATIONAL STANDBY PRACTICES (ISP98), INTERNATIONAL CHAMBER OF COMMERCE PUBLICATION NO. 590.

IF YOU REQUIRE ANY ASSISTANCE OR HAVE ANY QUESTIONS REGARDING THIS TRANSACTION, PLEASE CALL 800-370-7519.

Jessica Walsh

ORIGINAL

BANK OF AMERICA

DATE: APRIL 29, 2025
IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER: 68204043

APPLICANT
FLEXICARE INCORPORATED
15281 BARRANCA PARKWAY #D
IRVINE, CA 92618

BENEFICIARY
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

ISSUING BANK
BANK OF AMERICA, N.A.
ONE FLEET WAY
PA6-580-02-30
SCRANTON, PA 18507-1999

AMOUNT
NOT EXCEEDING USD 25,000.00
NOT EXCEEDING TWENTY FIVE THOUSAND AND 00/100'S US DOLLARS

EXPIRATION
APRIL 30, 2026 AT OUR COUNTERS

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF FLEXICARE INCORPORATED, BANK OF AMERICA, N.A. HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT (CREDIT) IN THE PRINCIPAL SUM OF $25,000.00.

2. WE ARE ADVISED BY THE APPLICANT THAT THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE APPLICANT/LICENSEE.

3. WE ARE FURTHER ADVISED BY THE APPLICANT THAT THIS CREDIT IS INTENDED BY THE PARTIES TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY APPLICANT/LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAW REGARDING APPLICANT/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. PURSUANT TO NRS 639.515(4), UPON THE IMPOSITION OF ANY FINES OR COSTS BY THE BOARD AGAINST THE APPLICANT/LICENSEE, THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN SUBSTANTIALLY THE SAME FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT THE ADDRESS ABOVE.

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE IN PERSON OR BY REGISTERED MAIL, RETURN RECEIPT REQUESTED OR OVERNIGHT COURIER SERVICE.

ORIGINAL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Flexicare, Inc. MDEG License # (if applicable) _____

Physical Address 15281 Barranca Pwy Ste D

City Irvine State CA Zip 92618

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Jesus Middle _____ Last Lopez

Alias(es, nicknames, name changes, etc.) Jesse

Date of Birth [redacted] SSN or ITIN _____ Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Santa Ana State CA Zip [redacted]

Telephone [redacted] Email jesus.lopez@flexicare.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Segerstrom High School			From - To (MM/YY – MM/YY): 09/06 - 06/09
Address: 2301 W. McArthur	City: Santa Ana	State: CA	Zip: 92704
Diploma/Degree obtained, if any: High school Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2015 - 11/201	[redacted]	Lake Forest	CA	[redacted]
11/2017 - present		Santa Ana	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)
Flexicare, Inc.		04/16 - present

Business Address	City	State	Zip
15281 Barranca Pkwy Ste. D	Irvine	CA	92618

Phone	Title	Number of Employed Hours
949-450-9999	Warehouse Supervisor	40 hrs.

Description of Duties
Lead, train, and manage warehouse staff. Oversee all inbound and outbound shipments.

Business Name		From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name		From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name		From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name		From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/6/25
Date

I, Jesus Lopez, certify that as the MDEG Administrator for Flexicare, Inc.,

that I (initial that you have read and meet the following requirements):

1. ✓ Have a high school diploma or its equivalent;
2. a. Have
   (a.) At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ✓ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ✓ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jesus Lopez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/6/25
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Flexicare, Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 15281 Barranca pkwy Ste D

City: Irvine State: CA Zip: 92618

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 949-450-9999 Website:

Licensing Company Email: jesus.lopez@flexicare.com

Section 2: Personal Information

First: Jesus Middle: Last: Lopez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Santa Ana State: CA Zip: [redacted]

Telephone: [redacted] Email: jesus.lopez@flexicare

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622-120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Segerstrom High School		2005-2009	
Address	**City**	**State**	**Zip**
2301 West MacArthur Boulevard	Santa Ana	CA	92704
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2015-11/2017	[redacted]	Lake Forest	CA	[redacted]
11/2017-Present	[redacted]	Santa Ana	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above:

Business Name: Flexicare, Inc.			From - To (MM/YY – MM/YY): 04/2016-present
Business Address: 15281 Barranca Pkwy Ste D	City:	State: CA	Zip: 92618
Phone: 949-450-9999	Title:		Number of Employed Hours:
Description of Duties: Warehouse Supervisor			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Jesus Lopez, certify that as the designated representative for

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JL I am at least 21 years of age;
3. JL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JESUS LOPEZ
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/3/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JESUS LOPEZ

Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

4/3/25

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

DATE 4/4/25 NOTARY INITIALS GN (Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Orange

Subscribed and sworn to (or affirmed) before me on this 4th day of April, 2025, by Jesus Lopez

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

GRACE NYARIKI
COMM. # 2508104
NOTARY PUBLIC-CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. DEC 25, 2028

RRS2 RRS2

(Seal) Signature

Flexicare Employees as of April 14, 2025

Full name	Employee Title
Addy, Jack L	Regional Sales Leader
Amato III, Michael T	Business Development Manager
Anderson, Sherri L	Regional Sales Leader
Annunziata, Andrew D	Regional Sales Leader
Arita, Gabriela M	Marketing Coordinator
Barefoot, David W	Regional Sales Leader
Barnes, Derek B	Regional Sales Leader
Basdikis, Justin	National Accounts Manager
Beckman, Andrew S	Regional Sales Leader
Behrendt, Tyler R	Regional Sales Leader
Boehm, Joseph Harry Thomas	Regional Sales Leader
Brand, Kenneth M	Regional Sales Leader
Brannon, Kyle T	Regional Sales Leader
Clay, Ryan J	Area Sales Director
Cortes, Justina E	Regional Sales Leader
Deulin, Savva	Regional Sales Leader
Devine, Michael J	President
DiGiovanni, Nicholas G	Regional Sales Leader
Donnelly, Reed B	Regional Sales Leader
Doria, Arianna J	Product Manager
Falcone, Ryan M	Regional Sales Leader
Gaffney, James M	Regional Sales Leader
Ghnaim, Deya D	Regional Sales Leader
Gonzalez, Abraham	Warehouse Associate
Gorman, Arthur P	Area Sales Director
Hale, Victoria A	Customer Service representitive
Hirt, Eric B	Vice President - Sales
Holliday, Jasmin D	Regional Sales Leader
Hopper, Matthew J	Regional Sales Leader
Hovan, Mitchell C	Regional Sales Leader
James, Aryana E	Customer Service Supervisor
Krone, Greyson	Regional Sales Leader
Lopez Jr, Jesus	Warehouse Supervisor
Lopez, Isaiah A	Warehouse Associate
Marco, Dominic J	Warehouse Associate
Miller, Ryan E	Area Sales Director
Motamedi, Ashley	Vice President - Administration
Pendley, Spencer I	Regional Sales Leader
Pettit, Joshua	Regional Sales Leader
Pham, David H	Senior Business Analyst
Poole, Shahrzad	Vice President - Business Development
Poormand, Ghassem	CEO/CFO
Riley, Jaclyn L	Area Sales Director
Ross, Ian K	Global Product Director – Airway Management & Anesthesia
Ryan Jr, Shawn P	Regional Sales Leader
Santos, Reynaldo S	Warehouse Associate
Sauer, Peter J	Head of Legal (US)
Shuman, Abigail	Quality & Licensing Specialist
Sims, Eric D	Warehouse Associate
Stear, Benjamin A	Regional Sales Leader
Sumner, Brianna N	Finance
Taylor, Brian L	Warehouse Supervisor
Tellez, Cynthia C	Warehouse Associate
Tingen, Courtland	Business Development Manager, Latin America, Caribbean, Puerto Rico, Canada
Trice, Deyzmun D	Warehouse Associate
Velasquez, Gabriela	Customer Service representitive
Wahlenmaier, Garrett R	Regional Sales Leader
Waugh, Caleb J	Regional Sales Leader
Wendel, Nicholas F	Dirctor of operation/ATL
Wicks, Drew W	Senior Analyst
Wilson, Amanda K	Regional Sales Leader
Wright, Lorenzo J	Warehouse Associate
Zambrano, Stacey D	Financial Controller

Flexicare Independent Contractors and Consultants as of April 14, 2025

Anesthesia Specialties, Inc.	475 Ken Mar Industrial Parkway, Broadview Heights, OH 44147
Brother Lung Solutions	9910 Santa Anita Ave, Montclair, CA 91763
Dr. Pretham Suresh	UC San Diego, 9500 Gilman Drive, La Jolla, CA 92093
Dr. Jeffrey Tully	UC San Diego, 9500 Gilman Drive, La Jolla, CA 92093
Jeremy Arner	213 S. Smith Rd, Danville, PA 17821

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☐ Ownership Change* ☐ Name Change* ■ Location Change* (in-state only)	* If making a change, provide current license number: WH 03230	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Innovative Neurotronics, Inc.

Physical Address: 1170 Trademark Drive, Suite 104

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 1.800.350.1100 Website: www.ACPLUS.com/technology/walkaide

Name of Designated Representative (DR): Jacob Bond Dukes

Licensing Company Email: acp-customersupport@hanger.co DR Email: JDukes@Hanger.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: ZMI Electronics Limited
Address: 6F-1, 286-4 Shin Ya Road City: Kaohshung State: Taiwan Zip:
Name: Cardinal Health
Address: 700 Cardinal Place City: Dublin State: OH Zip: 43017
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Hanger, Incl.
Corporation/Organization Name: Hanger, Inc.
Mailing Address: 10190 Domain Drive, Suite 300
City: Austin State: TX Zip: 78758
Telephone: 1.512.777.3800 Email: MegWilliams@Hanger.com
Contact Person Name: Meghan Williams - External Communications Manager

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Innovative Neurotronics, Inc.

Facility Name

Zlatko Larry Hodin

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/1/2025

Date

Board Use Only	Date Received: 7/3/25	Amount: $1000-ck 0899

/help/index.html)

DRLM Home (mainMenu.htm) > View Your Registrations and Listings

View Your Registered Facilities

Owner/Operator:

Clear Sort and Filter

Show 10 per page

Filter:

Registration Number	Registration Status	Registration Status Reason	Facility Name/ Trade Name(s)	Address	Expiration Date	Action
3005694504	Active	Legacy Data - Registration activated	INNOVATIVE NEUROTRONICS INC.	1170 TRADEMARK DR STE 104, RENO, NEVADA 89521 UNITED STATES	2025-12-31	

Showing 1 to 1 of 1 entries

Previous 1 Next

< Previous (drlm.htm?_flowExecutionKey=_cB17EB27E-6E58-72A4-07A4-4FE285720211_k4495C77E-0F23-A3ED-97FD-90CC8C48C0ED&_eventId=back)

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
INNOVATIVE NEUROTRONICS INC.
4999 AIRCENTER CIR STE 103
Reno, NV 89502
Registration Number: 3005694504
FEI Number*: 3005694504
Status: Active
Date Of Registration Status: 2023

Owner/Operator:
Innovative Neurotronics[6]
4999 Aircenter Cir.
Suite 103
Reno, NV US 89502
Owner/Operator Number: 9076839[7]

Official Correspondent:
Lee T Grasseschi
4999 Aircenter Cir.
Suite 103
Reno, NV 89502
Phone: 1-775-2231391

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 04/24/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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Hanger Inc
84-0904275
100% Direct owner

Hanger
Empowering Human Potential

INDIRECT Owners

Legal Name	Address	Phone	FEIN	Percentage of Indirect Ownership in Provider	Confirmation of No Adverse Actions
Hero Parent, Inc.	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3548884	100% indirect	None
Hero Intermediate Holdings, Inc.	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3597550	100% indirect	None
PSC Hero Holdings, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3558625	100% indirect	None
PSC Hero Aggregator, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3763319	97.77% indirect	None
PSC Hero Coinvest, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	88-3457821	24.77% indirect	None
Patient Square Equity Partners, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	86-2475113	26.22% indirect	None
Patient Square Equity Partners-A, LP	2884 Sand Hill Road, Suite 100 Menlo Park, CA 94025	(650)384-6558	86-2515974	44.72% indirect	None

Innovative Neurotronics, Inc.

Subsidiary of Hanger, Inc.

Directors

Peter A. Stoy

Thomas E. Kiraly

Officers

Peter A. Stoy	Chief Executive Officer
Spencer D. LeGrand	President
Thomas E. Kiraly	Executive Vice President, Assistant Treasurer an Assistant Secretary
Thomas E. Hartman	Senior Vice President, General Counsel and Secretary
Joseph C. Talley	Treasurer and Assistant Secretary

Innovative Neurotronics, Inc.

Subsidiary of Hanger, Inc.

List of Shareholders

Name	Percent Ownership
Hanger, Inc.	100%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "INNOVATIVE NEUROTRONICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF JUNE, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "INNOVATIVE NEUROTRONICS, INC." WAS INCORPORATED ON THE TWENTY-FOURTH DAY OF NOVEMBER, A.D. 2003.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

3731325 8300

SR# 20253182761

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204050128

Date: 06-26-25

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 12/27/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

Holder Identifier :

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Hanger, Inc. & all its wholly owned subsidiaries 10910 Domain Dr. Ste. 300 Austin TX 78758-7807 USA	INSURER A: Travelers Property Cas Co of America	25674
	INSURER B: The Travelers Indemnity Co.	25658
	INSURER C: Lloyd's Syndicate No. 3623	AA1120055
	INSURER D: ACE Property & Casualty Insurance Co.	20699
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570110072149 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
C	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			W38C61250101	01/01/2025	01/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $50,000 $5,000 $2,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			TJCAP-1R572736-TIL-25	01/01/2025	01/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$2,000,000
D	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $100,000			G28196842009	01/01/2025	01/01/2026	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
A B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory In NH) Y/N: N N/A If yes, describe under DESCRIPTION OF OPERATIONS below			UB2X7193742551K All other states UB2X7164642551R For AZ, MA, WI	01/01/2025 01/01/2025	01/01/2026 01/01/2026	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $1,000,000 $1,000,000 $1,000,000
C	Products Liability			W38C61250101 Claims Made SIR applies per policy terms & conditions	01/01/2025	01/01/2026	Each Claim Aggregate	$10,000,000 $10,000,000

Certificate No : 570110072149

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Evidence of Insurance. Product Liability/Completed Operations Retro Date 01/01/2004

CERTIFICATE HOLDER

Hanger, Inc. &
all its wholly owned subsidiaries
10910 Domain Drive #300
Austin TX 78758 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

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AGENCY CUSTOMER ID: 570000092454
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Hanger, Inc. & all its wholly owned
POLICY NUMBER: See Certificate Number: 570110072149	
CARRIER: See Certificate Number: 570110072149 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
C	Hospital Professional/General Liability			W38C61250101 Claims Made SIR applies per policy terms & conditions	01/01/2025	01/01/2026	Each Claim	$10,000,000
							Aggregate	$10,000,000

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GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	CMS0334101
For	NV Pharmaceutical Wholesaler Bond
Dated effective	01/18/2024 (MONTH, DAY, YEAR)
Executed by	Innovative Neurotronics, Inc. , as Principal, (PRINCIPAL)
And by	RLI Insurance Company, as Surety, (SURETY)
And in favor of	Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Principal Address	4999 Aircenter Circle, Suite 103	1170 Trademark Drive, Suite 104
Principal Zip	89502	89521

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **07/22/2025**
(MONTH, DAY, YEAR)

Signed and Sealed **06/20/2025**
(MONTH, DAY, YEAR)

Innovative Neurotronics, Inc.
PRINCIPAL

BY _____
TITLE

RLI Insurance Company
SURETY

BY Scott D. Chapman
Scott D. Chapman, ATTORNEY-IN-FACT

POWER OF ATTORNEY

RLI Insurance Company
Contractors Bonding and Insurance Company

9025 N. Lindbergh Dr. Peoria, IL 61615
Phone: 800-645-2402

Know All Men by These Presents:

That this Power of Attorney is not valid or in effect unless attached to the bond which it authorizes executed, but may be detached by the approving officer if desired.

That **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, each an Illinois corporation, (separately and together, the "Company") do hereby make, constitute and appoint:

Scott D. Chapman, Rosalyn D. Hassell, Elaine Lewis, Kevin McQuain, Stacy Owens, Kimberly Stanley, Cheryl Colson, Misty Witt, jointly or severally

in the City of The Woodlands, State of Texas its true and lawful Agent(s) and Attorney(s) in Fact, with full power and authority hereby conferred, to sign, execute, acknowledge and deliver for and on its behalf as Surety, in general, any and all bonds and undertakings in an amount not to exceed **Twenty Five Million** Dollars (**$25,000,000.00**) for any single obligation.

The acknowledgment and execution of such bond by the said Attorney in Fact shall be as binding upon the Company as if such bond had been executed and acknowledged by the regularly elected officers of the Company.

RLI Insurance Company and/or **Contractors Bonding and Insurance Company**, as applicable, have each further certified that the following is a true and exact copy of a Resolution adopted by the Board of Directors of each such corporation, and is now in force, to-wit:

"All bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or Agents who shall have authority to issue bonds, policies or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile."

IN WITNESS WHEREOF, the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, as applicable, have caused these presents to be executed by its respective Vice President with its corporate seal affixed this 2nd day of September, 2020.

CONTRACTORS BONDING AND INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI Insurance Company
Contractors Bonding and Insurance Company

By: B. W. D.
Barton W. Davis — Vice President

State of Illinois }
County of Peoria } SS

On this 2nd day of September, 2020, before me, a Notary Public, personally appeared Barton W. Davis, who being by me duly sworn, acknowledged that he signed the above Power of Attorney as the aforesaid officer of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** and acknowledged said instrument to be the voluntary act and deed of said corporation.

By: Catherine D. Glover
Catherine D. Glover — Notary Public

CATHERINE D. GLOVER
OFFICIAL SEAL
Notary Public - State of Illinois
My Commission Expires
March 24, 2024

CERTIFICATE

I, the undersigned officer of **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, do hereby certify that the attached Power of Attorney is in full force and effect and is irrevocable; and furthermore, that the Resolution of the Company as set forth in the Power of Attorney, is now in force. In testimony whereof, I have hereunto set my hand and the seal of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** this 20th day of June, 2025.

RLI Insurance Company
Contractors Bonding and Insurance Company

By: Jeffrey D Fick
Jeffrey D Fick — Corporate Secretary

I210334020212

A0058D19

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

COPY

Bond No. CMS0334101

Application/License No. _____

Innovative Neurotronics, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4999 Aircenter Circle, Suite 103, Reno, NV. 89502 (Address of Applicant/Principal), as PRINCIPAL, and RLI Insurance Company (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 9025 N. Lindbergh Drive , Peoria, IL 61615 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 18, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

POWER OF ATTORNEY

RLI Insurance Company
Contractors Bonding and Insurance Company

9025 N. Lindbergh Dr. Peoria, IL 61615
Phone: 800-645-2402

Know All Men by These Presents:

That this Power of Attorney is not valid or in effect unless attached to the bond which it authorizes executed, but may be detached by the approving officer if desired.

That **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, each an Illinois corporation, (separately and together, the "Company") do hereby make, constitute and appoint:

Scott D. Chapman, Rosalyn D. Hassell, Elaine Lewis, Kevin McQuain, Stacy Owens, Kimberly Stanley, Cheryl Colson, Misty Witt,
jointly or severally

in the City of The Woodlands, State of Texas its true and lawful Agent(s) and Attorney(s) in Fact, with full power and authority hereby conferred, to sign, execute, acknowledge and deliver for and on its behalf as Surety, in general, any and all bonds and undertakings in an amount not to exceed Twenty Five Million Dollars ($25,000,000.00) for any single obligation.

COPY

The acknowledgment and execution of such bond by the said Attorney in Fact shall be as binding upon the Company as if such bond had been executed and acknowledged by the regularly elected officers of the Company.

RLI Insurance Company and/or **Contractors Bonding and Insurance Company**, as applicable, have each further certified that the following is a true and exact copy of a Resolution adopted by the Board of Directors of each such corporation, and is now in force, to-wit:

"All bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or Agents who shall have authority to issue bonds, policies or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile."

IN WITNESS WHEREOF, the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, as applicable, have caused these presents to be executed by its respective Vice President with its corporate seal affixed this 2nd day of September, 2020.

CONTRACTORS BONDING AND INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI Insurance Company
Contractors Bonding and Insurance Company

By: _____
Barton W. Davis — Vice President

State of Illinois }
County of Peoria } SS

On this 2nd day of September, 2020, before me, a Notary Public, personally appeared Barton W. Davis, who being by me duly sworn, acknowledged that he signed the above Power of Attorney as the aforesaid officer of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** and acknowledged said instrument to be the voluntary act and deed of said corporation.

By: _____
Catherine D. Glover — Notary Public

CATHERINE D. GLOVER
OFFICIAL SEAL
Notary Public - State of Illinois
My Commission Expires
March 24, 2024

COPY

CERTIFICATE

I, the undersigned officer of **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, do hereby certify that the attached Power of Attorney is in full force and effect and is irrevocable; and furthermore, that the Resolution of the Company as set forth in the Power of Attorney, is now in force. In testimony whereof, I have hereunto set my hand and the seal of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** this 18th day of January, 2024.

RLI Insurance Company
Contractors Bonding and Insurance Company

By: _____
Jeffrey D. Fick — Corporate Secretary

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of January, 2024.

APPLICANT/PRINCIPAL

Innovative Neurotronics, Inc.
COMPANY

By: _____
Authorized Representative

COPY

SURETY

RLI Insurance Company

By: _____
Surety Company's Representative

COPY

Scott D. Chapman Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

Elaine Lewis
Witness Elaine Lewis

Rosalyn Hassell
Witness Rosalyn Hassell

Countersigned by:

Nevada Resident Agent Scott D. Chapman
License No. 746741

Posted February 20, 2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Innovative Neurotronics, Inc. MDEG License # (if applicable): WHO3230

Physical Address: 1170 Trademark Drive Suite 104

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 775-685-4000 Website: www.Acplus.com/Technology/FES

Licensing Company Email: CustomerServiceInInc@InInc.us

Section 2: Personal Information

First: Jacob Middle: Bond Last: Dukes

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Reno State: NV Zip: [redacted]

Telephone: [redacted] Email: Jdukes@hanger.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	X	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northern Nevada Homeschool Association		08/04 - 07/08	
Address	**City**	**State**	**Zip**
2795 Arrow Smith Drive	Sparks	NV	89436
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/24 - Current	[redacted]	Reno	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
01/23 - 01/24		Fallon	NV	
From - To (MM/YY – MM/YY)		City	State	
03/22 - 01/23		Reno	NV	
From - To (MM/YY – MM/YY)		City	State	
04/21 - 03/22		Reno	NV	
From - To (MM/YY – MM/YY)		City	State	
08/19 - 04/21		Sparks	NV	
From - To (MM/YY – MM/YY)		City	State	
10/18 - 08/19		Sparks	NV	
From - To (MM/YY – MM/YY)		City	State	
09/17 - 10/18		Sparks	NV	
From - To (MM/YY – MM/YY)		City	State	
07/17 - 09/17		Reno	NV	
From - To (MM/YY – MM/YY)		City	State	
02/13 - 07/17		Sparks	NV	
From - To (MM/YY – MM/YY)	Address	City	State	

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Innovative Neurotronics, Inc.		02/12 - Current	
Business Address	**City**	**State**	**Zip**
1170 Trademark Drive Suite 104	Reno	NV	89502
Phone	**Title**	**Number of Employed Hours**	
800-350-1100	Manager, Service Center	24,880	
Description of Duties			
Oversee the return, repair, distribution of each medical device throughout three departments			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

08/05/2025

Date

I, Jacob Bond Dukes, **certify that as the MDEG Administrator for**

Innovative Neurotronics, Inc.,

that I (initial that you have read and meet the following requirements):

1. JD Have a high school diploma or its equivalent;
2. JD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jacob Dukes
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/05/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler INNOVATIVE NEUROTRONICS, INC.

Pharmacy/Wholesaler License # (if applicable) WH03230

Physical Address 1170 TRADEMARK DRIVE, SUITE 104

City RENO State NV Zip 89521

Mailing Address (if different from physical address)

City State Zip

Telephone 775 685 4000 Website WWW.ACPLUS.COM/TECHNOLOGY/WALKABOUT

Licensing Company Email ACP-CUSTOMERSUPPORT@HANGER.COM

Section 2: Personal Information

First JACOB Middle BOND Last DUKES

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City BOND State NV Zip [redacted]

Telephone [redacted] Email JDUKES@HANGER.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	X	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
NORTHERN NEVADA HOMESCHOOL ASSOCIATION			08/04 – 07/08	
Address	**City**		**State**	**Zip**
2795 ARROW SMITH DR	SPARKS		NV	89436
Diploma/Degree obtained, if any				
DIPLOMA				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/24 –	[redacted]	RENO	NV	[redacted]
01/23 – 01/24		RENO	NV	
03/22 – 01/23		RENO	NV	
04/21 – 03/22		RENO	NV	
08/19 – 04/21		SPARKS	NV	
10/18 – 08/19		SPARKS	NV	
09/19 – 10/18		SPARKS	NV	
07/17 – 09/17		RENO	NV	
02/13 – 07/17		SPARKS	NV	

Section 7- A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
INNOVATIVE NEUROTRONICS, INC			02/12 – CURRENT
Business Address	**City**	**State**	**Zip**
4999 MERCENTER CIRCLE, ST. 103	RENO	NV	89502
Phone	**Title**	**Number of Employed Hours**	
800 350 1100	MANAGER, SERVICE CTR.	29,000	
Description of Duties			
OVERSEE THE RETURN, REPAIR, DISTRIBUTION of MEDICAL DEVICES			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, JACOB BOND DUKES, **certify that as the designated representative for** INNOVATIVE NEUROTRONICS, INC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JD I am at least 21 years of age;
3. JD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JACOB BOND DUKES

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/24/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jacob Bond Dykes

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/24/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Jacob Dykes, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/24/2025

Date

Subscribed and Sworn to before me this 24th day of June 2025.

Hancy Alexandra Vasquez

Notary Public Signature

HANCY ALEXANDRA VASQUEZ
NOTARY PUBLIC
STATE OF NEVADA
APPT NO. 24-5543-02
APPT EXPIRES JULY 9, 2028

(Seal)

Accelerated Care Plus Leasing, Inc. - Reno Employees

Employee ID	*Last Name*	*First Name*	*Location Name*	*Job Title*
119183	Abeyta	Troy	Reno,NV [Service Center]	Service Technician III
127403	Abid	Erin	Reno,NV [Service Center]	Material Handler II
124081	Aguilar	Jesus	Reno,NV [Service Center]	Material Handler IV
123344	Buckley	Laurie	Reno,NV [Finance]	Accounting Specialist II
103097	Carrell	Nancy	Reno,NV [Service Center]	Material Handler IV
124184	Coville	Tracy	Reno,NV [Customer Support]	Customer Service Rep II
124251	Cranford	James	Reno,NV [Service Center]	Service Technician III
126455	Curby	Luviminia	Reno,NV [Quality Assurance]	QA Analyst-ACP
118111	Diehl	Matthew	Reno,NV [Finance]	ACP Financial Controller
121359	Dukat	Judit	Reno,NV [Finance]	Staff Accountant
118285	Dukes	Jacob	Reno,NV [Service Center]	Mgr, Service Center-ACP
125441	Faillers	Afton	Reno,NV [Finance]	Sr Accountant
123996	Grasseschi	Lee	Reno,NV [Quality Assurance]	Mgr,Compliance and QA
125997	Grohs	Melissa	Reno,NV [Finance]	Accounting Specialist II
117992	Guzman	Theresa	Reno,NV [Finance]	Mgr,Accounting
117926	Hodin	Zlatko	Reno,NV [Quality Assurance]	Dir,Quality & Compl-ACP
126284	Johnson	Kyle	Reno,NV [Service Center]	Service Technician IV
130048	Khan	Aiman	Reno, Nevada H130048	Customer Service Rep II
125481	Lee	Christopher	Reno,NV [Service Center]	Service Technician III
122277	Maley	Lois	Reno,NV [Customer Support]	Customer Service Rep II
117977	Masters	Susan	Reno,NV [Finance]	Sr Accountant
121462	Moore	Karen	Reno,NV [ACP Lease Program]	Administrative Asst II
124179	Nathan	Geraldine	Reno,NV [Clinical Education]	Clinical Education Coord III
126754	Quesada Arias	Andrea	Reno,NV [Finance]	Accounting Specialist II
125360	Retherford	Christian	Reno,NV [Customer Support]	Lease Administrator II
118030	Scheuermann	Dorothy	Reno,NV [Finance]	Accounting Specialist III
123680	Seidman	Lance	Reno,NV [Service Center]	Service Technician II
118097	Thomson	Barry	Reno,NV [Product Development]	Dir,Operations-ACP
121488	Young	Christopher	Reno,NV [Customer Support]	Supv,Customer Service
124318	Young	Gordon	Reno,NV [Customer Support]	Customer Service Rep II

Accelerated Care Plus Leasing, Inc. - All Employees

Employee ID	Last Name	First Name	Location Name	Job Title
119183	Abeyta	Troy	Reno,NV [Service Center]	Service Technician III
127403	Abid	Erin	Reno,NV [Service Center]	Material Handler II
124081	Aguilar	Jesus	Reno,NV [Service Center]	Material Handler IV
118002	Akst	Andree	Cumming, GA H118002	Clinical Ed Consultant IV
118100	Alexander	Danielle	Dryden, MI H118100	Regional Mgr,Ops-ACP
118053	Applegate	William	Edmond, OK 118053	Clinical Program Consultant
118043	Barnes	Tara	Memphis, TN H118043	Clinical Prog Consult- Float
128941	Boger	Toni	Jacksonville, FL H128941	Clinical Program Consultant
118384	Bryant	Alyssa	Birmingham, AL H118384	Clinical Program Consultant
123344	Buckley	Laurie	Reno,NV [Finance]	Accounting Specialist II
113934	Burzynski	Jodi	Coeur d'Alene,ID H113934	Clinical Ed Consultant IV
118710	Calvo	Daniel	St. Augustine, FL H118710	Reg Clinical Prog Consultant
118037	Campbell	John	Phoenixville, PA H118037	ACP Sales & Bus Dev Region Mgr
118079	Capella	Debra	Frederick, MD H118079	Clinical Program Consultant
103097	Carrell	Nancy	Reno,NV [Service Center]	Material Handler IV
128216	Castillo-Ornelas	Janet	Las Vegas, NV H128216	Customer Service Rep II
117958	Chiquito	Juan	Miramar, FL H117958	Clinical Program Consultant
117949	Contreras	Kelly	Tolland, CT H117949	Sr Mgr,Remote Clinical Svcs-AC
129875	Cook	Jamie	Lakewood, WA H129875	Regional Mgr,Ops-ACP
124184	Coville	Tracy	Reno,NV [Customer Support]	Customer Service Rep II
124251	Cranford	James	Reno,NV [Service Center]	Service Technician III
118056	Cullagh	Shannon	Norfolk, MA H118056	Division Business Leader-ACP
126455	Curby	Luviminia	Reno,NV [Quality Assurance]	QA Analyst-ACP
122222	Dankert	Jason	Oak Creek, WI H122222	Clinical Program Consultant
117955	Davis	Karen	Greenwood, IN H117955	Clinical Program Consultant
118111	Diehl	Matthew	Reno,NV [Finance]	ACP Financial Controller
117960	Donaldson	Mark	Saco, ME H117960	Clinical Program Consultant
118003	Dueker	John	Ballwin, MO H118003	Clinical Prog Consult- Float
121359	Dukat	Judit	Reno,NV [Finance]	Staff Accountant
118285	Dukes	Jacob	Reno,NV [Service Center]	Mgr, Service Center-ACP
118039	Dunlap	Jeremy	Chalfont, PA H118039	Market Leader
118065	Dunlay	Edward	Harrison, TN H118065	Dir,Market Development-ACP
117940	Engelmann	Richard	Hickory, NC H117940	Clinical Ed Consultant IV
117945	Escovedo	Ernest	Windsor, CA H117945	Clinical Program Consultant
125441	Faillers	Afton	Reno,NV [Finance]	Sr Accountant
118101	Fiore	Edward	Denver, NC H118101	ACP Sales & Bus Dev Region Mgr
117968	Fortunato	Lawrence	Winter Park, FL H117968	Clinical Program Consultant
118041	Fournie	Lynn	Columbia, IL H118041	Reg Clinical Prog Consultant
118078	Freedman	Joana	Portland, OR H118078	Clinical Prog Consult- Float
117954	Fruits	Angela	Greenwood, IN H117954	Clinical Program Consultant
121226	Gianpetro	Anthony	Plainfield, IL H121226	Clinical Program Consultant
124637	Goggin	Dawn	Flowery Branch, GA H124637	Mgr,Supplier & Inventory Mgmt
124855	Gohel	Sonal	Brooklyn, NY H124855	Clinical Program Consultant
123996	Grasseschi	Lee	Reno,NV [Quality Assurance]	Mgr,Compliance and QA

125997	Grohs	Melissa	Reno,NV [Finance]	Accounting Specialist II
117962	Gurnani	Seema	Chicago, IL H117962	Sr Mgr,Clinical Services
117992	Guzman	Theresa	Reno,NV [Finance]	Mgr,Accounting
118028	Havrilla	Karleen	Canfield, OH H118028	Clinical Program Consultant
118059	Hayes	Ann Marie	Ellington, CT H118059	Clinical Program Consultant
118118	Heimes	Christine	Kansas City, KS H118118	Clinical Program Consultant
117982	Hobbs	Manda	Raleigh, NC H117982	Clinical Program Consultant
117946	Hobbs	Amy	Winston Salem, NC H117946	VP,Clinical Ops-ACP
117926	Hodin	Zlatko	Reno,NV [Quality Assurance]	Dir,Quality & Compl-ACP
118085	Hooks	Darcirae	Delaware, OH H118085	Clinical Program Consultant
121095	Hughes	Robert	Las Vegas, NV H121095	Clinical Program Consultant
117969	Huller	Elizabeth	Lincoln Univ,PA H117969 118073	ACP Sales & Bus Dev Region Mgr
119019	Huntley	Kelly	South Glens Falls, NY H119019	Regional Mgr,Ops-ACP
117947	Jackson	Susan	Bowling Green, KY H117947	Regional Mgr,Ops-ACP
126284	Johnson	Kyle	Reno,NV [Service Center]	Service Technician IV
117967	Jordan	Timothy	Maryville, TN H117967	Clinical Program Consultant
117976	Keck	Jessica	Whitefish,MT [H117976]	Staff Financial Analyst
118264	Kendrick	Rubye	Tyler, TX H118264	Clinical Program Consultant
130048	Khan	Aiman	Reno, Nevada H130048	Customer Service Rep II
117959	Kopp	Donna	Olathe, KS H117959	Division Business Leader-ACP
129821	Kubala	Carrie	Wayne, PA H129821	Clinical Program Consultant
117974	Lang	Lori	Burgaw, NC H117974	Division Business Leader-ACP
119832	Larson	Wendy	Tacoma, WA H119832	Clinical Program Consultant
125481	Lee	Christopher	Reno,NV [Service Center]	Service Technician III
118075	Lindsey	Toni	Irving, TX H118075	Clinical Program Consultant
118027	Lysons	Dylan	Tulsa, OK H118027	QA Inspector III
122277	Maley	Lois	Reno,NV [Customer Support]	Customer Service Rep II
117956	March	Susan	Winter Park, FL H117956	Regional Mgr,Ops-ACP
117921	Martocci	Lynne	Guilford, CT H117921	Clinical Prog Consult- Float
117977	Masters	Susan	Reno,NV [Finance]	Sr Accountant
117971	McNamara	Debra	Laguna Niguel, CA H117971	Clinical Program Consultant
118894	Meyer	Amy	Marlboro, NJ H118894	Clinical Program Consultant
119235	Micko	Kenneth	Hillsborough, NJ H119235	Clinical Program Consultant
122230	Middleton	Valerie	Jamestown, NC H122230	Clinical Program Consultant
123972	Moore	Tawny	Livingston, TX H123972	Clinical Education Coord III
121462	Moore	Karen	Reno,NV [ACP Lease Program]	Administrative Asst II
121523	Morrow	Dawn	Katy, TX H121523	Clinical Program Consultant
128388	Musselman	Mark	Fort Mill, SC H128388	Clinical Program Consultant
129969	Myers	Elizabeth	Wheeling, WV H129969	Clinical Program Consultant
124624	Nagy	Michelle	Harrisburg, PA H124624	Clinical Program Consultant
124179	Nathan	Geraldine	Reno,NV [Clinical Education]	Clinical Education Coord III
118080	Nitcher	Chad	New Orleans, LA H118080	ACP Sales & Bus Dev Region Mgr
117919	Norton	Tracy	Chatsworth, CA H117919	Clinical Program Consultant
119427	ODonnell	Karin	Chicago, IL H119427	Clinical Program Consultant
118115	OKeeffe	Catherine	Norfolk, MA H118115	Clinical Program Consultant
118088	Oltmans	Jaclyn	Omaha, NE H120206 118088	Clinical Prog Consult- Float
118063	Paddock	Jeffrey	Kenner, LA H118063	Clinical Program Consultant
118055	Panisak	Shannon	Mountain Top, PA H118055	Clinical Program Consultant

117984	Peterson	Janine	Star Prairie, WI H117984	Clinical Program Consultant
126727	Pfeil	Amanda	Rancho Santa Margt, CA H126727	Clinical Program Consultant
129268	Polyak	Marina	Manalapan, NJ H129268	Clinical Program Consultant
117975	Pride	Sherrie	Louisville, KY H117975	Clinical Program Consultant
119812	Purvis	Heather	Wilmington, NC H119812	Market Leader
126754	Quesada Arias	Andrea	Reno,NV [Finance]	Accounting Specialist II
128896	Rainey	Jordan	Lakeland, TN H128896	Clinical Program Consultant
119296	Redublo	Alduaine	Corpus Christi, TX H119296	Clinical Program Consultant
125360	Retherford	Christian	Reno,NV [Customer Support]	Lease Administrator II
129183	Rothstein	Allison	Sayville, New York H129183	Clinical Program Consultant
129240	Rys	Katherine	Lakeland, FL H129240	Clinical Program Consultant
118030	Scheuermann	Dorothy	Reno,NV [Finance]	Accounting Specialist III
119213	Sears	Helena	Austin, TX H119213	Regional Mgr,Ops-ACP
123680	Seidman	Lance	Reno,NV [Service Center]	Service Technician II
129706	South	Laureta	Garden City, NY H129706	Clinical Program Consultant
123359	Steffenilla	Tod	N. Chesterfield, VA H123359	Clinical Program Consultant
129587	Steinmeyer	Julie	Lincoln, NE H129587	Clinical Program Consultant
118050	Stevens	Tera	Pearland, TX H118050	Clinical Program Consultant
129676	Stewart	Jeremy	Remote Work Loc - Texas	Business Dev Associate-ACP
118086	Subramanian	Sharadha	Newburgh, IN H118086	Clinical Program Consultant
117995	Tawfik	John	Schnecksville, PA H117995	Dir,Clinical Services
117973	Thakkar	Hetarthi	Alpharetta, GA H117973	Clinical Program Consultant
118116	Thompson	Karen	Des Moines, IA H118116	Clinical Program Consultant
118097	Thomson	Barry	Reno,NV [Product Development]	Dir,Operations-ACP
118008	Tobin	Susan	Lancaster, OH H118008	Clinical Program Consultant
124783	Verdicchio	Jenna	Portland, OR H124783	Clinical Program Consultant
121940	Vollen	Ronald	Winchester, VA H121940	Clinical Program Consultant
117996	Weinschenk	Karen	Hudson, MA H117996	Clinical Program Consultant
118024	Whittemore	Chara	Friendsville, MD H118024	Clinical Prog Consult- Float
121488	Young	Christopher	Reno,NV [Customer Support]	Supv,Customer Service
124318	Young	Gordon	Reno,NV [Customer Support]	Customer Service Rep II
117993	Zeigler	Diane	Arlington, TX H117993	Clinical Program Consultant

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Ivy Technology, LLC

Physical Address: 11201 Electron Drive

City: Louisville State: KY Zip: 40299

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: (502) 240-1000 Website: www.ivytech.com

Name of Designated Representative (DR): Jeffrey McCubbins

Licensing Company Email: Jeffrey.mccubbins@ivytech.com DR Email: Jeffrey.mccubbins@ivytech.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☑ Others: See Attachment A

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

I/A Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company (Limited Liability Company)

State of Incorporation/Organization: Delaware

Parent Company (if any): Ivy Technology Holdings, LLC

Corporation/Organization Name: Ivy Technology, LLC

Mailing Address: 11201 Electron Drive

City: Louisville State: KY Zip: 40299

Telephone: (502) 240-1000 Email: Jeffrey.mccubbins@ivytech.com

Contact Person Name: Jeffrey McCubbins

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

N/A Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment D		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly owned by parent company.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant** See Attachment G	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment H	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment I	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment J	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8) N/A				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Ivy Technology, LLC

Facility Name

Jeffrey McCubbins

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/26/2025

Date

Board Use Only	Date Received: 7/14/25	Amount: $1000-ck 2645

Attachment A

Nature of Business

Ivy Technology, LLC "Ivy Tech" repairs and will ship prescription medical devices utilized for compression therapy. Ivy Tech will not own the product it ships.

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Ivy Technology
11201 ELECTRON DR.
Jeffersontown, KY 40299
Registration Number: 1531264
FEI Number*: 3002865632
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
Ivy Technology[6]
11201 ELECTRON DR.
Louisville, KY US 40299
Owner/Operator Number: 9042494[7]

Official Correspondent:
Jeffrey W Mccubbins
11201 ELECTRON DR.
Louisville, KY 40299
Phone: 502-2401052

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9042494&OwnerOperatorName=&ProductCode=
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9042494&OwnerOperatorName=&ProductCode=

Page Last Updated: 05/26/2025

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Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

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Attachment D

LLC Information

Ivy Technology, LLC
1120 Electron Drive
Louisville KY 40299

Parent Company:

Ivy Technology Holdings, LLC
11201 Electron Drive
Louisville, KY 40299
Ownership: 100%

Corporate Officers:

John Orleans
Senior Vice President, General Counsel

James Rodriguez
Senior Vice President

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "IVY TECHNOLOGY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF APRIL, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7108838 8300

SR# 20251540609

Authentication: 203426359

Date: 04-13-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Third Party Logistics

NUMBER: TPL00353

EFFECTIVE DATE: 10/08/2020

EXPIRATION DATE: 06/30/2026

Facility Contact Person: Jeffrey McCubbins

Issued to:

Ivy Technology Llc

11201 Electron Drive
Louisville, KY 40299

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address, and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 06/06/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:
Aon Risk Services, Inc of Florida 701 Brickell Avenue Suite 3200 Miami FL 33131 USA	PHONE (A.C. No. Ext): (866) 283-7122 FAX (A.C. No.): (800) 363-0105 E-MAIL ADDRESS:

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Ivy Technology Master Holdings LLC 11201 Electron Drive Louisville KY 40299 USA	INSURER A: Endurance American Specialty Ins Co.	41718
	INSURER B: American Casualty Co. of Reading PA	20427
	INSURER C: The Continental Insurance Company	35289
	INSURER D: Valley Forge Insurance Co	20508
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER: 570113091739** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY			6076246573	06/03/2025	06/03/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$15,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$1,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$2,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$2,000,000
D	AUTOMOBILE LIABILITY			6076246587	06/03/2025	06/03/2026	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			6076246590 (AOS)	06/03/2025	06/03/2026	X PER STATUTE OTH-ER	
B	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: Y (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		6076246606 (CA)	06/03/2025	06/03/2026	E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000
A	Cyber Liability			PRO30008034103 Claims-Made SIR applies per policy terms & conditions	06/16/2024	06/16/2025	Limit SIR	$5,000,000 $150,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Cyber Liability policy includes Tech E&O. RE: Ivy Technology AMS Global Services. Evidence of Insurance.

CERTIFICATE HOLDER

Ivy Technology Master Holdings LLC
11201 Electron Dr.
Louisville KY 40299 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Inc of Florida

Holder Identifier :

Certificate No : 570113091739

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 285077178

Application/License No. _____

IVY TECHNOLOGY, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 11201 Electron Drive Louisville, KY 40229 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 26, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of June, 20 25.

APPLICANT/PRINCIPAL
IVY TECHNOLOGY, LLC

Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sara Owens, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Casey Smith

Witness Patricia Dorsaneo

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual SURETY

POWER OF ATTORNEY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8213593 - 019022**

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Annmarie Breene, Babette Ward, Cathy H. Ho, Dana Donahue, Joanne C. Wagner, Kimberly G. Sherrod, Lori S. Shelton, Marisa Thielen, Patricia A. Rambo, Patricia Dorsaneo, Patrick Breene, Pedro Gonzalez, Jr. , Sara Owens, Wayne G. McVaugh

all of the city of Philadelphia state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 3rd day of April , 2025 .

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 3rd day of April , 2025 before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of June , 2025 .

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/24

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2024

Assets	
Cash and Bank Deposits	$4,608,826,756.00
*Bonds – U.S Government	$4,281,375,446.74
*Other Bonds	$21,566,489,527.26
*Stocks	$15,589,644,012.00
Real Estate	$86,497,925.00
Agents' Balances or Uncollected Premiums	$7,512,975,129.00
Accrued Interest and Rents	$225,249,712.00
Other Admitted Assets	$19,367,663,200.00
Total Admitted Assets	**$74,539,483,661.00**

Liabilities	
Unearned Premiums	$9,890,896,878.00
Reserve for Claims and Claims Expense	$29,467,071,865.00
Funds Held Under Reinsurance Treaties	$341,948,172.00
Reserve for Dividends to Policyholders	$954,025.00
Additional Statutory Reserve	$150,547,865.00
Reserve for Commissions, Taxes and Other Liabilities	$5,049,906,410.00
Total	**$47,104,416,171.00**
Special Surplus Funds	$174,153,086.00
Capital Stock	$10,000,075.00
Paid in Surplus	$13,209,595,772.00
Unassigned Surplus	$13,415,980,561.00
Surplus to Policyholders	$27,435,067,490.00
Total Liabilities and Surplus	**$74,539,483,661.00**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2024, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2025.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

Attachment I

Medical Devices, Equipment and Gases (MDEG) Administrator Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Ivy Technology, LLC — MDEG License # (if applicable): Pending

Physical Address: 11201 Electron Drive

City: Louisville — State: KY — Zip: 40299

Mailing Address (if different from physical address): Same as physical address above.

City: — State: — Zip:

Telephone: (502) 240-1000 — Website: www.ivytech.com

Licensing Company Email: Jeffrey.mccubbins@ivytech.com

Section 2: Personal Information

First: Jeffrey — Middle: Wayne — Last: McCubbins

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ■ M ☐ F ☐ X

Mailing Address: 11201 Electron Drive

City: Louisville — State: KY — Zip: 40299

Telephone: (502) 240-1052 — Email: Jeffrey.mccubbins@ivytech.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Indiana Wesleyan University		2001 - 2002	
Address	**City**	**State**	**Zip**
4201 S. Washington Street	Marion	IN	46953
Diploma/Degree obtained, if any			
N/A - 19 hours towards BS in Business Management			
School Name		**From - To (MM/YY – MM/YY)**	
National Radio Institute		1995 - 1996	
Address	**City**	**State**	**Zip**
1401 Constitution Avenue, NW	Washington	DC	20230
Diploma/Degree obtained, if any			
Microcomputer Technology			
School Name		**From - To (MM/YY – MM/YY)**	
Doss High School		1985 - 1989	
Address	**City**	**State**	**Zip**
7601 St. Andrews Church Road	Louisville	KY	40214
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2004 - Current	[redacted]	Louisville	KY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Ivy Technology, LLC			12/96 - Current	
Business Address		**City**	**State**	**Zip**
11201 Electron Drive		Louisville	KY	40299
Phone	**Title**		**Number of Employed Hours**	
(502) 240-1000	Sr. Global Quality Manager		56,000+ hours	

Description of Duties
Business Management, Operations Management, Lean Manufacturing, Engineering Management, Quality and Regulatory. FDA Correspondent. Environmental, Health, and Safety. Security. Facilities.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

N/A

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, Jeffrey McCubbins, **certify that as the MDEG Administrator for**

Ivy Technology, LLC,

that I (initial that you have read and meet the following requirements):

1. JWM Have a high school diploma or its equivalent;
2. JWM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JWM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JWM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey McCubbins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/26/2025

Date

Board Use Only	Date Received: 7/14/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Ivy Technology, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 11201 Electron Drive

City: Louisville State: KY Zip: 40299

Mailing Address (if different from physical address): Same as physical address above.

City: State: Zip:

Telephone: (502) 240-1000 Website: www.ivytech.com

Licensing Company Email: Jeffrey.mccubbins@ivytech.com

Section 2: Personal Information

First: Jeffrey Middle: Wayne Last: McCubbins

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 11201 Electron Drive

City: Louisville State: KY Zip: 40299

Telephone: (502) 240-1052 Email: Jeffrey.mccubbins@ivytech.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Indiana Wesleyan University		2001-2002	
Address	**City**	**State**	**Zip**
4201 S Washington St.	Marion	IN	46953
Diploma/Degree obtained, if any			
N/A - 19 hours towards BS in Business Management			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
1401 Constitution Ave., NW	Washington	DC	20230
Diploma/Degree obtained, if any			
Microcomputer Technology			
School Name		**From - To (MM/YY – MM/YY)**	
Doss High School		1985 - 1989	
Address	**City**	**State**	**Zip**
7601 St. Andrews Church Road	Louisville	KY	40214
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2004-Current	[redacted]	Louisville	KY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Ivy Technology, LLC			12/1996 - Current	
Business Address		**City**	**State**	**Zip**
11201 Electron Drive		Louisville	KY	40299
Phone	**Title**		**Number of Employed Hours**	
(502) 240-1000	Sr. Global Quality Manager		56,000+ hours	
Description of Duties				
Business Management, Operations Management, Lean Manufacturing, Engineering Management, Quality and Regulatory. FDA Correspondent. Environmental, Health, and Safety. Security. Facilities.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Jeffrey McCubbins, **certify that as the designated representative for**

Ivy Technology, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JWM I am at least 21 years of age;
3. JWM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JWM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JWM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JWM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JWM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jeffrey McCubbins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/26/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey McCubbins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/26/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Jefferson

I, Jeffrey McCubbins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/26/2025

Date

Subscribed and Sworn to before me this 26 day of June 2025.

CLS

Notary Public Signature

ELIZABETH L. STELTENPOHL
Notary Public - State at Large
State of Kentucky
Notary ID KYNP30467
My Commission Expires July 17, 2025

ELIZABETH L. STELTENPOHL
Notary Public - State at Large
State of Kentucky
Notary ID KYNP30467
My Commission Expires July 17, 2025

(Seal)

User/Employee ID	Last Name	First Name
9058	Aguaviva	John Mark
9040	Aguaviva	Fermin III
8929	Aguilar Tavera	Neider
6785	Aliazon	Jerone
6182	allen	Brandy
6183	Allen	Brittany
8853	Alvarado Ovando	Cruz Leyver
6198	Andraca Muñoz	Luis
8048	Andrade	Ana
6070	Anthony	Darrell
5676	Aquino	Brenda
8546	Arias Almaguer	Onel
8211	Arias Salina	Jose
8698	Armas Viera	Leidys
7317	Asiryan	Anzhela
6965	Avila Benitez	Yetzy
6290	Bañuelos Acosta	Mario
3662	Barbosa	Lucas
8952	Bartee	Shauntae
7568	bautista	esteban
8326	Bautista Sanchez	Maria
3057	Bera	Patrik
5385	Bermudez Solis	Jose
8931	Bernal Garcia	Yanier
8436	Bernal Hernandez	Rene
8237	Betancourt	Kari
5583	Bline	David
6324	Bossa	Brech
1021	Bowling	Mark
6410	BROWN	DONALD
5775	Brown	Robert
6564	Brown	Eric
8930	Burgos Holguin	Nestor
8634	Caballero Romero	Marleana
3887	Cabanban	Edward
8512	Cabria	Herman
8162	Caceres Méndez	Wendy
8460	Camacho	Sermir

8554	Camacho Cobos	Javier
6044	Canales	Julieta
7134	Carmichael	Taylor
8800	Casas	Maria
8966	Castillo Morales	Fernando Fortino
5889	Cecena Castro	Jose Maria
8172	Cepero Morales	Eilin
8976	Cespedes Canizares	Cesar
8996	Chiquito	Jessica
8635	Chiquito Magallon	Nancy Guadalupe
6474	Chiquito Magallon	Frania
4475	Clark	Christopher
1321	Clemons	Lionel
8155	Climaco	Garret
8340	Cole	Jeremy
8189	Colon	Daer
1130	Colyer	Tobby
5572	Conley	Kevin
7926	Cortes	Jasmin
7555	Cortez	Evelina
8965	Crittenden	Antuane
8821	Crowder	Jesicah
8798	Cruz Reyes	Ismael
5592	Cunningham	Mandy
6427	Davis	Joshua
7622	Devore	Jeffrey
7906	Diaz Diaz	Ivet
7810	Farias	Paola
6718	Fernandez	Mayoli
8647	Fernandez Garcia	Jorge
5528	Fernandez Garcia	Nury
8484	Fernandez Perez	Casandra
8318	Fiallo Ledea	Rodolfo
5530	Fojo Gutierrez	Hector
6346	Foley	Tina
8486	French	Jessica
7924	Frometa	Armando
7509	Garcia	Rafael
8315	García Gomez	Juliana

8666	Garcia Hernandez	Fabian
8432	Garcia Morales	Leticia
6156	Girton	Derek
8638	Gonzalez	Hernan
8758	Green	Paul
1041	Greenwell	Justin
8051	Guedez	Karla
8550	Guedez Castellanos	Fiorella
8120	Gumaru	Mark Edward
5069	Haby	Brittany
7605	Hamilton	Cameron
8937	Hardman	Brian
1037	Harmon	James
4667	hayden	parrish
7316	Hayes	MinYawn
6005	Heineman	Matthew
4389	Hernandez	Carlos
8430	Hernandez	Jocelyn
8960	Hernandez Caceres	Leonardo
8115	Hernandez Comendador	Katia
8513	Hernández Delfin	Jairo
5692	HERNANDEZ MACIAS	GLORIA
8599	Hernandez Ramirez	Maria
8345	Hernandez Rodriguez	Virgen
8253	Hidalgo Rosillo	Jose
6291	Hiracheta Torres	Reynaldo
4758	Hocker	Tiffany
1255	Horváth	Gábor
1378	Hozdic	Fikreta
1883	Huguley	Demetrius
8375	Hurtado	Angelica
8403	Infante Rivas	Javier
5398	James	Charlene
8938	Jankowski	Coltan
8607	Jeffries	Damon
6284	Jimenez Brambila	Carlos
2534	Johnson	Jackie
6090	Jones	Patrick
6195	Joyner	Erick

1390	Kozlowska	Dorota
1343	Kozlowski	Rafal
6400	Lackey	Bradley
2824	Lagua	Rolando Calaparan
6315	Lara Garcia	Fernando
8598	Leon Gopar	Guillermo
8587	Lewis	Phillip
3263	Leyva	Alejandro
5461	Lopez	Yoselin
6768	Lopez	Mariana
8485	Lopez	Flor
8252	Lopez Marino	Jorge
8705	Lopez Paez	Ariel
3219	Lopez Ramirez	Yanicet
6255	Love	Timothy
8888	Loyola navarro	Silvio
6311	Luis Toledo	Christian
8187	Mallari	Alvin
8027	Manalili	Bryan
8950	Manresa Rodriguez	Arian
4767	Marquez	Ana
8341	Marrero Batista	Jesús
7603	Martinez Garcia	Leisy
8019	Martinez Garcia	Leidy
8395	Martinez Mulet	Aracelia
8886	Martínez Simón	Carlos
3004	Mask	Gerald
7896	Massa	Jade
8215	Matos Perez	Niurbis
6026	mays	kenya
6121	Mbuya	Lievin Marcel Mutambayi
7157	McClellon Jr	Eric
3000	McClure	Stephen
8995	Mendoza	Erika
6196	Mendoza	Javier
8765	Mendoza Ramirez	Alejandra
4410	Millar	Anacleto
9017	Minrath	William
5095	Molina Yserns	Ana

8859	Montilla Guainet	Maury
8119	Moody	Titus
7257	Morales	Oliver
6308	Morales Cortes	Octavio
7256	Morales Cortes	Perla
4312	Moronta Yusty	Hermen
8231	Morrison	Kenneth
7922	Moses	Rebecca
8794	Moya	Wilfredo
8767	Mullins	Kaitlyn
5677	MUNIZ	GRICELDA
5721	Murphy	Caden
5525	NAJI	WALEED
5496	Neguss	Mahlet
1277	Nelson	Cory
1031	Nguyen	Phuc Xuan
4287	Nguyen	Dung
1047	Nguyen	Huong K
7069	Noor	Halima
7479	Ortiz	Alejandro
8567	Oxima	Endrian
8548	Pantoja Guerra	Maria
3243	Payne	Kelly
7878	Perez	Darlys
8439	Perez Diaz	Walter
6076	Perez Mancilla	Juana
8961	Pérez Rodriguez	María
8793	Pérez Sánchez	Indira
8710	Petty	Reginald
2373	Pfister-Mosser	Heather
8854	Pina Terrazas	David
5423	poling	teresa
6977	Pullen	Rodney
3073	Punn	Arminder
6157	Pupo Hidalgo	Diana
4680	queija	silverio
8499	Radford	Gregory
8862	Rameau	Rozenn
8440	Ramirez	Juan

7658	Ramirez Zavaleta	Lizeth
4812	Recktenwald	Kelsey
7847	Reyes Ramirez	Yaniset
8532	Rhodes	Monique
1922	Rideg	Roland
4531	Rivera	Edith
8232	Robles	Alejandro
8171	Roche	César
7255	Rodriguez	Karime
6652	Rodriguez	Jaciel
3212	Rodriguez Martinez	Aramis
8860	Roig Perez	Mayelin
8153	Rojas	Danna
7927	Rojas Ticora	Karen
5011	Rollins	Luke
8113	Romero	Dario
3218	Rondon	Jose
8314	Rosillo Bosch	Jose
8208	Rosillo Bosch	Aimee
8343	Rosqueza Santiaguez	Odalis
6286	Ruiz Garcia	Esteban
5362	Saguier	Miguel
8824	Sall	Amadou
8534	Sanchez Alarcon	Rosana
8547	Sanchez Simon	Ratzel
5066	Santiago	Juan
8588	Sarmiento	Hanny
8234	Schoenbachler	Anthony
7319	Segovia Ruiz	José
8304	Shrestha	Diwash
8616	Silva Dominguez	Pedro
7971	Silva Pacheco	Heyser
8125	Simpson	Trena
1045	Skidmore	Howard
8822	Soler Montilla	Marielys
6071	Solis Cordero	Moises
1068	Spencer	Christopher
2588	Staebler	Thomas
8411	Sunley	Tracy

2059	Swanson	Corey
5972	Swearingin	Brian
8959	Tacsuan	John
5801	Taylor	Senica
5063	Then	jacqueline
6314	Torres Hernandez	Jose
3666	Trembóczki	Gábor
8160	Trujillo Hernández	Martha
5338	Trujillo Leon	Jose
8179	Tsueda	Christian
8158	Turbay Reyes	Liz
8197	Uribe Gurrola	Rafael
5910	urquiola	carolay
4305	Velasquez Camacho	Ofelia
7872	Velazquez	Alexis
6165	Villanueva	Yadira
6285	Villaseñor	Carlos
8489	Villatoro Herrera	Zaydi
1323	Waiters	Augustus
8410	Watts	Shaquille
8239	Weird	Marik
1022	Wright	Desmond
8902	Yancey	Corey
4340	Yuliansyah	Andrie
6340	Zamora Liévanos	Kevin

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Leica Biosystems Imaging Inc.

Physical Address: 1360 Park Center Dr

City: Vista State: CA Zip: 92081

Mailing Address (if different from physical address): 1360 Park Center Dr

City: Vista State: CA Zip: 92081

Telephone: (714) 699-0938 Website: www.leicabiosystems.com

Name of Designated Representative (DR): Brian Cox

Licensing Company Email: LBS-licensing@leicabiosystems.com DR Email: brian.cox@leicabiosystems.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: No Drugs or drug components	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A No Suppliers Sold/Dispensed/Distributed to within last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Leica Microsystems, Inc.

Corporation/Organization Name: Leica Biosystems Imaging, Inc.

Mailing Address: 1360 Park Center Dr

City: Vista State: CA Zip: 92081

Telephone: (202) 973-2585 Email: christi.eggstaff@danaher.com

Contact Person Name: James O'Reilly

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Leica Biosystems Imaging Inc.
Facility Name

Brian Cox
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/5/25
Date

Board Use Only	Date Received: 5/6/25	Amount: $1000-ck 3388

FDA

SEARCH

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search Back To Search Results

Establishment:
Leica Biosystems Imaging, Inc.
1360 Park Center Drive
Vista, CA 92081
Registration Number: 3006791373
FEI Number*: 3006791373
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
Leica Biosystems, Division Of Leica Microsystems, Inc.
21440 W. Lake Cook Road
Floor 5
Deer Park, IL US 60010
Owner/Operator Number: 10054155

Official Correspondent:
April Komplin
Leica Biosystems Imaging, Inc.
1360 Park Center Dr.
Vista, CA 92081
Phone: 1-760-5205056

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 03/17/2025
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products
Advisory Committees
Science & Research
Regulatory Information
Safety
Emergency Preparedness
International Programs
News & Events
Training and Continuing Education
Inspections/Compliance
State & Local Officials
Consumers
Industry
Health Professionals
FDA Archive
Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

Description of Operations

Leica Biosystems Imaging Inc is a medical device manufacturer and distributor of Class I and Class II medical devices without drugs or drug components. Leica Biosystems Imaging Inc's products are distributed to hospitals for use in laboratories.

FDA FEI Number:
FDA Registration: 3006791373

Manufacturer/Distributor Information:
Leica Biosystems Imaging Inc
1360 Park Center Dr., Vista, CA 92081
Contact: Brian Cox, (714) 699-0938

Leica Biosystems Imaging Inc has 169 employees working on site during normal business hours.

Leica Biosystems Imaging Inc's hours of operation are 9:00 am – 5:00 pm Monday through Friday and closed on Saturday and Sunday.

Leica Biosystems Imaging Inc's records are stored at their Vista, CA facility.

Leica Biosystems Imaging Inc's facility square footage is 36,700.

Company Information

Company Name: Leica Biosystems Imaging Inc.
Address: 1360 Park Center Dr.
City, State, Zip: Vista, CA 92081
Phone: (714) 699-0938
Website: www.leicabiosystems.com
E-mail: LBS-licensing@leicabiosystems.com

FEIN: 33-0939292
State of Formation: Delaware
Date Incorporated: 04/01/2011
File Number: 4914325

Ownership Information

Leica Biosystems Imaging Inc's Parent Company is Leica Microsystems Inc.

Parent Company Address: Ten Parkway North, Suite 300, Deerfield, IL 60015
Parent Company Phone: (202) 973-2585
Parent Company FEIN: 22-2701363

Officers

Brian Cox, Senior Director, Operations, and Product Development
Business Address: 1360 Park Center Dr., Vista, CA 92081
Business Phone: (714) 699-0938
Email: LBS-licensing@leicabiosystems.com
Ownership: 0%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LEICA BIOSYSTEMS IMAGING, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIRST DAY OF APRIL, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "LEICA BIOSYSTEMS IMAGING, INC." WAS INCORPORATED ON THE FIRST DAY OF APRIL, A.D. 2011.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charumi Patibanda-Sanchez, Secretary of State

4914325 8300

SR# 20251659819

Authentication: 203485187

Date: 04-21-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Leica Biosystems Imaging, Inc.
1360 Park Center Drive
Vista, CA 92081

LICENSE NUMBER: 47874
EXPIRATION DATE: 4/16/2025

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 7/6/2023

OSP 07 102308

State of California—Health and Human Services Agency
California Department of Public Health

Food and Drug Branch
P.O. Box 997435, MS 7602
Sacramento, CA 95899-7435
1-800 495-3232 Toll Free

LICENSE / REGISTRATION VERIFICATION REQUEST

Requestor: Complete Items 1-6 only, then forward to California Department of Public Health, Food and Drug Branch at the address above.

1. Name of Firm or Exemptee / DBA
Leica Biosystems Imaging Inc.

2. Facility Address (number, street)
1360 Park Center Dr

3. City	State	Zip Code
Vista	California	92081

4. Type of Firm
☐ Retailer ☐ Warehouse ☒ Manufacturer

5. Requestor's Name
Nichole Frame, Senior Licensing Analyst

6. Requestor's Address
[redacted]

City	State	ZIP Code	Email
Martinsburg	WV	[redacted]	nichole.frame@twolabs.com

Requestor's Mailing Address (if different or P.O. Box number)
same as above

City	State	ZIP Code

DO NOT WRITE BELOW THIS LINE – TO BE COMPLETED BY STATE AGENCY

License Type	License Number	Date Issued	Expiration Date
Medical Device	47874	04/16/2007	04/16/2027

License / Registration Status:

☑ **Valid** ☐ **Suspended/Revoked** ☐ **Surrendered** ☐ **Expired**
☐ **No record of firm / individual** ☐ **Application received / license pending**

Official Signature/Title: Drug & Medical Device Safety Analyst Date: 04/25/2025
Emily Chu

CDPH 8707 (10/2024)

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Leica Biosystems Imaging, Inc.
1360 Park Center Drive
Vista
California
92081
USA

Facility ID Number: F000262

Holds Certificate No: **MDSAP 689425**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and development, manufacture, distribution, installation, and servicing of in vitro diagnostic digital image capture devices and digital image viewing, management and analysis software for use in clinical pathology as an aid to cancer diagnosis.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-03-28 Effective Date: 2022-03-28 Expiry Date: 2025-03-27

bsi.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 11/15/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Aon Risk Services Central, Inc. Philadelphia PA Office 100 North 18th Street 16th Floor Philadelphia PA 19103 USA	CONTACT NAME: PHONE (A/C. No. Ext): (866) 283-7122 FAX (A/C. No.): (800) 363-0105 E-MAIL ADDRESS:
INSURED LEICA BIOSYSTEMS IMAGING, INC. 1360 PARK CENTER DRIVE VISTA CA 92081 USA	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: ACE American Insurance Company — 22667 INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** 570109430834 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			HDOG47311962	07/01/2024	10/15/2025	EACH OCCURRENCE	$2,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$2,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$5,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$5,000,000
	OTHER:							
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / HIRED AUTOS ONLY / SCHEDULED AUTOS / NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	
	DED [ ] RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE [ ] OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A						E.L. EACH ACCIDENT	
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	
							E.L. DISEASE-POLICY LIMIT	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance. RE: 1360 Park Center Dr., Vista, CA 92081.

CERTIFICATE HOLDER

Leica Biosystems Imaging Inc.
1360 Park Center Drive
Vista CA 92081 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570109430834

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 019095614

Application/License No. _____

LEICA BIOSYSTEMS IMAGING INC., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
1360 Park Center Drive Vista, CA 92081, as
(Address of Applicant/Principal)
PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY, a
(Surety Company)
corporation organized under the laws of the state of MA
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
175 Berkeley Street Boston, MA 02116 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 5, 2024.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8212360-019022

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Annmarie Breene, Patrick Breene, Dana Donahue, Patricia Dorsaneo, Pedro Gonzalez, Jr., Cathy H. Ho, Wayne G. McVaugh, Sara Owens, Patricia A. Rambo, Lori S. Shelton, Kimberly G. Sherrod, Marisa Thielen, Joanne C. Wagner, Babette Ward

all of the city of Philadelphia state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 30th day of August, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 30th day of August, 2024 before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 5th day of November, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIO WAIC Multi Co 02/24

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2023

Assets		Liabilities	
Cash and Bank Deposits	$1,850,245,073.00	Unearned Premiums	$10,298,863,305.00
*Bonds – U.S Government	$3,859,565,383.00	Reserve for Claims and Claims Expense	$28,848,537,243.00
*Other Bonds	$21,048,805,773.00	Funds Held Under Reinsurance Treaties	$360,714,151.00
*Stocks	$19,937,271,802.00	Reserve for Dividends to Policyholders	$1,310,198.00
Real Estate	$122,228,711.00	Additional Statutory Reserve	$296,126,000.00
Agents' Balances or Uncollected Premiums	$8,208,660,427.00	Reserve for Commissions, Taxes and Other Liabilities	$7,622,413,466.63
Accrued Interest and Rents	$186,906,667.00	**Total**	**$47,428,064,363.63**
Other Admitted Assets	$15,677,869,683.63	Special Surplus Funds	$209,508,757.00
Total Admitted Assets	**$70,891,553,519.63**	Capital Stock	$10,000,075.00
		Paid in Surplus	$13,834,867,488.00
		Unassigned Surplus	$9,409,112,836.00
		Surplus to Policyholders	$23,463,489,156.00
		Total Liabilities and Surplus	**$70,891,553,519.63**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2023, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2024.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of November, 20 24.

APPLICANT/PRINCIPAL
LEICA BIOSYSTEMS IMAGING INC.

Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sara Owens, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Dana Donahue

Witness Trisha Dorsaneo

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Leica Biosystems Imaging Inc. MDEG License # (if applicable): New

Physical Address: 1360 Park Center Dr

City: Vista State: CA Zip: 92081

Mailing Address (if different from physical address): 1360 Park Center Dr

City: Vista State: CA Zip: 92081

Telephone: (714) 699-0938 Website: www.leicabiosystems.com

Licensing Company Email: LBS-licensing@leicabiosystems.com

Section 2: Personal Information

First: Brian Middle: Patrick Last: Cox

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 1360 Park Center Dr

City: Vista State: CA Zip: 92081

Telephone: (714) 699-0938 Email: LBS-licensing@leicabiosystems.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California-San Diego		/16 - /16	
Address	**City**	**State**	**Zip**
9500 Gilman Dr	La Jolla	CA	92093
Diploma/Degree obtained, if any			
MBA			
School Name		**From - To (MM/YY – MM/YY)**	
University of California-Los Angeles		/14 - /14	
Address	**City**	**State**	**Zip**
405 Hilgard Avenue	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
MSc Engineering Management			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/16/2011 Current	[redacted]	Encinitas	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Leica Biosystems Imaging Inc			From - To (MM/YY – MM/YY): 11/22 - present	
Business Address: 1360 Park Center Dr	City: CA		State: Vista	Zip: 92081
Phone: (714) 699-0938	Title: Sr Dir., Product Dev. & Ops. - Vista Site Leader		Number of Employed Hours: 40/week	
Description of Duties: see attached resume				

Business Name: Leica Biosystems Imaging Inc			From - To (MM/YY – MM/YY): 06/21-11/22	
Business Address: 1360 Park Center Dr	City: Vista		State: CA	Zip: 92081
Phone: (714) 699-0938	Title: Global Marketing Growth Leader		Number of Employed Hours: 40/week	
Description of Duties: see attached resume				

Business Name: Leica Biosystems Imaging Inc			From - To (MM/YY – MM/YY): 03/19-06/21	
Business Address: 1360 Park Center Dr	City: Vista		State: CA	Zip: 92081
Phone: (714) 699-0938	Title: DBS Leader - Quality, Regulatory, and Clinical Affairs		Number of Employed Hours: 40/week	
Description of Duties: see attached resume				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		x
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		x

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # N/A **. Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted) Date

I, Brian Cox, **certify that as the MDEG Administrator for**

Leica Biosystems Imaging Inc.,

that I (initial that you have read and meet the following requirements):

1. BPC Have a high school diploma or its equivalent;
2. BPC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. BPC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. BPC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian Cox
Print Name (First, Last)

B-P Cx
Original Signature (electronic, copies or stamps not accepted)

3/5/25
Date

Board Use Only	Date Received:

Time Type	Full time
FTE	100.00%
Location	USA - Vista - Leica Biosystems Imaging, Inc.
Hire Date	07/05/2011
Original Hire Date	07/05/2011
Continuous Service Date	07/05/2011
Length of Service	13 year(s), 4 month(s), 16 day(s)
Time in Position	3 year(s), 5 month(s), 14 day(s)
Time in Job Profile	2 year(s), 0 month(s), 20 day(s)

Contact Information - Public

Phone	[redacted]
Email	Brian.Cox@leicabiosystems.com

Work Address

1360 Park Center Drive
Vista, CA 92081
United States of America

Career

Job History

Job History

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Senior Director, Product Development and Operations, Vista Site Leader	Leica Biosystems	11/21/2022		Overall site responsibility for Leica Biosystems in Vista, CA including Operations, R&D, Program Management, Field Support, and Facilities. Through my tenure in this role, we have increased production output by double digits while keeping direct labor flat. In this same time period, product failure rates in the field have reduced by over 50%. On the R&D front, our New Product Development velocity has more than doubled with the introduction of our new Innovation Engine and robust PPG Standard Work.		



Senior Director, Product Development & Operations, Vista Site Leader

Phone Number [redacted]

Email Address Brian.Cox@leicabiosystems.com

Location USA - Vista - Leica Biosystems Imaging, Inc.



Naveen Chandra
Manager

Job

Job Details

Job Details

Associate ID	194892
Supervisory Organization	Danaher CEO (Rainer Blair) >> Leica Biosystems - Business Unit/General Management - Executive (Naveen Chandra)
Job	Management
Business Title	Senior Director, Product Development & Operations, Vista Site Leader
Job Profile	M4 - Business Unit/General Management
Job Family	Management > Business Unit/General Management
Associate Type	Regular
Management Level	Management - M4

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Global Marketing Growth Leader	Leica Biosystems	06/14/2021	11/21/2022	Own and drive the continued optimization and integration of the various commercialization growth processes and tools (MMP, LEx, CI) that enable LBS to achieve its incremental Revenue Achievement targets. Focusing on innovation, strengthening Leica Biosystems' vision through strong cross-functional and customer-centric standard work within the commercialization process.		
DBS Leader - Quality, Regulatory, and Clinical Affairs	Leica Biosystems	03/25/2019	06/04/2021	Global role responsible for leading DBS and Project Management within Leica Biosystems' quality, regulatory, and clinical (QRAC) organization. Architecting and delivering against a 3 year QRAC strategic plan including global quality system simplification, EU In Vitro Diagnostic Regulation (IVDR) compliance, and DBS integration and execution with the QRAC space.		
Operations Manager	Radiometer / SenDx Medical	11/01/2016	03/22/2019	Responsible for all manufacturing operations at Radiometer Carlsbad / SenDx Medical, a team of 125 associates. Direct management of 4 value stream managers, 1 process engineering manager, and 1 facilities staff to deliver $60MUSD annually of blood gas analyzer instruments and consumables (thick film sensors, solution packs, and service parts) supported through safety initiatives (4E + Kamishibai), internal and external quality improvements (PSP + VM/DM + FMEA), increased OTD (PSP + SW + Capacity Modelling), inventory reduction and control (Kanban + 5S), and increased productivity (SW + SMED).		

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Value Stream Manager	Radiometer / SenDx Medical	11/01/2015	11/01/2016	Responsible for managing a team of 25 direct labor associates, 1 process engineer, 1 value stream buyer, and 1 engineering technician in the thick film manufacturing Substrate Value Stream. Responsible for meeting safety, quality, delivery, inventory, and productivity goals. During this 12 month assignment, yields increased from 79% to 82% for our N&W production lines and from 78% to 83% for our SC80 production line. Enabled through a 35% productivity increase, our value stream was able to fully meet customer demand and build critical safety stock for the first time in company history. These improvements were accomplished without adding headcount or purchasing capital equipment, but through DBS deployment and effective talent management.		

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Senior Engineering Project Manager	Radiometer / SenDx Medical	03/01/2013	11/01/2015	Responsible for managing all aspects of new product development, specifically for the ABL9, a new blood gas analyzer platform targeting emerging markets. Successful management from TG2 through TG4 resulted in a project release that was on time and under budget, meeting all product design and cost requirements. The ABL9 is now released for global sales and meeting all field quality and reliability targets. Regarding reliability, I presented a paper at the Danaher Conference on Innovation in 2014 on the implementation of the DSB tool Design for Reliability on the ABL9 project. This role required the management of project schedules, design reviews, NPD metrics, and budgets. This required a hands-on working knowledge of IEC 61010, IEC 61326, IEC 62304, ISO 14971, ISO 13485, CE marking, and CFDA (China) regulations and processes. Coordinate and align project deliverables with Marketing, Engineering, Software, Manufacturing, Quality, and Regulatory Affairs. Actively involved in global launch and marketing activities. Broad experience with lean management principled, tiered daily management, failure mode effects analysis (FMEA), risk management, speed design review, visual management, reliability engineering, user experience (UX), voice of customer, market needs and wants analysis, and usability engineering.		

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Senior Electrical Engineer	Radiometer / SenDx Medical	07/01/2011	06/01/2013	Electronics design for ARM processors, high-impedance sensor measurement circuits, fluidics control, power and battery management, digital and wireless communication systems. Responsible for validation, verification, new product introduction (NPI), and compliance activities for FDA, CFDA, CE, and IVD. FMEA Master Black Belt and Certified Trainer.		
Electrical Engineer	AutoGenomics, Inc.	08/01/2009	07/01/2011	Electrical engineer and circuit board designer for FDA 510(k) cleared molecular diagnostic instrument. Electronics designs for microcontrollers, ADCs, DACs, power electronics, displays, camera optics, liquid level sensing, stepper / servo motors, optical QC for microarray manufacturing, LED illumination for imaging, optical sensing, fluidics, and precision temperature sensors.		
Systems Engineer Researcher	University of California Los Angeles	06/01/2008	07/01/2009	Electrical engineer designer for medical device and imaging research. Projects included flexible ultrasound imaging, wireless haptic feedback systems for lower-limb prosthesis, and wireless patient identification wristbands.		

Achievements

Achievements

Title	Type	Date	Edit Achievement	Remove Achievement
2014 Danaher Conference on Innovation (DCI) - Presenter	Accomplishment	2014		
Publication	Accomplishment	2011		
Publication	Accomplishment	2010		
Publication	Accomplishment	2010		
Publication	Accomplishment	2009		
Publication	Accomplishment	2009		
Publication	Accomplishment	2009		
Publication	Accomplishment	2009		

Certifications

Certifications

Certification	Issuer	Issued Date	Expiration Date	Edit Certification	Remove Certification
Certificate in Systems Engineering - University of California, Los Angeles	University of California, Los Angeles	06/14/2014			
Fund Transactional Process Improvement (TPI) CP - 1. DBSO - Fundamental	1. DBSO - Fundamental	04/12/2021			
Lean Failure Mode Effects Analysis ACP - 3. DBSO - Lean	3. DBSO - Lean	09/12/2019			

Education

Education

School	Degree	Field of Study	Year Degree Received	Last Year Attended	Edit Education	Remove Education
University of California-San Diego	Master of Business Administration (MBA)	Business Administration/Management	2016	2016		
University of California-Los Angeles	Master of Science (MSc)	Engineering Management	2014	2014		
University of California-Los Angeles	Bachelor of Science (BSc)	Electrical Engineering	2009	2009		

Training

Training

Training	Training Type	Completed On	Edit Training	Remove Training
Standard Work	DBS Classroom Training			
FMEA	DBS Classroom Training			
SMED	DBS Classroom Training			
Problem Solving Process	DBS Classroom Training			
Value Stream Mapping	DBS Classroom Training			
SDR	DBS Classroom Training			
3P	DBS Classroom Training			
Design for Reliability	DBS Classroom Training			
Dynamic Kanban	DBS Classroom Training			
TFTI	DBS Classroom Training			
5S	DBS Classroom Training			
Leadership Essentials	DBS Classroom Training			
Situational Leadership	DBS Classroom Training			
Crucial Conversations	DBS Classroom Training			
MLP 1	DBS Classroom Training			
MLP 2	DBS Classroom Training			
Lean Conversion	DBS Classroom Training			
Visual Daily Management (VDM)	DBS Classroom Training			
Executive Champion Orientation	DBS Classroom Training			
Visual Project Management (VPM)	DBS Classroom Training			

Training	Training Type	Completed On	Edit Training	Remove Training
Transactional Process Improvement (TPI)	DBS Classroom Training			

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Leica Biosystems Imaging Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 1360 Park Center Dr

City: Vista State: CA Zip: 92081

Mailing Address (if different from physical address): 1360 Park Center Dr

City: Vista State: CA Zip: 92081

Telephone: (714) 699-0938 Website: www.leicabiosystems.com

Licensing Company Email: LBS-licensing@leicabiosystems.com

Section 2: Personal Information

First: Brian Middle: Patrick Last: Cox

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 1360 Park Center Dr

City: Vista State: CA Zip: 92081

Telephone: (760) 953-0980 Email: brian.cox@leicabiosystems.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California-San Diego		/16 -	/16
Address	**City**	**State**	**Zip**
9500 Gilman Dr	La Jolla	CA	92093
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
University of California-Los Angeles		/14 -	/14
Address	**City**	**State**	**Zip**
405 Hilgard Avenue	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
MSc Engineering Management			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/11 - Present	[redacted]	Encinitas	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Leica Biosystems Imaging Inc			11/22 - present
Business Address	**City**	**State**	**Zip**
1360 Park Center Dr	Vista	CA	92081
Phone	**Title**	**Number of Employed Hours**	
(714) 699-0938	Sr Dir., Product Dev. & Ops. - Vista Site Leader	40/week	
Description of Duties			
see attached resume			

Business Name			From - To (MM/YY – MM/YY)
Leica Biosystems Imaging Inc			06/21-11/22
Business Address	**City**	**State**	**Zip**
1360 Park Center Dr	Vista	CA	92081
Phone	**Title**	**Number of Employed Hours**	
(714) 699-0938	Global Marketing Growth Leader	40/week	
Description of Duties			
see attached resume			

Business Name			From - To (MM/YY – MM/YY)
Leica Biosystems Imaging Inc			03/19-06/21
Business Address	**City**	**State**	**Zip**
1360 Park Center Dr	Vista	CA	92081
Phone	**Title**	**Number of Employed Hours**	
(714) 699-0938	DBS Leader - Quality, Regulatory, and Clinical Affairs	40/week	
Description of Duties			
see attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		x
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Brian Cox, **certify that as the designated representative for**

Leica Biosystems Imaging Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BPC I am at least 21 years of age;
3. BPC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BPC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BPC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BPC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BPC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brian Cox

Print Name (First, Last)

BPC

Original Signature (electronic, copies or stamps not accepted)

3/5/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian Cox

Print Name (First, Last)

BPC

Original Signature (electronic, copies or stamps not accepted)

3/5/25

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, BRIAN COX, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

BPC

Original Signature

3/5/25

Date

Subscribed and Sworn to before me this _____ day of _____.

_____

Notary Public Signature

See Attachment

(Seal)

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of San Diego

Subscribed and sworn to (or affirmed) before me on

this 05 (Date) day of March (Month), 2025 (Year), by

(1) Brian Cox

(and (2) _____).

Name(s) of Signer(s)



proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____

Signature of Notary Public

Place Notary Seal and/or Stamp Above

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Nevada- Application for License

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

©2019 National Notary Association

Leica Biosystems Imaging Inc - Employee List
Last, First Name
Crandall,Victoria
Banks,Johnathan
Rybka,David
Kishi,Christine
Symington,Ila
Zou,Yunlu
Salinthone,Vundith
Thomson,Carl B
Brailko,Nickolay
Arias,Narciso C
Nguyen,Philip
Decottle,Karla D
Boarman,Christopher C
Thede,Karen K
Ramirez,Lucina E
Pokorna,Weilan
De La Rosa,Liliana
Snow,Teri
Aiello-Hebert,Amber L
MOWEN,SEAN
Fenstermaker,Craig
Bonilla,Nazar
Camaratta,Chris
Bonafede,Linda H
Frushone,Kevin
Lopez,Guillermo E
Knepper,Erin L
Smith,James J
Malone,William
Thompson,Aubrey
Cruz,Ronald J
Salazar,Miguel A
Lopez,Yedith V
Chatterjee,Uddipan
Dufour,Alissa
Thai,Tu T
Currier,Jesse
Wicka,Kaylee
Sheet,Nancy
La,Danny
Garvey,Andrew S
Hirsch,Jessica

Mohammad,Nora A
Miller,Derek
Ballesteros,Frank
Barrios,Justin
Grosky,Alyssa
Chiweshe,Joseph
Harrison,Steven F
Vazquez,Juana E.
Khorramshahi,Payam
Wang,Ji
Arshad,Sheheryar Ali
Komplin,April
Melton,Tamatha
Miller,Mariah
Sayed,Daniel
Desire,Jean R
May,Jason
O'Glasser,Elliot W
Ajibade,Ade
Shah,Ashish K
Silberman,Georgia
Usrey,Thomas
Younger,James A
Harrel,Paige
Zhou,Xiaozhi
Eslami Manoochehri,Hafez
Brown,Bryce
Foreman,Mary
Lewis,Jenny V
Brewer,Terrance A
Ainge,Yuki
LEE,HSIANG
Saraga,Simon
Clardy,William L
Baty,Andrea F
MACHARLA,Venkata Sai Mahi Charan
Choksi,Lopa
Dikonda,Tanuj
Pong,Ping
Chapman,Kenneth D
Evensen,Andrea L
Carter,Ryan
Slocomb,Jason
Perez-Fernandez,Julio-Gustavo

Reif,Melissa L
Jabbour,Michael
Sanchez,Andrew
Hart,Thaddeus
Ring,Mike
Leitner,Christoph
Keeney,Alice
Ni,Duojiao
Burnett,Morgan
Hickson,Mark
Nwankwo,Laurrette O
Reyes,Edgar A
Elfenbein,Jason
Newbould,Shanon N
Duberow,Eilene
Dunn,Ronald D
Lagrimas,Norraine
Cox,Brian P
Cruz Torres,Mercedes
Henshaw,Rebecca
Doblack,Joseph
Padilla,Monica
TOFT,CARL
Mohammed,Iram
Chandra,Naveen
Dunn,Ted
Susana,Fnu
Wilson,Simone
Nunes Goncalves,Renato
Kanthapanit,Chanitnan
Schmidt,Micah
Gracey,Ryan M
Conn,Bryan L
Krach,Emily
Patel,Anish
Deshmane,Mrudula
Ferman,Karla
Loving,Latoya
Pickering,Bruce D
Uematsu,Jessica
Truscelli,Gianni
Grady,Richard
MILLER,SANDRA
Biello,Antonio A

Dussault,Jessica
Le Gree,Dominique
Jeffers,Michael
Bhogal,Aditi
Arora,Karan
Arole,Hareesh
LaPel,Donald
Murillo Gonzalez,Lizbeth
Daly,Tiffany R
Smart,Kimberly M
Siah,Shawn
Chen,Philip
Baldwin,Destoni
Vicente Navarro,Maria del Carmen
Li,Yida
Dey,William
Kozachenko,Yuliya
Suarez,Sarai
Bricke,Sokleen
Dela Rosa,Nalani L
Chen,Tiffany
Davydenko,Olga
Crothers,Melissa R
Towe,Jason A
Fast,Alexander
Cummings,Hannah
Slemons,Danielle
Hubbard,William
Brown,Shikeya
Martinez,Alejandro
Lampley,Joseph
Ma,Jing
Williams,Deonte A
Garrett,Lisa N
Andrade,Joseph Allem
Brigham,Magali
Robinson,Brittany
Lanie,Jason S
Soriano,Edgar
Noboa,Emma
Baumann,Jessica
Sanchez,Asiria
Rees,Kaitlyn
Mooney,Brendan J

Klee,Martin
IBRAHIM,YASEMIN N
Miller,Shawn P
Schwan,Lars Josef
Kumar,Theenash
Lui,Simon K
Connolly,Zoe

Barbara D. Richardson, Commissioner of Insurance

Non-Resident Producer

Casualty, Property

SARA P OWENS

100 N 18TH ST FL 16
PHILADELPHIA, PA 19103-2707

is authorized to transact business as described above

License No: 3447025 Issue Date: 06-12-2019 Expiration Date: 07-01-2025

Generated by Sircon 269669374

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

SARA P OWENS
100 N 18TH ST FL 16, PHILADELPHIA, PA 19103-2707

LICENSE NUMBER: 3447025

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Non-Resident Producer
Casualty, Property

Issue Date: 06-12-2019 Expiration Date: 07-01-2025

Generated by Sircon 269669374



Senior Director, Product Development & Operations, Vista Site Leader

Phone Number [redacted]

Email Address Brian.Cox@leicabiosystems.com

Location USA - Vista - Leica Biosystems Imaging, Inc.



Naveen Chandra
Manager

Job

Job Details

Job Details

Associate ID	194892
Supervisory Organization	Danaher CEO (Rainer Blair) >> Leica Biosystems - Business Unit/General Management - Executive (Naveen Chandra)
Job	Management
Business Title	Senior Director, Product Development & Operations, Vista Site Leader
Job Profile	M4 - Business Unit/General Management
Job Family	Management > Business Unit/General Management
Associate Type	Regular
Management Level	Management - M4

Time Type	Full time
FTE	100.00%
Location	USA - Vista - Leica Biosystems Imaging, Inc.
Hire Date	07/05/2011
Original Hire Date	07/05/2011
Continuous Service Date	07/05/2011
Length of Service	13 year(s), 4 month(s), 16 day(s)
Time in Position	3 year(s), 5 month(s), 14 day(s)
Time in Job Profile	2 year(s), 0 month(s), 20 day(s)

Contact Information - Public

Phone	[redacted]
Email	Brian.Cox@leicabiosystems.com

Work Address

1360 Park Center Drive
Vista, CA 92081
United States of America

Career

Job History

Job History

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Senior Director, Product Development and Operations, Vista Site Leader	Leica Biosystems	11/21/2022		Overall site responsibility for Leica Biosystems in Vista, CA including Operations, R&D, Program Management, Field Support, and Facilities. Through my tenure in this role, we have increased production output by double digits while keeping direct labor flat. In this same time period, product failure rates in the field have reduced by over 50%. On the R&D front, our New Product Development velocity has more than doubled with the introduction of our new Innovation Engine and robust PPG Standard Work.		

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Global Marketing Growth Leader	Leica Biosystems	06/14/2021	11/21/2022	Own and drive the continued optimization and integration of the various commercialization growth processes and tools (MMP, LEx, CI) that enable LBS to achieve its incremental Revenue Achievement targets. Focusing on innovation, strengthening Leica Biosystems' vision through strong cross-functional and customer-centric standard work within the commercialization process.		
DBS Leader - Quality, Regulatory, and Clinical Affairs	Leica Biosystems	03/25/2019	06/04/2021	Global role responsible for leading DBS and Project Management within Leica Biosystems' quality, regulatory, and clinical (QRAC) organization. Architecting and delivering against a 3 year QRAC strategic plan including global quality system simplification, EU In Vitro Diagnostic Regulation (IVDR) compliance, and DBS integration and execution with the QRAC space.		
Operations Manager	Radiometer / SenDx Medical	11/01/2016	03/22/2019	Responsible for all manufacturing operations at Radiometer Carlsbad / SenDx Medical, a team of 125 associates. Direct management of 4 value stream managers, 1 process engineering manager, and 1 facilities staff to deliver $60MUSD annually of blood gas analyzer instruments and consumables (thick film sensors, solution packs, and service parts) supported through safety initiatives (4E + Kamishibai), internal and external quality improvements (PSP + VM/DM + FMEA), increased OTD (PSP + SW + Capacity Modelling), inventory reduction and control (Kanban + 5S), and increased productivity (SW + SMED).		

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Value Stream Manager	Radiometer / SenDx Medical	11/01/2015	11/01/2016	Responsible for managing a team of 25 direct labor associates, 1 process engineer, 1 value stream buyer, and 1 engineering technician in the thick film manufacturing Substrate Value Stream. Responsible for meeting safety, quality, delivery, inventory, and productivity goals. During this 12 month assignment, yields increased from 79% to 82% for our N&W production lines and from 78% to 83% for our SC80 production line. Enabled through a 35% productivity increase, our value stream was able to fully meet customer demand and build critical safety stock for the first time in company history. These improvements were accomplished without adding headcount or purchasing capital equipment, but through DBS deployment and effective talent management.		

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Senior Engineering Project Manager	Radiometer / SenDx Medical	03/01/2013	11/01/2015	Responsible for managing all aspects of new product development, specifically for the ABL9, a new blood gas analyzer platform targeting emerging markets. Successful management from TG2 through TG4 resulted in a project release that was on time and under budget, meeting all product design and cost requirements. The ABL9 is now released for global sales and meeting all field quality and reliability targets. Regarding reliability, I presented a paper at the Danaher Conference on Innovation in 2014 on the implementation of the DSB tool Design for Reliability on the ABL9 project. This role required the management of project schedules, design reviews, NPD metrics, and budgets. This required a hands-on working knowledge of IEC 61010, IEC 61326, IEC 62304, ISO 14971, ISO 13485, CE marking, and CFDA (China) regulations and processes. Coordinate and align project deliverables with Marketing, Engineering, Software, Manufacturing, Quality, and Regulatory Affairs. Actively involved in global launch and marketing activities. Broad experience with lean management principled, tiered daily management, failure mode effects analysis (FMEA), risk management, speed design review, visual management, reliability engineering, user experience (UX), voice of customer, market needs and wants analysis, and usability engineering.		

Job Title	Company	Start Date	End Date	Responsibilities and Achievements	Edit Job History	Remove Job History
Senior Electrical Engineer	Radiometer / SenDx Medical	07/01/2011	06/01/2013	Electronics design for ARM processors, high-impedance sensor measurement circuits, fluidics control, power and battery management, digital and wireless communication systems. Responsible for validation, verification, new product introduction (NPI), and compliance activities for FDA, CFDA, CE, and IVD. FMEA Master Black Belt and Certified Trainer.		
Electrical Engineer	AutoGenomics, Inc.	08/01/2009	07/01/2011	Electrical engineer and circuit board designer for FDA 510(k) cleared molecular diagnostic instrument. Electronics designs for microcontrollers, ADCs, DACs, power electronics, displays, camera optics, liquid level sensing, stepper / servo motors, optical QC for microarray manufacturing, LED illumination for imaging, optical sensing, fluidics, and precision temperature sensors.		
Systems Engineer Researcher	University of California Los Angeles	06/01/2008	07/01/2009	Electrical engineer designer for medical device and imaging research. Projects included flexible ultrasound imaging, wireless haptic feedback systems for lower-limb prosthesis, and wireless patient identification wristbands.		

Achievements

Achievements

Title	Type	Date	Edit Achievement	Remove Achievement
2014 Danaher Conference on Innovation (DCI) - Presenter	Accomplishment	2014		
Publication	Accomplishment	2011		
Publication	Accomplishment	2010		
Publication	Accomplishment	2010		
Publication	Accomplishment	2009		
Publication	Accomplishment	2009		
Publication	Accomplishment	2009		
Publication	Accomplishment	2009		

Certifications

Certifications

Certification	Issuer	Issued Date	Expiration Date	Edit Certification	Remove Certification
Certificate in Systems Engineering - University of California, Los Angeles	University of California, Los Angeles	06/14/2014			
Fund Transactional Process Improvement (TPI) CP - 1. DBSO - Fundamental	1. DBSO - Fundamental	04/12/2021			
Lean Failure Mode Effects Analysis ACP - 3. DBSO - Lean	3. DBSO - Lean	09/12/2019			

Education

Education

School	Degree	Field of Study	Year Degree Received	Last Year Attended	Edit Education	Remove Education
University of California-San Diego	Master of Business Administration (MBA)	Business Administration/Management	2016	2016		
University of California-Los Angeles	Master of Science (MSc)	Engineering Management	2014	2014		
University of California-Los Angeles	Bachelor of Science (BSc)	Electrical Engineering	2009	2009		

Training

Training

Training	Training Type	Completed On	Edit Training	Remove Training
Standard Work	DBS Classroom Training			
FMEA	DBS Classroom Training			
SMED	DBS Classroom Training			
Problem Solving Process	DBS Classroom Training			
Value Stream Mapping	DBS Classroom Training			
SDR	DBS Classroom Training			
3P	DBS Classroom Training			
Design for Reliability	DBS Classroom Training			
Dynamic Kanban	DBS Classroom Training			
TFTI	DBS Classroom Training			
5S	DBS Classroom Training			
Leadership Essentials	DBS Classroom Training			
Situational Leadership	DBS Classroom Training			
Crucial Conversations	DBS Classroom Training			
MLP 1	DBS Classroom Training			
MLP 2	DBS Classroom Training			
Lean Conversion	DBS Classroom Training			
Visual Daily Management (VDM)	DBS Classroom Training			
Executive Champion Orientation	DBS Classroom Training			
Visual Project Management (VPM)	DBS Classroom Training			

Training	Training Type	Completed On	Edit Training	Remove Training
Transactional Process Improvement (TPI)	DBS Classroom Training			

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Osteal Therapeutics, Inc.

Physical Address: 100 Cummings Center, Unit 324-D

City: Beverly State: MA Zip: 01915

Mailing Address (if different from physical address): 4835 Lyndon B Johnson Fwy Ste 635

City: Dallas State: TX Zip: 75244

Telephone: (317) 997-2930 Website: https://www.ostealtx.com/

Name of Designated Representative (DR): Joseph Fischer

Licensing Company Email: jfischer@ostealtx.com DR Email: jfischer@ostealtx.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors		☒ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): See Attached

Corporation/Organization Name: Osteal Therapeutics, Inc.

Mailing Address: 4835 Lyndon B Johnson Fwy Ste 635

City: Dallas State: TX Zip: 75244

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Osteal Therapeutics, Inc.
Facility Name

David Thompson
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2/25/2025
Date

Board Use Only	Date Received: 4/8/25	Amount: $1000 ck 3576

Senneth Greene

From: Senneth.Greene@twolabs.com
Subject: FW: Labeler Code Request Approved

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Tuesday, November 29, 2022 3:18 PM
To: Kathy Burke <kburke@ostealtx.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 29-NOV-2022
Labeler DUNS: 081368831
Labeler Name: Osteal Therapeutics, Inc.
Labeler Code Assigned: 83138

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

OSTEAL
THERAPEUTICS

Company & Ownership Information

Company Name: Osteal Therapeutics, Inc.
Address: 100 Cummings Center, Unit 324-D
City, State, Zip: Beverly, MA 01915
Phone: (317) 997-2930
Website: https://www.ostealtx.com/
E-mail: jfischer@ostealtx.com

FEIN: 90-0939060
State of Formation: DE
Date Incorporated: 07/28/2014
File Number: 5576066

Osteal Therapeutics is a privately held corporation, 100% owned by 125+ multiple individuals/legal entities (shareholders)

Officers

David Thompson, Chairman & CEO
Business Address: 4835 LBJ Fwy, Ste 635 - Dallas, TX 75244
Business Phone: (469) 809-2630
Email: dthompson@ostealtx.com

OSTEAL
THERAPEUTICS

Description of Operations

Osteal Therapeutics, Inc. is a Virtual Manufacturer. Osteal Therapeutics, Inc.'s products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors by their Third-Party Logistics Provider, J KNIPPER AND COMPANY INC , who is licensed to ship pharmaceutical products into your state.

Labeler Code: 83138

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

Hospira, Inc. (Pfizer)
1776 North Centennial Drive
McPherson, KS 67460
FEI #: 1925262

Hospira, Inc. (Pfizer)
Highway 301 North
Rocky Mount, NC 27801
FEI #: 1021343

Hainan Poly Pharm. Co., LTD
Guilinyang Economic Dev Zone
Haikou, Hainan, 571127, China
FEI #: 3005115952

At no time does Osteal's CMOs own the product, contract with Osteal Therapeutics, Inc.'s customers, invoice, nor sell a Osteal Therapeutics, Inc. product. Osteal Therapeutics, Inc.'s products are not Controlled Substances; accordingly, Osteal does not hold DEA Registration.

Third Party Logistic Information:
For distribution into the commercial supply channels, J KNIPPER AND COMPANY INC acts as Osteal Therapeutics, Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of Osteal Therapeutics, Inc.'s product-throughout the United States. J KNIPPER AND COMPANY INC's address is:

J KNIPPER AND COMPANY INC
1250 Patrol Road
Charlestown, IN 08701

Additional Facility Information:

- Osteal Therapeutics, Inc. has 1 employee working on site during normal business hours
- Osteal Therapeutics, Inc.'s hours of operation are 9:00 am – 5:00pm Monday through Friday
- Osteal Therapeutics, Inc.'s records are stored at Osteal Corporate HQ in Dallas, TX
- Osteal Therapeutics, Inc.'s facility is 300 sq ft

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OSTEAL THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF MAY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5576066 8300

5R# 20252131696

Authentication: 203645283

Date: 05-08-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Osteal Therapeutics Inc
100 Cummings Center, Unit 324-D
Beverly, MA 01915

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200110

Type: Virtual Manufacturer

Issue Date: 12/26/2024

Expiration Date: 12/26/2025

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

* No Devices *

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 5/20/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
IMA, Inc. - Salt Lake City
95 S State Street
Suite 1300
Salt Lake City UT 84111

License#: PC-1210733

CONTACT NAME: IMA Wichita Team
PHONE (A/C, No, Ext): 316-267-9221 **FAX (A/C, No):**
E-MAIL ADDRESS: certs@imacorp.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Federal Insurance Company	20281
INSURER B : Continental Casualty Company	20443
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Osteal Therapeutics, Inc.
4835 LBJ FWY Ste 520
Dallas TX 75244

OSTETHE-01

COVERAGES **CERTIFICATE NUMBER:** 1191311865 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY X CLAIMS-MADE ☐ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY ☐ PRO-JECT ☐ LOC OTHER:			36054745 WUC	3/27/2025	3/27/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ Excluded $
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY ☐ SCHEDULED AUTOS X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY			73606939	3/27/2025	3/27/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ $ $ $
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB ☐ CLAIMS-MADE DED X RETENTION $ 0			78188312	3/27/2025	3/27/2026	EACH OCCURRENCE AGGREGATE $	$ 4,000,000 $ 4,000,000 $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N ☐ N/A If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE ☐ OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $
B	Products Liability			ADT6080562120	3/27/2025	3/27/2026	Each Claim Aggregate Deductible	$10,000,000 $10,000,000 $50,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
RE: 100 CUMMINGS CENTER, SUITE 324D, BEVERLY, MA 01915.

CERTIFICATE HOLDER

For Information Only

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Brenda Vinsant

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Docusign Envelope ID: E338A73D-62D9-4455-AC21-6A5412A8D6AD

Figure 4.1: Typical Change Rider

CHANGE RIDER

To be attached to and form a part of Bond No. 34BSBJG6081

in the amount of $ 25,000.00 issued by Hartford Fire Insurance Company

on behalf of Osteal Therapeutics

in favor of Nevada State Board of Pharmacy

It is understood and agreed that the bond described above is hereby modified so as to effective 06/25/2025 add location 100 Cummings Center, Ste 324D, Beverly, MA 01915

It is further expressly understood and agreed that the aggregate liability of the penal sum under said bond to the obligee herein mentioned shall not exceed the amount stated above.

Nothing herein contained shall be held to vary, alter, waive, or extend any of the terms, agreements, conditions or limitations of the above-mentioned bond, other than as above stated.

Signed sealed and dated this 25th day of June, 2025.

HARTFORD FIRE INSURANCE CO. INCORPORATED 1810

DocuSigned by:

By: _____
David Thompson President & CEO

By: _____
Emily Olan Attorney-in-Fact

Surety Phone No. 888-656-0817

WC-4173/EP 2/&95

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: IMA INC
Agency Code: 34-470744

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Emily Olan
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 34BSBJG6081
Naming Osteal Therapeutics as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of June 25, 2025.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 34BSBJG6081

Application/License No. _____

Osteal Therapeutics, doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
4835 LBJ FWY Ste 520 Dallas, TX 75244, Dallas, TX 75244, as
(Address of Applicant/Principal)
PRINCIPAL, and Hartford Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Connecticut
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is

_____ as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 13, 2024.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

34BSBJG6081

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 13th day of September, 2024.

APPLICANT/PRINCIPAL

Osteal Therapeutics

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Brittanie Kehr, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

POWER OF ATTORNEY

Direct inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

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- [ ] **Hartford Insurance Company of the Midwest,** a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Brittanie Kehr

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 34BSBJG6081
Naming Osteal Therapeutics as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of September 13, 2024.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Osteal Therapeutics, Inc.

Pharmacy/Wholesaler License # (if applicable) Pending

Physical Address 100 Cummings Center, Unit 324-D

City Beverly State MA Zip 01915

Mailing Address (if different from physical address) 4835 Lyndon B Johnson Fwy Ste 635

City Dallas State TX Zip 75244

Telephone (317) 997-2930 Website https://www.ostealtx.com/

Licensing Company Email jfischer@ostealtx.com

Section 2: Personal Information

First Joseph Middle Robert Last Fischer

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 100 Cummings Center, Unit 324-D

City Beverly State MA Zip 01915

Telephone 3179972930 Email jfischer@ostealtx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Indiana University of Indianapolis			
Address	**City**	**State**	**Zip**
Indianapolis	1400 East Hanna Avenue	IN	46227
Diploma/Degree obtained, if any			
MBA, Business			
School Name		From - To (MM/YY – MM/YY)	
Purdue University			
Address	City	State	Zip
701 W Stadium Ave #3000	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
BS, Mechanical Engineering Technology			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2024 - Present	[redacted]	Beverly	MA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
03/22 - 03/24		Gurgaon		
From - To (MM/YY – MM/YY)		City	State	
11/19 - 03/22		Brookline	MA	
From - To (MM/YY – MM/YY)		City	State	
06/14 - 11/19		10343 Abercorn Street	IN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Osteal Therapeutics, Inc.			03/24 - Present	
Business Address		**City**	**State**	**Zip**
100 Cummings Center, Unit 324-D		Beverly	MA	01915
Phone	**Title**		**Number of Employed Hours**	
(317) 997-2930	Senior Director, Trade and Distribution		1400+	
Description of Duties				
See Attached Resume				

Business Name			From - To (MM/YY – MM/YY)	
SPERO THERAPEUTICS, INC			06/20 - 02/22	
Business Address		**City**	**State**	**Zip**
675 Massachusetts Ave		Cambridge	MA	02139
Phone	**Title**		**Number of Employed Hours**	
	Senior Director, Trade and Distribution		3200+	
Description of Duties				
See Attached Resume				

Business Name			From - To (MM/YY – MM/YY)	
INTARCIA THERAPEUTICS, INC			09/19 - 04/20	
Business Address		**City**	**State**	**Zip**
1 Marina Park Drive		Boston	MA	02210
Phone	**Title**		**Number of Employed Hours**	
	Director, Trade and Distribution		1300	
Description of Duties				
See Attached Resume				

Business Name			From - To (MM/YY – MM/YY)	
ELI LILLY & COMPANY			08/00 - 08/19	
Business Address		**City**	**State**	**Zip**
893 S Delaware St		Indianapolis	IN	46285
Phone	**Title**		**Number of Employed Hours**	
	Consultant, Specialty Pharmacy Contracting & Performance		39,000+	
Description of Duties				
See Attached Resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Joseph R. Fischer

[redacted]

Trade and Distribution Professional

Collaborative relationship builder generating value in strategic channel development. Experienced in all aspects from channel strategy development to selection and onboarding of 3PL, Specialty Pharmacy, Distributor, GPO and Data Aggregator partners. Skilled at bridging internal customer needs to external partner capabilities and teaching others to navigate channel complexity. Critical thinker with well-rounded background in account management, negotiation, sales leadership and insights analysis. Experience in creating specialty networks for launch products and facilitating on-time, on-budget delivery of contracted services. Trusted subject matter expert motivated to share knowledge, pursue continuous learning and sustain a competitive edge

Core Competencies

Trade & Distribution | Specialty Pharmacy, Distributor & Channel Management | Contract Negotiation & Compliance
Operations & Process Management | Complexity Navigation & Training | Sales & Account Management
Vendor Management | Data Analytics & Insights | Strategic Planning | Managed Markets & Payer Performance
Team Leadership & Development | Customer Needs & Creative Solutions Development | Cross-functional Coordination

Experience

OSTEAL THERAPEUTICS, INC. Dallas, TX **(Mar 2024 - present)** *Returned to USA Mar 2024*

Senior Director, Trade and Distribution

- Accountable for all aspects of channel readiness for a drug and device product including channel strategy, 3PL selection, distributor selection, contract preparation and negotiation, state licensing, inventory management

AUTHOR, Gurugram, Haryana, India (Mar 2022 – present) *Moved to India in support of spouse's career*

- Completed *Your Novel Blueprint* writing curriculum by NY Times best-selling author Jerry Jenkins
- Finished first novel, Well Made, October 2023. Pursuing commercial publication
- Presently writing sequel, Well Done

SPERO THERAPEUTICS, INC. Cambridge, MA (Jun 2020 – Feb 2022) *Left to support spouse's career overseas*

Senior Director, Trade and Distribution

- Accountable for all aspects of channel readiness including channel strategy, 3PL selection, distributor and pharmacy selection, contracting and negotiation, state licensing and fair market value
- Developed channel capabilities to enable ultra-rapid shipment (<48 hrs) of an oral antibiotic for severe patient need
- Co-developed unique patient support services and ensured compatibility with channel partners through contracted, enhanced services
- Established GPO strategy, identification and negotiation approach
- Leveraged extensive commercial experience to consult and guide enterprise-wide launch preparations including data aggregation selection and implementation, product packaging and track and trace capabilities

INTARCIA THERAPEUTICS, INC. Boston, MA (Sep 2019 – Apr 2020) *CRL eliminated all commercial functions Apr 2020*

Director, Trade and Distribution

- Accountable for the design, development, implementation and management of the channel strategy
- Integrated highlighted values from brand, payer, clinical and patient services owners into channel designs
- Developed specialized channel capabilities to ensure appropriate shipment of an implanted drug and delivery device to placement-certified HCPs
- Authored and negotiated direct purchase agreements with specialty pharmacies, specialty distributors and IDNs
- Drove selection process of key vendor partners including data aggregator, data tokenization provider, external legal counsel for channel contracting oversight and fair market value
- Analyzed and developed CPT code positioning, Reverse Supply Chain processing and State Licensing preparations

ELI LILLY & COMPANY, Indianapolis, IN (Aug 2000 – Aug 2019)

Consultant, Specialty Pharmacy Contracting & Performance – Indianapolis, IN (May 2015 – Aug 2019)

- Managed all aspects of specialty pharmacy (SP) data contracting across five specialty brands.
- Authored and negotiated contracts with SPs and data aggregator.
- Collaborated with external benchmarking and fair market value parties to establish and improve value positions within contract language and executed agreements. Trained account executives on technical aspects of SP contracts
- Created new capability to manage SP data across a limited dispensing network. Collected, stewarded, analyzed, and reported SP data into downstream assets. Delivered quality data on-time to analysts and IT assets. Reduced time-to-1st-data by 50% over prior launch. Measured contract compliance; validated and approved SP invoices. Expanded enterprise-wide capabilities for measurable data quality and insights
- Developed and managed vendor relationship with data aggregator to receive, validate, steward, and aggregate SP data across multiple networks. Increased inbound data quality to enable accurate analytics for internal consumers.

Consultant, Global Payer Market Research – Indianapolis, IN (Apr 2014 – May 2015)

- Forecasted Share of Market (SOM) changes for various product access levels on insurance formularies
- Facilitated profitable contracting negotiations with insurance providers.

Sr. Account Manager, Cardiovascular Health – Pasadena, CA (Apr 2012 – Apr 2014)

- Owned promotion of Lilly's Cardiovascular and Diabetes portfolios to major hospital networks in NE Los Angeles
- Drove conversion of Humalog from pens to 5 ml vials and leveraged Effient's differential trial data on DES/STEMI
- Earned Rookie of the Year Award, Leading Through Transition Award and Chief Business Owner Award, 2014
- Earned 18 Excellence Awards in Sales Leadership, Action, Values, and Performance, 2013

Consultant, Global Health, Safety & Environmental (HSE) – Indianapolis, IN (Oct 2010 – Apr 2012)

- Promoted HSE initiatives to internal sales leaders. Produced all metrics and dashboards
- Transformed sales leadership perspective on safety to reduce work-place injuries
- Led the 2011 Global HSE Workshop. An annual four-day conference of Lilly leadership, 2011
- Earned multiple Excellence awards from HSE leadership despite having no previous HSE experience.

Team Leader/Marketing Consultant, U.S. Affiliate Sales Operations – Indianapolis, IN (Jul 2006 – Oct 2010)

- Managed promotional material warehousing, Knowledge Management, HSE, and business tools design
- Earned Excellence awards for the design and launch of a Field Portal serving 5,000 field-based sales reps, 2008, 2009
- Awarded Exemplary Performer (top 10% of employees). Earned Lean Six Sigma Green Belt certification, 2007
- Led development of Lilly's first U.S. Sampling Strategy, 2006. Created a new method to optimize sample allocation

ELI LILLY & COMPANY (cont)

Business Analyst, Primary Care Neuroscience Sales Operations – Indianapolis, IN (Feb 2003 – Jul 2006)

- Analyzed sales data and optimized resource utilization based on sales trend recognition
- Awarded Lilly's Greyhound Award for excellence in Sales Operations, 2005
- Oversaw sales data analysis efforts for West Area - Primary Care Neuro resulting in #1 sales performance, 2004
- Led Sales Productivity Process (SPP) workshops to identify and improve sales implementation behaviors, resulting in positive behavioral shifts of +30% as measured by SPP scores in 2003 and 2004

Marketing Associate, PKC ß Inhibitor Product Team – Indianapolis, IN (Jul 2002 – Feb 2003)

- Developed Lilly's first neuropathy diagnostic strategy to facilitate the diagnosis of peripheral neuropathy, 2003
- Created performance management tools to measure and display progress towards departmental goals, 2002

Sales/Sr. Sales Representative, Specialty Sales, Indianapolis Diabetes Care – Indianapolis, IN (Aug 2000 – Jul 2002)

- Achieved top sales performance by consistently surpassing quota and mentoring other teammates
- Finished #8 out of 510 sales representatives, 2001. #47 out of 510 sales representatives, 2002
- Earned Business Acumen and Disease States Champion for two Indiana sales districts and the Midwest area, 2002
- Received three Peer Awards for excellence in sales training and development, 2000 & 2001.

FIRESTONE INDUSTRIAL PRODUCTS COMPANY, Carmel, IN (Jun 1992 - Aug 2000)

- Drove sales, managed accounts, negotiated contracts, developed strategic plans and designed air suspensions

EDUCATION

- **MASTER of BUSINESS ADMINISTRATION** (MBA)
  INDIANA UNIVERSITY, Bloomington, IN

- **BACHELOR of SCIENCE** (BS)
  Mechanical Engineering Technology
  PURDUE UNIVERSITY, West Lafayette, IN

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

I, Joseph Fischer, **certify that as the designated representative for**

Osteal Therapeutics, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Joseph Fischer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

FEB 28, 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Fischer
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

FEB 28, 2025
Date

Please have this section completed in the presence of a Notary Public.

State of MASSACHUSETTS, ss. County of ESSEX

I, JOSEPH FISCHER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

MARCH 10, 2025
Date

Subscribed and Sworn to before me this 10th day of MARCH, 2025

Notary Public Signature

Elizabeth S. Graham
NOTARY PUBLIC
Commonwealth of
Massachusetts
My Commission Expires
5/20/2027

Elizabeth S. Graham
NOTARY PUBLIC
Commonwealth of
Massachusetts
My Commission Expires
5/20/2027

(Seal)

OSTEAL
THERAPEUTICS®

Facility Information

Company Name: Osteal Therapeutics, Inc.
Address: 100 Cummings Center, Unit 324-D
City, State, Zip: Beverly, MA 01915

Employee List

Joe Fischer - Senior Director, Trade and Distribution

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Radiometer America Inc.

Physical Address: 6836 ENGLE ROAD

City: MIDDLEBURG HEIGHTS State: OH Zip: 44130

Mailing Address (if different from physical address): 250 South Kraemer Boulevard Mailstop B1.SW.11

City: Brea State: CA Zip: 92821

Telephone: (800) 736-0600 Website: www.radiometer.com

Name of Designated Representative (DR): Cheryl Borcher

Licensing Company Email: orderbox@radiometeramerica.com DR Email: cborcher@radiometeramerica.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Rx Medical Devices with no Drug	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No suppliers sold, dispensed, or distributed w/in last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Life Sciences Holdings France SAS

Corporation/Organization Name: Radiometer America Inc.

Mailing Address: 250 South Kraemer Boulevard Mailstop B1.SW.11

City: Brea State: CA Zip: 92821

Telephone: (800) 736-0600 Email: orderbox@radiometeramerica.com

Contact Person Name: Helio Sgambato

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

NA

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://[illegible]/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://[illegible]		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://[illegible].pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://[illegible]/Business/.		✓	✓	✓

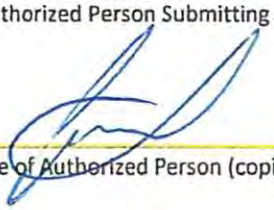
I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Radiometer America Inc.

Facility Name

Helio Sgambato

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

3-1-2025

Date

Board Use Only	Date Received: _____	Amount: _____

RADIOMETER

Description of Operations

Radiometer America Inc. is a medical device repackager, relabeler, and distributor of Class I and Class II medical devices. Radiometer America Inc.'s products are distributed to hospitals.

FDA FEI Number:
1523456

Distributor Information:
Radiometer America Inc.
6836 Engle Road, Middleburg Heights, OH 44130
Contact: Helio Sgambato, (714) 622-7124

Radiometer America Inc. has 20 employees working on site during normal business hours.

Radiometer America Inc.'s hours of operation are 6:00 am – 4:00pm Monday through Friday.

Radiometer America Inc.'s records are stored at their Middleburg Heights, OH facility.

Radiometer America Inc.'s facility square footage is 20,067.

Follow FDA En Español SEARCH

FDA

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search Back To Search Results

Establishment:
RADIOMETER AMERICA, INC.
6836 Engle Rd
Middleburg Heights, OH 44130
Registration Number: 1523456
FEI Number*: 1523456
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
RADIOMETER MEDICAL APS
AAKANDEVEJ 21
BROENSHOEJ, Hovedstaden DK 2700
Owner/Operator Number: 8020503

Official Correspondent:
Hsiao-Qing Chow
AAKANDEVEJ 21
BROENSHOEJ, Hovedstaden DK 2700
Phone: 45-38-273583

---

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified 8/15/25

Page Last Updated: 12/09/2024
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products
Advisory Committees
Science & Research
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Emergency Preparedness
International Programs
News & Events
Training and Continuing Education
Inspections/Compliance
State & Local Officials
Consumers
Industry
Health Professionals
FDA Archive
Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

RADIOMETER

Company Information

Company Name: Radiometer America Inc.
Address: 6836 Engle Road
City, State, Zip: Middleburg Heights, OH 44130
Phone: (800) 736-0600
Website: www.radiometer.com
E-mail: orderbox@radiometeramerica.com

FEIN: 34-1115839
State of Formation: Delaware
Date Incorporated: 03/10/1971
File Number: 770715

Ownership Information

Radiometer America Inc. is 100% owned by Life Sciences Holdings France S.A.S.

Parent Company Address: 26-28 AVENUE DE WINCHESTER, SAINT-GERMAIN-EN-LAYE, FRANCE 78100
Parent Company Phone: +33 1 30 61 38 00
Parent Company FEIN: n/a

Officers

Helio Sgambato, Senior Finance Director
Business Address: 250 South Kraemer Boulevard, Brea, CA 92821
Business Phone: (714) 622-7124

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RADIOMETER AMERICA INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF JULY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RADIOMETER AMERICA INC." WAS INCORPORATED ON THE TENTH DAY OF MARCH, A.D. 1971.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

770715 8300

SR# 20243067771

Authentication: 203863633

Date: 07-05-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Ohio Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2027.

Radiometer America, Inc

6836 Engle Rd

Middleburg Heights, OH 44130-7910

License Number: 0150000113

License Type: Manufacturer - Category 2

Sub-Category: MF – Manufacturer

Expiration Date: June 30, 2027

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
Helio Sgambato	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 04/28/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Philadelphia PA Office 100 North 18th Street 16th Floor Philadelphia PA 19103 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE		NAIC #
Radiometer America, Inc 250 S. Kraemer Boulevard Brea CA 92821 USA	INSURER A:	ACE American Insurance Company	22667
	INSURER B:	Indemnity Insurance Co of North America	43575
	INSURER C:	ACE Fire Underwriters Insurance Co.	20702
	INSURER D:	ACE Property & Casualty Insurance Co.	20699
	INSURER E:		
	INSURER F:		

COVERAGES **CERTIFICATE NUMBER:** 570112273487 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE / X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY / PRO-JECT / LOC OTHER:			HDOG47311962	07/01/2024	10/15/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$2,000,000 $2,000,000 $10,000 $2,000,000 $5,000,000 $5,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY / SCHEDULED AUTOS HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY			ISAH10705629	07/01/2024	10/15/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$5,000,000
D	X UMBRELLA LIAB / X OCCUR EXCESS LIAB / CLAIMS-MADE DED / X RETENTION			XEUG71535290006 SIR applies per policy terms & conditions	07/01/2024	10/15/2025	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
B A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		WLRC70304454 WC AOS WLRC70304417 WC(AZ,CA,MA)	07/01/2024 07/01/2024	07/01/2025 07/01/2025	X PER STATUTE / OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $2,000,000 $2,000,000 $2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Radiometer, 6836 Engle Road, Middleburg Heights, Ohio 44130.

CERTIFICATE HOLDER

Radiometer America, Inc.
250 S. Kraemer Blvd.
Brea CA 92821 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc

Holder Identifier :

Certificate No : 570112273487

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AGENCY CUSTOMER ID: 570000096789

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Radiometer America, Inc
POLICY NUMBER: See Certificate Number: 570112273467	
CARRIER: See Certificate Number: 570112273467 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	WORKERS COMPENSATION							
C		N/A		SCFC70304491 WC (WI)	07/01/2024	07/01/2025		

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RIDER

To be attached to and form part of:

Bond Number 019093583

dated June 17, 2024

issued by the LIBERTY MUTUAL INSURANCE COMPANY

in the amount of $ 100,000.00

on behalf of RADIOMETER
(Principal)

and in favor of STATE OF NEVADA AND THE NEVADA STATE BOARD OF PHARMACY
(Obligee)

Now therefore, it is agreed that in consideration of the premium charged, the attached bond shall be amended as follows:

The Following Locations are covered under this bond:

- 250 S. Kraemer Blvd. Bldg. D| Brea, CA 92821 (Brea Office)
- 6836 ENGLE ROAD - MIDDLEBURG HEIGHTS, OHIO 44130

It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This Rider is to be Effective this 17th day of June, 2024.

Signed, Sealed & Dated this 17th day of June, 2024.

RADIOMETER
(Principal)

By: _____

LIBERTY MUTUAL INSURANCE COMPANY
(Surety)

By: _____
Patricia Dorsaneo, Attorney-in-Fact

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8209496-019022

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Annmarie Breene; Babette Ward; Cathy H. Ho; Dana Donahue; Erin M. Dennison; George Gionis; Joanne C. Wagner; Kimberly G. Sherrod; Lori S. Shelton; Marisa Thielen; Patricia A. Rambo; Patricia Dorsaneo; Pedro Gonzalez, Jr.; Sara Owens; Wayne G. McVaugh

all of the city of Philadelphia state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 28th day of February, 2023.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 28th day of February, 2023 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 17th day of June, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02.21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 016093583

Application/License No. _____

RADIOMETER, doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
250 S. Kraemer Blvd Brea, CA 92821, as
(Address of Applicant/Principal)
PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY, a
(Surety Company)
corporation organized under the laws of the state of MA
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
175 Berkeley Street Boston, MA 02116 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 17, 2024.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 17th day of June, 2024.

APPLICANT/PRINCIPAL
RADIOMETER COMPANY

Authorized Representative

SURETY
LIBERTY MUTUAL INSURANCE COMPANY

Sara Owens
Surety Company's Representative

Sara Owens, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Dana Donahue

Witness Trisha Dorsaneo

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8209496-019022

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Annmarie Breene; Babette Ward; Cathy H. Ho; Dana Donahue; Erin M. Dennison; George Gionis; Joanne C. Wagner; Kimberly G. Sherrod; Lori S. Shelton; Marisa Thielen; Patricia A. Rambo; Patricia Dorsaneo; Pedro Gonzalez, Jr.; Sara Owens; Wayne G. McVaugh

all of the city of Philadelphia state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 28th day of February, 2023.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 28th day of February, 2023 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 17th day of June, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2023

Assets	
Cash and Bank Deposits	$1,850,245,073.00
*Bonds – U.S Government	$3,859,565,383.00
*Other Bonds	$21,048,805,773.00
*Stocks	$19,937,271,802.00
Real Estate	$122,228,711.00
Agents' Balances or Uncollected Premiums	$8,208,660,427.00
Accrued Interest and Rents	$186,906,667.00
Other Admitted Assets	$15,677,869,683.63
Total Admitted Assets	**$70,891,553,519.63**

Liabilities	
Unearned Premiums	$10,298,963,305.00
Reserve for Claims and Claims Expense	$28,848,537,243.00
Funds Held Under Reinsurance Treaties	$360,714,151.00
Reserve for Dividends to Policyholders	$1,310,198.00
Additional Statutory Reserve	$296,126,000.00
Reserve for Commissions, Taxes and Other Liabilities	$7,622,413,466.63
Total	**$47,428,064,363.63**
Special Surplus Funds	$209,508,757.00
Capital Stock	$10,000,075.00
Paid in Surplus	$13,834,867,488.00
Unassigned Surplus	$9,409,112,836.00
Surplus to Policyholders	$23,463,489,156.00
Total Liabilities and Surplus	**$70,891,553,519.63**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2023, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2024.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Radiometer America Inc. MDEG License # (if applicable) New

Physical Address 6836 ENGLE ROAD

City MIDDLEBURG HEIGHTS State OH Zip 44130

Mailing Address (if different from physical address) 250 South Kraemer Boulevard Mailstop B1.SW.11

City Brea State CA Zip 92821

Telephone (800) 736-0600 Website www.radiometer.com

Licensing Company Email orderbox@radiometeramerica.com

Section 2: Personal Information

First Cheryl Middle Marie Last Borcher

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Brea State CA Zip [redacted]

Telephone (800) 736-0600 Email orderbox@radiometeramerica.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Baldwin Wallace College		12/1976 /1980	
Address	**City**	**State**	**Zip**
275 Eastland Rd,	Berea	OH	44017
Diploma/Degree obtained, if any			
B.A.			

School Name		From - To (MM/YY – MM/YY)	
WESTLAKE HIGH SCHOOL		09/72 - 06/76	
Address	**City**	**State**	**Zip**
HILLIARD BLVD	WESTLAKE	OH	44145
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/26/1958 Current	[redacted]	Westlake	OH	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Radiometer America, Inc			From - To (MM/YY – MM/YY): 01/19 - present	
Business Address: 6836 ENGLE ROAD		City: MIDDLEBURG	State: OH	Zip: 44130
Phone: (800) 736-0600	Title: Manager, Ops and Logistics		Number of Employed Hours: 40/week	
Description of Duties: See attached Resume				

Business Name: Radiometer America, Inc			From - To (MM/YY – MM/YY): 01/99-12/18	
Business Address: 6836 ENGLE ROAD		City: MIDDLEBURG	State: OH	Zip: 44130
Phone: (800) 736-0600	Title: Accounting Manager		Number of Employed Hours: 40hrs/week	
Description of Duties: see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		x
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		x

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

NA

Original Signature (electronic, copies or stamps not accepted) Date

I, Cheryl Borcher, **certify that as the MDEG Administrator for**

Radiometer America Inc.,

that I (initial that you have read and meet the following requirements):

1. CMB Have a high school diploma or its equivalent;
2. CMB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CMB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CMB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cheryl Borcher

Print Name (First, Last)

Cheryl Borcher

Original Signature (electronic, copies or stamps not accepted)

3-1-2025

Date

Board Use Only	Date Received: _____

Cheryl Borcher

Home Address: [redacted] Westlake, Ohio [redacted]

Work Address: 6836 Engle Road Middleburg Heights, Ohio 44130

[redacted] Work 657-286-1047 cborcher@radiometeramerica.com

Radiometer America Inc (Danaher Operating Company)

Operation & Logistics Manager — January 2019 - Current

Responsible for overseeing the local warehouse in Middleburg Heights, Ohio. Includes shipping and receiving of product from our main warehouse in Poland and distribution to our direct customers through-out the United States and Canada.

Radiometer America Inc (Danaher Operating Company)

Accounting Manager — January 1999 - December 2018

Responsible for accounting department – A/R, A/P and financial accountants. Responsible for Sox reporting, revenue recognition and other financial monthly reporting. Internal and External audits and implementation of new AXAPTA computer system

Radiometer America Inc (Danaher Operating Company)

Accounting Supervisor — January 1991 – December 1998

Oversee financial reporting and AP. Directly responsible for various monthly reports for submission to local and corporate office. Annual audits with external accountants

Radiometer America Inc (Danaher Operating Company)

Staff Accountant — March 1981 – December 1990

Account reconciliation, preparation of journal entries and gather information for external audits and sales tax audits.

EDUCATION:

1980 B.A. Accounting - Baldwin Wallace College – Berea, Ohio

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Radiometer America Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 6836 ENGLE ROAD

City MIDDLEBURG HEIGHTS State OH Zip 44130

Mailing Address (if different from physical address) 250 South Kraemer Boulevard Mailstop B1.SW.11

City Brea State CA Zip 92821

Telephone (800) 736-0600 Website www.radiometer.com

Licensing Company Email orderbox@radiometeramerica.com

Section 2: Personal Information

First Cheryl Middle Marie Last Borcher

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 6836 ENGLE ROAD

City MIDDLEBURG HEIGHTS State OH Zip 44130

Telephone (657) 286-1047 Email cborcher@radiometeramerica.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Baldwin Wallace College		12 /M - 06 /1980	
Address	City	State	Zip
275 Eastland Rd,	Berea	OH	44017
Diploma/Degree obtained, if any			
B.A.			

School Name		From - To (MM/YY – MM/YY)	
WESTLAKE HIGH SCHOOL		09/74 - 06/76	
Address	City	State	Zip
HILLIARD BLVD	WESTLAKE	OH	44146
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/26/1958	[redacted]	Westlake	OH	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Radiometer America, Inc			01/19 - present
Business Address	**City**	**State**	**Zip**
6836 ENGLE ROAD	MIDDLEBURG HEIGHTS	OH	44130
Phone	**Title**	**Number of Employed Hours**	
(800) 736-0600	Manager, Ops and Logistics	40/week	
Description of Duties			
see attached resume			

Business Name			From - To (MM/YY – MM/YY)
Radiometer America, Inc			01/99-12/18
Business Address	**City**	**State**	**Zip**
6836 ENGLE ROAD	MIDDLEBURG HEIGHTS	OH	44130
Phone	**Title**	**Number of Employed Hours**	
(800) 736-0600	Accounting Manager	40/week	
Description of Duties			
see attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		NA
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Cheryl Borcher, **certify that as the designated representative for**

Radiometer America Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CB I am at least 21 years of age;
3. CB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Cheryl Borcher

Print Name (First, Last)

Cheryl Burke

Original Signature (electronic, copies or stamps not accepted)

3-1-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cheryl Borcher

Print Name (First, Last)

Cheryl Burke — 3-1-2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of OHIO, ss. County of CUYAHOGA ~~COUNTY~~

I, Cheryl Borcher, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Cheryl Burke — 3-1-2025

Original Signature — **Date**

Subscribed and Sworn to before me this 1 day of March 2025

Nichole Tick

Notary Public Signature

NICHOLE TICK
Notary Public
State of Ohio
(Seal) mm. Expires
March 13, 2029

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License APP-000884750

Radiometer America, Inc

6836 Engle Rd
Middleburg Heights, OH 44130-7910
Cuyahoga County

Manufacturer - Category 2

DDD Inspection Updated 1/15/2025

March 4, 2025

License APP-000884750 - Radiometer America, Inc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Devon Turski
Start 3/4/2025 9:20 AM
End 3/4/2025 10:10 AM

Organization

Name
Radiometer America, Inc

License Type
Manufacturer - Category 2

Category

License Number
APP-000884750

Business Type
MF - Manufacturer

DEA Number

Responsible Person
Helio Sgambato

Hours of Operation

Contact

Address
6836 Engle Rd
Middleburg Heights, OH 44130-7910
Cuyahoga County

Primary Number
(714) 622-7124

Fax Number
(440) 871-2510

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Cheryl Borcher				(440) 292-7979	cborcher@radiometeramerica.com
Helio Sgambato		Responsible Person			

1) General Inspection Information

1) Document personnel conducting inspection

Observation
Inspector Devon Turski.

2) Were multiple inspection guides used during this inspection?

No

3) Facility Description and Type

Observation
Manufacturer - Category 2.

4) Have there been any changes in the DDD's ownership, business name or trade name, category, or address without submitting a new application to the Board?

No

5) Does the DDD have a valid registration issued by the Drug Enforcement Administration?

No

6) Is the Responsible Person present during the inspection?

No

3.1) Responsible Person- Drug Distributor (OAC 4729:6-2-01)

1) Does the Responsible Person match what is listed in elicense?

Yes

2) Was the Board notified within 10 days of the effective date of appointment of the new responsible person?

Not Applicable

3) Was a complete inventory of controlled substances completed on the effective date of the change of responsible person?

Not Applicable

4) Is the responsible person physically present at the location for a sufficient amount of time?

Yes

5) Does the Responsible Person have the required credentials to be the responsible person for the DDD classification/business type?

Yes

3.4) Drug Distributor Applications (OAC 4729:6-2-04)

1) Was all required information submitted with an application to the Board of Pharmacy for licensure?

Yes

4.2) Report of theft or sig loss of dang drugs, controlled subs, and drug documents (OAC 4729:6-3-02)

1) Did the distributor of dangerous drugs experience a theft or significant loss of dangerous drugs, controlled substances, and drug documents?

No

4.3) Inspections and corrective actions (OAC 4729:6-3-03)

1) Inspection Information

Observation
OAC 4729:6-3-03 Inspections and corrective actions. Effective 8/31/24
(A) Pursuant to section 3719.13 of the Revised Code, an entity licensed by state board of pharmacy in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code is subject to an on-site inspection by the board. An authorized board employee may, without notice, carry out an on-site inspection or investigation of an entity licensed by the board. Upon verification of the board employee's credentials, the agent shall be permitted to enter the licensed entity.
(B) Submission of an application for a license, in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code, with the state board of pharmacy constitutes permission for entry and on-site inspection by an authorized board employee.
(C) If an employee of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the employee may provide written notice, in a manner determined by the board, of the nature of the observed violations to the responsible person on the license or application. The licensee or applicant may also be subject to disciplinary actions pursuant to Chapter 4729. of the Revised Code and this division of the Administrative Code.
(D) Violations may include any of the following:
(1) Violating any rule of the board;
(2) Violating any provision of Chapter 4729. of the Revised Code;
(3) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301, or Chapter 3715. of the Revised Code; or
(4) Violating any provision of the federal drug abuse control laws or regulations or Chapter 2925. or 3719. of the Revised Code.
(E) The licensee or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of this rule, in a manner determined by the board, either of the following:
(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

9.1) Manufacturers - General Operations (OAC 4729:6-8-01)

1) Facility: Is the facility of suitable size and construction to facilitate cleaning, maintenance, and proper operations?

Yes.

2) Facility: Does the facility have areas designed to meet specified storage requirements?

Yes.

3) Facility: Does the facility maintain a quarantine area for adulterated drugs?

Yes.

4) Facility: Is the facility clean and orderly?

Yes.

5) Facility: Is the facility free from infestation?

Yes.

6) Facility: Is the facility a registered business entity and operating in a commercial zone?

Yes.

7) Training: Do employees have appropriate training, experience, and/or education to assume responsibility for positions related to compliance with Ohio Administrative Code?

Yes.

8) Security: Is the facility secure from unauthorized entry?

Yes: Access from outside the premises is kept to a minimum and well controlled.

Yes: The outside perimeter of the premises is well lit.

Yes: Entry into areas where dangerous drugs are stored is limited to authorized personnel.

Yes: All facilities where dangerous drugs are stored are equipped with an alarm system to detect unauthorized entry after hours.

Yes: Facility is equipped with a security system which provides suitable protection against theft and diversion including that facilitated by tampering with computers or electronic records.

9) Security: Did the facility notify the Board of any new facilities, work or storage areas constructed or utilized for dangerous drugs?

Yes.

10) Security: Does the licensee's common or contract carriers have adequate security to guard against in-transit losses?

Yes.

11) Security: Is the licensee's responsible for selecting a facility which will provide adequate security to guard against storage losses?

Yes.

13) Security: Does the licensee employ precautions to guard against storage or in-transit losses?

Yes.

14) Security: Does the licensee have adequate security to guard against theft and diversion while dangerous drugs are being stored or handled by agent(s)?

Yes.

15) Temperature: Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?

Yes.

16) Temperature: Does the facility regularly document proper storage of dangerous drugs and maintain documentation for at least three years?

Yes.

17) Shipments: Are all outside shipping containers visually examined upon receipt?

Yes.

18) Shipments: Is each outgoing shipment carefully inspected?

Yes.

19) Adulterated Drugs: Are expired/adulterated/damaged drugs appropriately segregated from the facility's active inventory?

Yes.

20) Adulterated Drugs: Are expired/adulterated drugs stored no longer than two years from the date of expiration/adulteration?

Yes.

28) P & P: Does the wholesale distributor have written policies and procedures for the receipt, security, storage, inventory, and distribution of dangerous drugs?

Yes.

29) P & P: Does the facility have a written procedure for handling recalls and withdrawals of dangerous drugs?

Yes.

30) P & P: Does the facility have a written procedure in case of a natural disaster or emergency situation?

Yes.

32) Compliance: Does the facility operate in compliance with applicable federal, state, and other local laws, rules, and regulations?

Yes.

33) Compliance: Does the facility comply with the provisions of any applicable federal, state, or local laws, rules, or regulations that relate to dangerous drug salvaging or reprocessing?

Yes.

34) Compliance: Does the facility permit properly identified and authorized board agents or law enforcement officials to enter for inspection?

Yes.

35) Did the manufacturer comply with current good manufacturing practices pursuant to Section 501 of the Federal Food, Drug and Cosmetic Act (5/28/2015)

Yes

9.2) Manufacturers - Record Keeping (OAC 4729:6-8-02)

1) Did the manufacturer maintain records for the source of the drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped?

Yes

2) Did the manufacturer maintain records of the name, national drug code, quantity of the drugs received, distributed, sold, disposed or returned?

Yes

3) Did the manufacturer establish and maintain inventory and records of the dates of receipt, sale and distribution of the drugs?

Yes

4) Did the manufacturer establish and maintain inventory and records of the name and principle address of the purchaser or receiver and the address of the location where the drugs were shipped?

Yes

5) Did the manufacturer establish and maintain inventory and records which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code?

Yes

8) Can the manufacturer maintaining records at a location other than licensed by the board, authorize an agent of the board access to the records within three business days?

Yes

9) Did the manufacturer maintain records for all damaged, deteriorated, misbranded, or adulterated dangerous drugs in accordance with paragraph (A) of this rule?

Yes

10) Did the manufacturer submit wholesale sale information to the drug database?

Yes

16) Inspection Affirmation

1) Inspection Affirmation

Observation
*This document only addresses compliance with the rules or laws specifically identified above.

As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Cheryl Borcher

(signature)

Radiometer America Inc - Employee List

Name
Treese,Jay A
Myers,Lloyd G
Borcher,Cheryl M
Lilly,Sidney E
Rowley,Frank J
Moran,Michelle M
Masters II,Donald W
Rodriguez,Wilfredo
Cook,Deanna M
Rall III,Charles A
Austin,Barbara A
McFadden,Michael J
Ackerman,Matt
Hernandez,Paul A
Braatz,David P
Burnside,Toby G
Murphy,Tiffany H
Aponte,James
Hoffman,Kurt M
Gibbons,James M
Farley,Alison M
Verquer,Robert J
Lucas,Paul E
Sneska,James A
Rutrough,Matthew
Bosteder,Donna J
Ziegler,Mark M
Custer,Jerry A
Hirth,Mary Rose L
Powers,Stephen J
Castanedo,Frank
Martin,Lauretta A
Gillispie,Brent E
Smith,Michael K
Losasso,James A
McClain,Steven W
Ghaneian,Nora
Jimenez,Jose R
Martz,Bruce R
Turman Jr.,Richard T
Franklin,Patricia A
Barnes,Michael T
McCormick,James H
Heitsman,Richard K
Sedlacek,Ryan J

Neese,Hollis E
Bafford,Jeffrey K
Harris,Deborah A
Crist,Kimberly
Terwilliger,Michael J
Suellentrop,Bart N
Scannell,Katelyn
McKenzie,Kevin C
Blazek,Sandra A
Mignella,Michael C
Topaloff,David S
Vazquez,Brian A
Rose,Daniel N
Elliott,Kevin M
Barnett,Chris A
Budic,Grant M
Hansen,John S
Sargent,Cheryllee
Cwikla,Adam M
Kishmarton,Michael T
Leifker,Nicholas J
Casatelli,Keven L
Narvaez,Daniel A
Barajas,Yvette M
Bentley,Stephanie R
Searls,Trevor L
Williams,Patrick F
Craft,Florence W
Emery,Nicole
Hecht,Sean
Jones,Terri
Miranda,Carlos
Shi,Song
Reagle,Scott
Peng,David
Sookdeo,Hetram
Koeck,Michaela L
Willis,Lee A
Furcick,Rachel L
Mendoza,Margarita
Osbey,Cynthia C
Abdelaziz,Khaled
Parasram,Scarlett
Iwankovitsch,James R
Curry,Jon M
Harper II,Dennis
Pichardo,Pedro

Hammock,Kelly M
Scortia,Magnolia
Brown,Adam J
Deese,Gregory R
Begnoche,Cassidy
Reynolds,Matthew
Meyer,James A
Bigante,Elizabeth R
Carlisle,Rayshawn
Kansara,Rajan
Reed,Laurene
Castro,Pauline J
Daspit,Jon
Taylor,Erin D
Sgambato Junior,Helio
Banaag,Michael A
Gutierrez,Maryjoyceann A
Liu,Shiwei
Vang,Shuefong
Tedeholm,Annika
Robinson,Alesia
Campos,Sheira
Capaldi,William R
Tay,Ivan
James,Jeffrey S
Marin,Eduardo
Ciliberti,Biagio
Antinoja,David
Karber,Grayson Q
Squibbs,Sean K
Wlodkowski,Eric
McBride,Lia
Ward,Michael J
Thomas,Karen M
Corn,Gary S
Hernandez,Guillermo E
Martinez,Rodolfo
D'Agostino,Kevin
Williams,Laura
Pham,Tracy
Allen,LaToya
Bordner Blank,Anne
Prajapati,Shrey Y
Tran,Sara
Pellegrino,John
Hancock,Christian M
Ramirez,Michele

Roberts,LeAnn
Tatalovic,Kathleen
Benavidez,Rene
Munoz,Christian
DeBartolo,Robert
Swingle,Andrea
Trottier,Erin
Bradley,Matthew J
Garner-Parker,Kimberly
Vasquez,Victor A
Ketelhohn,Lauren
Cruz,Enrique
Mayorga,Robert
Weeden,Tabitha
Fisher,Cecily A
Spoerry,Julia
Carreon,Jeffrey
Johnson,Robert
Barta,Luke
Brady,Cole
Honeyman,Susan T
Yankelevich,Tatiana
De La Cruz,Evelyn
Florentino,Kelly
Spencer,Jeffrey W
Fournier,Donald
Smith,Brian
Smith,Stephen K
Kumnick,Andrew
Colvin,Michael F
Walker,Erin
Whitt,Ilene
Steiner,William
Schnur,Jonathan
Castro,Beronica
Piedra,Juan Carlos
Budic,Caleb
Steiner,James
Burks,Terry
Martinez,Miguel
Hai,Sharon
Thao,William
Goldstein,Steven R
Ramirez,Louise
Napire,Carmelo
Chaney,Ebony
Gillon,William D

Abrego,Alexi
Pedersen,Ronnie
Vidola,Mccullen
Sermet,Muhammed Omer
Smith,Michael
Kilker,James A
Tillemans,Derek
Tribbett,Jennifer
Young,Philip
Guichard,Nicholas
Hansen,Janet
Sheridan III,Paul J
Eckenwiler,Michael
Kadir,Faris
Lacy,Lillian
Rink,Brandon
Luzghin,Serhii
Fann,Jennifer
Terrell,Edmund
Johnson,Robert
Mungin,Kierre
Smith,Spencer P
Dalmacio,Jade
Greene,Terrance
Stoga,Jeffrey
Morsdorf,Pete
Skodje,Claire
Aponte,Anthony
Castro,Sean
Murray,Candice
Saitta,Nikki
Alexander,Nichole
Quig,Karalee
Gayre,Calley
Marquez,Liliana
Christopherson,Joseph
Vanwart,Nicole
Rose,Russell
Kaba,Dominique
Radke,Magen
Vergara,Phillip E
Eppes,Tyler
Rankin,Terrance
Mayes,Shaquan
Nelson,Jessica
Tumma ,Ravali R
Robertson,Margaret

Shah,Waqas
Collin,Diane
Westwater,John
Amyotte,Matthew
Sheehan,David
Grewal,Avninder
Bolton,Neil
Peta,Michael
Kort,Rima
Younes,Khaled
Singh,Jitesh
Renaud,Michelle
Groot-Mclaren,Joseph
Knapman,David
Sharma,Shradma

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals

Physical Address: 330 Wyckoff Mills Road

City: East Windsor State: NJ Zip: 08520

Mailing Address (if different from physical address): c/o State License Servicing, Inc., 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.risingpharma.com

Name of Designated Representative (DR): George F Skibo Jr.

Licensing Company Email: RPI@slsny.com DR Email: gskibo@risingpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☒ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: OTC Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: US Government		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

No discipline to report

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Amerisource Bergen Drug Corporation
Address: 5100 Jaindl Blvd City: Bethlehem State: PA Zip: 18017
Name: Cardinal Health
Address: 5995 Commerce center Drive City: Groveport State: OH Zip: 43125
Name: McKesson Medical Surgical Inc.
Address: 4250 Patriot Drive, Ste 100 City: Grapevine State: TX Zip: 76051
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Raisin Acquisition Co, Inc. 100% sole ownership
Corporation/Organization Name: Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals
Mailing Address: c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor
City: Middletown State: NY Zip: 10940
Telephone: (845) 544-2482 Email: RPI@slsny.com
Contact Person Name: Christine Cannon

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: Labeler Code: 64980	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals

Facility Name

Vimal Kavuru

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

06/19/2025

Date

Board Use Only	Date Received: 7/8/25	Amount: $1000-CK3993

An official website of the United States government Here's how you know

FDA

Home Drug Databases NDC Search Result

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Current through July 17, 2025

You have searched Finished drug products

Search Results: *'rising Pharma holdings'*

Back to Search Page

Showing 1 to 50 of 949 entries Show 50

Proprietary Name	NDC Package Code	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name
Abacavir	64980-405-24	ANDA077950	Rising Pharma Holdings, Inc.	64980-405	Abacavir Su
Abiraterone acetate	64980-418-12	ANDA208371	Rising Pharma Holdings, Inc.	64980-418	Abiraterone
Acetaminophen	57237-304-12	M013.50	Rising Pharma Holdings, Inc.	57237-304	Acetaminopl
Acetaminophen	57237-304-16	M013.50	Rising Pharma Holdings, Inc.	57237-304	Acetaminopl
Acetaminophen	57237-346-01	M013	Rising Pharma Holdings, Inc.	57237-346	ACETAMINC
Acetaminophen	57237-347-01	M013	Rising Pharma Holdings, Inc.	57237-347	ACETAMINC

Proprietary Name ▲	NDC Package Code	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name
+ Acetaminophen, Aspirin and Caffeine	57237-348-01	M013	Rising Pharma Holdings, Inc.	57237-348	Acetaminophen Aspirin and Caffeine
+ Adult Low Dose Aspirin	57237-349-12	M013	Rising Pharma Holdings, Inc.	57237-349	Aspirin
+ Albuterol	64980-442-01	ANDA207046	Rising Pharma Holdings, Inc.	64980-442	albuterol
+ Albuterol	64980-442-50	ANDA207046	Rising Pharma Holdings, Inc.	64980-442	albuterol
+ Albuterol	64980-443-01	ANDA207046	Rising Pharma Holdings, Inc.	64980-443	albuterol
+ Albuterol	64980-443-50	ANDA207046	Rising Pharma Holdings, Inc.	64980-443	albuterol
+ Albuterol Sulfate	64980-641-02	ANDA074880	Rising Pharma Holdings, Inc.	64980-641	Albuterol Su
+ Albuterol Sulfate	64980-641-03	ANDA074880	Rising Pharma Holdings, Inc.	64980-641	Albuterol Su
+ Albuterol Sulfate	64980-641-06	ANDA074880	Rising Pharma Holdings, Inc.	64980-641	Albuterol Su

Proprietary Name ▲	NDC Package Code	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name
+ Albuterol Sulfate	64980-642-03	ANDA075664	Rising Pharma Holdings, Inc.	64980-642	Albuterol Su
+ Albuterol Sulfate	64980-643-03	ANDA076355	Rising Pharma Holdings, Inc	64980-643	Albuterol Su
+ Albuterol Sulfate	64980-644-02	ANDA076355	Rising Pharma Holdings, Inc	64980-644	Albuterol Su
+ Alendronate Sodium	64980-340-01	ANDA090124	Rising Pharma Holdings, Inc.	64980-340	Alendronate Sodium
+ Alendronate Sodium	64980-340-03	ANDA090124	Rising Pharma Holdings, Inc.	64980-340	Alendronate Sodium
+ Alendronate Sodium	64980-341-12	ANDA090124	Rising Pharma Holdings, Inc.	64980-341	Alendronate Sodium
+ Alendronate Sodium	64980-341-14	ANDA090124	Rising Pharma Holdings, Inc.	64980-341	Alendronate Sodium

Proprietary Name ▲	NDC Package Code	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name
+ Alendronate Sodium	64980-342-01	ANDA090124	Rising Pharma Holdings, Inc.	64980-342	Alendronate Sodium
+ Alendronate Sodium	64980-342-14	ANDA090124	Rising Pharma Holdings, Inc.	64980-342	Alendronate Sodium
+ Alendronate Sodium	64980-342-50	ANDA090124	Rising Pharma Holdings, Inc.	64980-342	Alendronate Sodium
+ Alfuzosin Hydrochloride	57237-114-01	ANDA079060	Rising Pharma Holdings, Inc.	57237-114	Alfuzosin Hydrochloric
+ Alfuzosin Hydrochloride	57237-114-05	ANDA079060	Rising Pharma Holdings, Inc.	57237-114	Alfuzosin Hydrochloric
+ Alfuzosin Hydrochloride	57237-114-90	ANDA079060	Rising Pharma Holdings, Inc.	57237-114	Alfuzosin Hydrochloric
+ Allopurinol	16571-883-01	NDA016084	Rising Pharma Holdings, Inc.	16571-883	allopurinol
+ Allopurinol	16571-883-09	NDA016084	Rising Pharma Holdings, Inc.	16571-883	allopurinol
+ Allopurinol	16571-883-10	NDA016084	Rising Pharma Holdings, Inc.	16571-883	allopurinol

Proprietary Name ▲	NDC Package Code	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name
Allopurinol	16571-883-50	NDA016084	Rising Pharma Holdings, Inc.	16571-883	allopurinol
Allopurinol	16571-884-01	NDA016084	Rising Pharma Holdings, Inc.	16571-884	allopurinol
Allopurinol	16571-884-09	NDA016084	Rising Pharma Holdings, Inc.	16571-884	allopurinol
Allopurinol	16571-884-10	NDA016084	Rising Pharma Holdings, Inc.	16571-884	allopurinol
Allopurinol	16571-884-50	NDA016084	Rising Pharma Holdings, Inc.	16571-884	allopurinol
Allopurinol	16571-885-01	NDA016084	Rising Pharma Holdings, Inc.	16571-885	allopurinol
Allopurinol	16571-885-09	NDA016084	Rising Pharma Holdings, Inc.	16571-885	allopurinol
Allopurinol	16571-885-10	NDA016084	Rising Pharma Holdings, Inc.	16571-885	allopurinol
Allopurinol	16571-885-50	NDA016084	Rising Pharma Holdings, Inc.	16571-885	allopurinol
Aluminum Hydroxide, Magnesium Hydroxide and Simethicone	57237-316-31	M001.15	Rising Pharma Holdings, Inc.	57237-316	Aluminum Hydroxide, Magnesium Hydroxide, ε Simethicone

Proprietary Name	NDC Package Code	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name
Aluminum Hydroxide, Magnesium Hydroxide and Simethicone	57237-324-31	M001.15	Rising Pharma Holdings, Inc.	57237-324	Aluminum Hydroxide, Magnesium Hydroxide, a Simethicone
Amantadine Hydrochloride	16571-834-01	ANDA210129	Rising Pharma Holdings, Inc.	16571-834	Amantadine Hydrochloric
Amantadine Hydrochloride	16571-834-50	ANDA210129	Rising Pharma Holdings, Inc.	16571-834	Amantadine Hydrochloric
Amitriptyline Hydrochloride	16571-105-01	ANDA217411	Rising Pharma Holdings, Inc.	16571-105	Amitriptyline Hydrochloric
Amitriptyline Hydrochloride	16571-105-10	ANDA217411	Rising Pharma Holdings, Inc.	16571-105	Amitriptyline Hydrochloric
Amitriptyline Hydrochloride	16571-106-01	ANDA217411	Rising Pharma Holdings, Inc.	16571-106	Amitriptyline Hydrochloric
Amitriptyline Hydrochloride	16571-106-10	ANDA217411	Rising Pharma Holdings, Inc.	16571-106	Amitriptyline Hydrochloric
Amitriptyline Hydrochloride	16571-107-01	ANDA217411	Rising Pharma Holdings, Inc.	16571-107	Amitriptyline Hydrochloric
Amitriptyline Hydrochloride	16571-107-10	ANDA217411	Rising Pharma Holdings, Inc.	16571-107	Amitriptyline Hydrochloric

Previous 1 2 3 4 5 ... 19 Next

company particulars

Rising Pharma Holdings, Inc.
d/b/a Rising Pharmaceuticals

Corporate Address: 2 Tower Center Blvd, Suite 1401A, East Brunswick, NJ 08816 USA
FEIN: 83-3859401
www.risingpharma.com

Drug Labeler Code: 64980
Incorporation State: DE
Incorporation Date: 03/01/2019

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
WNJ	330 Wyckoff Mills Road East Windsor, NJ 08520 County: Mercer	N/A	N/A - No CS	116880195	No	(201) 961-9000	N/A

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
George F Skibo Jr.	[redacted]	Operations Manager		[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Raisin Acquisition Co, Inc.	1271 Avenue of the Americas #23 New York, NY 10020	N/A	100	N/A	87-3202338	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Vimal Kavuru	[redacted]	CEO	No	[redacted]		

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Corporation Service Company			

Good Standing

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RISING PHARMA HOLDINGS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTY-FIRST DAY OF MARCH, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RISING PHARMA HOLDINGS, INC." WAS INCORPORATED ON THE FIRST DAY OF MARCH, A.D. 2019.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7304068 8300

SR# 20251303998

Authentication: 203318049

Date: 03-31-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Homestate VOL

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 6/13/2025

Registration Number: 5002759 **Registered as:** Wholesale

Name: RISING PHARMA HOLDINGS INC.

DBA: RISING PHARMACEUTICALS

Address: 650 RANDOLPH RD, SOMERSET, NJ 08873

Original Issue Date: 01/12/2000 **Expiration Date:** 01/31/2026

Current Issue Date: 12/17/2024

Disciplines: No

Additional Registered Addresses:
330 WYCKOFF MILLS RD, EAST WINDSOR, NJ 08520

NJ does not issue official VOL

Mackenzie Winne - All Ope... > 77477

Reply | Add note | Forward | Close | Merge | Delete

Overdue

RE: [EXTERNAL] Verification of Licensure

DOH-PHFPP reported via email

Add summary

DOH-PHFPP reported via email
18 days ago (Fri, 11 Sep 2020 at 4:44 PM)

To: "'SLSNYSupport.com'" <help@slsnysupport.com>

Thank you. Due to limited resources, the NJ Department of Health cannot complete license verification forms for other states. Please utilize the online verification system on our webpage: https://nj.gov/health/ceohs/food-drug-safety/medical-device-reg/

Jennifer Steffee | Public Health Representative
NJ Department of Health | Public Health & Food Protection
PO Box 369 | 135 E State St | Trenton, NJ 08625
609.913.5150 | http://nj.gov/health/ceohs

Rider

IAT INSURANCE GROUP Surety

HARCO

RIDER

To be attached to and form part of Bond No. 0754159.

Issued on behalf of Rising Pharma Holdings, Inc. dba Rising Pharmaceuticals as Principal, and in favor of Nevada State Board of Pharmacy as Obligee.

It is agreed that:

☐ 1. The Surety hereby gives its consent to change the Name:

from: _____

to: _____

☐ 2. The Surety hereby gives its consent to change the Address:

from: _____

to: _____

☒ 3. The Surety hereby gives its consent to add the following additional location to the above-captioned bond:

330 Wycoff Mills Road, East Windsor, NJ 08520

This rider shall become effective as of March 28, 2025

PROVIDED, however, that the liability of the Surety under the attached bond as changed by this rider shall not be cumulative.

Signed, sealed and dated March 28, 2025.

Harco National Insurance Company

By: Robyn Rost

Robyn Rost
Attorney-in-Fact

Accepted: _____ or Rising Pharma Holdings, Inc. dba Rising Pharmaceuticals
Obligee Principal

By: _____ By: _____

S-4111 (8/66)

POWER OF ATTORNEY

Bond # 0754159

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY,** a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY,** a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

PAMELA LIPKIN-SAUERTIG, MICHAEL PARR, ROBYN ROST

Florham Park, NJ

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY,** as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under end by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED,** that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2023

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Michael F. Zurcher
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2023, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2029

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, March 28, 2025

B31765

Irene Martins, Assistant Secretary

HARCO NATIONAL INSURANCE COMPANY

1701 GOLF ROAD, SUITE 1-600, ROLLING MEADOWS, IL 60008

STATEMENT OF ASSETS, LIABILITIES, SURPLUS AND OTHER FUNDS
AT DECEMBER 31, 2024

ASSETS

Bonds (Amortized Value)	$151,003,602
Stocks (Preferred Stocks)	5,295,012
Stocks (Common Stocks)	1,117,319,913
Cash, Bank Deposits & Short-Term Investments	101,581,740
Other Invested Assets	0
Unpaid Premiums & Assumed Balances	147,431,464
Deferred Premiums, Agents Balances & Installments booked	12,276,867
Reinsurance Recoverable from Reinsurers	43,214,951
Reinsurance - Funds Held by or deposited with reinsured companies	15,163,786
Current Federal & Foreign Income Tax Recoverable & Interest	14,121,633
Investment Income Due and Accrued	2,090,174
Receivables from Parent Subsidiaries & Affiliates	14,302,543
Other Assets	1,052,236
TOTAL ASSETS	$1,624,853,921

LIABILITIES SURPLUS & OTHER FUNDS

Losses (Reported Losses Net as to Reinsurance Ceded and Incurred But Not Reported Losses)	$217,385,914
Reinsurance payable on paid losses & loss adjustment expense	661,855
Loss Adjustment Expenses	42,734,045
Commissions Payable, Contingent Commissions & Other Similar Charges	1,367,674
Other Expenses (Excluding Taxes, Licenses and Fees)	0
Taxes, Licenses & Fees (Excluding Federal Income Tax)	1,414,883
Current federal and foreign income taxes	0
Net Deferred Tax Liability	14,515,327
Unearned Premiums	164,124,841
Advance Premium	1,242,801
Ceded Reinsurance Premiums Payable	53,505,057
Funds held by Company under reinsurance treaties	29,506,468
Amounts Withheld by Company for Account of Others	62,460,811
Payable to Parent Subsidiaries & Affiliates	11,222,841
Other Liabilities	2,797,065
TOTAL LIABILITIES	$603,939,582
Common Capital Stock	$3,500,004
Gross Paid-in & Contributed Surplus	670,781,834
Unassigned Funds (Surplus)	346,632,501
Surplus as Regards Policyholders	$1,020,914,339
TOTAL LIABILITIES, SURPLUS & OTHER FUNDS	$1,624,853,921

I, John Mruk, Treasurer of HARCO NATIONAL INSURANCE COMPANY, certify that the foregoing is a fair statement of Assets, Liabilities, Surplus and Other Funds of this Company, at the close of business, December 31, 2024, as reflected by its books and records and as reported in its statement on file with the Insurance Department of the State of Illinois.

IN TESTIMONY WHEREOF, I have set my hand and affixed the seal of the Company, this 25th day of February, 2025.

HARCO NATIONAL INSURANCE COMPANY

SIGNED AND SWORN to before me on this 25th day of February, 2025.

NOTARY PUBLIC, STATE OF North Carolina

RYAN C. SMITH NOTARY PUBLIC FRANKLIN COUNTY, NC My Commission Expires 12-28-28

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0754159

Application/License No. _____

Rising Pharma Holdings, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 650 Randolph Road, Somerset, NJ 08873 (Address of Applicant/Principal), as PRINCIPAL, and International Fidelity Insurance Company (Surety Company), a corporation organized under the laws of the state of New Jersey (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1 Riverfront Plaza, Suite 920, Newark, NJ 07102 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 19, 2019 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 19th day of June, 2019.

APPLICANT/PRINCIPAL
Rising Pharma Holdings, Inc.

Authorized Representative

SURETY COMPANY
International Fidelity Insurance Company

Surety Company's Representative

Robyn Rost, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Pamela Wylie
Witness

Witness

Countersigned by:

Nevada Resident Agent

POWER OF ATTORNEY

Bond # 0754159

INTERNATIONAL FIDELITY INSURANCE COMPANY
ALLEGHENY CASUALTY COMPANY

One Newark Center, 20th Floor, Newark, New Jersey 07102-5207 PHONE: (973) 624-7200

KNOW ALL MEN BY THESE PRESENTS: That **INTERNATIONAL FIDELITY INSURANCE COMPANY,** a corporation organized and existing under the laws of the State of New Jersey, and **ALLEGHENY CASUALTY COMPANY** a corporation organized and existing under the laws of the State of New Jersey, having their principal office in the City of Newark, New Jersey, do hereby constitute and appoint

MICHAEL PARR, ROBYN ROST

Summmit, NJ

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **INTERNATIONAL FIDELITY INSURANCE COMPANY and ALLEGHENY CASUALTY COMPANY,** as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **INTERNATIONAL FIDELITY INSURANCE COMPANY** and **ALLEGHENY CASUALTY COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 20th day of July, 2010 and by the Board of Directors of **ALLEGHENY CASUALTY COMPANY** at a meeting duly held on the 10th day of July, 2015 :

"**RESOLVED,** that (1) the Chief Executive Officer, President, Executive Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **INTERNATIONAL FIDELITY INSURANCE COMPANY** and **ALLEGHENY CASUALTY COMPANY** have each executed and attested these presents on this 31st day of December, 2017

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1984 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

George R. James
Executive Vice President (International Fidelity Insurance Company) and
Vice President (Allegheny Casualty Company)

ALLEGHENY CASUALTY COMPANY 1936 NEW JERSEY

On this 31st day of December, 2017 , before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly swom, said he is the therein described and authorized officer of **INTERNATIONAL FIDELITY INSURANCE COMPANY** and of **ALLEGHENY CASUALTY COMPANY;** that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC MY COMMISSION EXPIRES 04-16-2019 STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2019

CERTIFICATION

I, the undersigned officer of **INTERNATIONAL FIDELITY INSURANCE COMPANY** and **ALLEGHENY CASUALTY COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, June 19, 2019

B31765 USI Insurance Services, LLC.

Maria H. Branco, Assistant Secretary

INTERNATIONAL FIDELITY INSURANCE COMPANY

ONE NEWARK CENTER, 20TH FLOOR, NEWARK, NEW JERSEY 07102-5207

STATEMENT OF ASSETS, LIABILITIES, SURPLUS AND OTHER FUNDS

AT DECEMBER 31, 2018

ASSETS	
Bonds (Amortized Value)	$126,525,302
Common Stocks (Market Value)	24,794,502
Mortgage Loans on Real Estate	344,840
Cash, Bank Deposits & Short Term Investments	42,240,486
Unpaid Premiums & Assumed Balances	9,544,138
Reinsurance Recoverable from Reinsurers	83,650
Electronic Data Processing Equipment	423,280
Investment Income Due and Accrued	1,307,538
Current Federal & Foreign income Tax Recoverable & Interest thereon	971,023
Net Deferred Tax Assets	1,298,541
Receivables from Parent, Subsidiaries & Affiliates	2,216,045
Other Assets	18,400,278
TOTAL ASSETS	$228,149,623

LIABILITIES, SURPLUS & OTHER FUNDS	
Losses (Reported Losses Net as to Reinsurance Ceded and Incurred But Not Reported Losses)	$8,729,241
Reinsurance Payable on Paid Losses and Loss Adjustment Expenses	1,255,433
Loss Adjustment Expenses	3,910,677
Commissions Payable, Contingent Commissions & Other Similar Charges	1,731,782
Other Expenses (Excluding Taxes, Licenses and Fees)	4,194,006
Taxes, Licenses & Fees (Excluding Federal Income Tax)	446,580
Unearned Premiums	38,599,862
Dividends Declared & Unpaid: Policyholders & Stockholders	700,000
Ceded Reinsurance Premiums Payable	2,452,973
Funds Held by Company under Reinsurance Treaties	1,031
Amounts Withheld by Company for Account of Others	70,169,700
Provision for Reinsurance	31,630
Payable to Parent, Subsidiaries and Affiliates	46,354
Other Liabilities	5,144
TOTAL LIABILITIES	$132,274,413
Common Capital Stock	$3,600,000
Gross Paid-in & Contributed Surplus	374,600
Surplus Notes	16,000,000
Unassigned Funds (Surplus)	81,855,190
Less: Treasury Stock at cost (50,682 shares common) (value incl. $45.)	5,954,580
Surplus as Regards Policyholders	$95,875,210
TOTAL LIABILITIES, SURPLUS & OTHER FUNDS	$228,149,623

I, John M Mruk, Treasurer of INTERNATIONAL FIDELITY INSURANCE COMPANY, certify that the foregoing is a fair statement of Assets, Liabilities, Surplus and Other Funds of this Company, at the close of business, December 31, 2018, as reflected by its books and records and as reported in its statement on file with the Insurance Department of the State of New Jersey.

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

IN TESTIMONY WHEREOF, I have set my hand and affixed the seal of the Company, this 22nd day of February, 2019.
INTERNATIONAL FIDELITY INSURANCE COMPANY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 330 Wyckoff Mills Road

City: East Windsor State: NJ Zip: 08520

Mailing Address (if different from physical address): c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.risingpharma.com

Licensing Company Email: RPI@slsny.com

Section 2: Personal Information

First: George Middle: F Last: Skibo

Alias(es, nicknames, name changes, etc.): George F Skibo Jr.

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Jackson State: NJ Zip: [redacted]

Telephone: [redacted] Email: gskibo@risingpharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
William Patterson University			01/2005 - 12/2005
Address	**City**	**State**	**Zip**
300 Pompton Rd.	Wayne	NJ	07470
Diploma/Degree obtained, if any			
N/A			

School Name			From - To (MM/YY – MM/YY)
Ocean County College			09/2004 - 12/2004
Address	**City**	**State**	**Zip**
1 College Dr.	Toms River	NJ	08754
Diploma/Degree obtained, if any			
N/A			

School Name			From - To (MM/YY – MM/YY)
Manchester Township High School			09/1999 - 06/2003
Address	**City**	**State**	**Zip**
Manchester Township High School	Manchester Township	NJ	08759
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2013 - Present	[redacted]	Jackson	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals			05/2025 - Present	
Business Address		**City**	**State**	**Zip**
330 Wyckoff Mills Road		East Windsor	NJ	08520
Phone	**Title**		**Number of Employed Hours**	
(201) 961-9000	Operations Manager		~ 259 hours	

Description of Duties
Oversee pharmaceutical warehouse operations to maintain efficiency and regulatory standards. Maintain rigorous compliance with FDA, GMP, and industry standards to ensure safe handling and storage of regulated products. Partner with supply chain teams to optimize inventory levels and support on-time, in-full delivery performance. Spearhead continuous improvements in warehouse processes, including enhancements to the Warehouse Management System (WMS) to boost productivity and reduce errors.

Business Name			From - To (MM/YY – MM/YY)	
Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals			11/2022 - 05/2025	
Business Address		**City**	**State**	**Zip**
650 Randolph Road		Somerset	NJ	08873
Phone	**Title**		**Number of Employed Hours**	
(201) 961-9000	Operations Manager (03/24 -05/2025) Assistant Operations Manager (11/22 - 03-24)		~ 5,198 hours	

Description of Duties
Oversee daily operations of a high-volume pharmaceutical warehouse, managing a team of 45 employees. Ensure compliance with FDA, GMP, and other regulatory requirements for handling and storage of pharmaceutical products. Implement and optimize warehouse management systems (WMS) to streamline inventory tracking and order fulfillment processes. Supported daily warehouse operations, including inventory management, order processing, and staff supervision. Assisted in the implementation of new processes and technologies to improve operational efficiency.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - No discipline to report

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, George F Skibo Jr., **certify that as the designated representative for**

Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. GS I am at least 21 years of age;
3. GS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. GS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. GS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. GS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. GS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

George F Skibo Jr.
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/18/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

George F Skibo Jr.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/18/25

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Middlesex

I, George Skibo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature George F Skibo Jr.

6/18/25

Date

Subscribed and Sworn to before me this 18 day of JUNE, 2025.

Notary Public Signature

MAUREEN CHIRCOP
NOTARY PUBLIC
STATE OF NEW JERSEY
MY COMMISSION EXPIRES OCTOBER 17, 2028
COMMISSION: #50214959

(Seal)

List of Employees

Rising

Rising Pharma Holdings, Inc.

List of current employees at the 330 Wyckoff Road East Windsor, NJ 08520 facility.

George Skibo - Ops Manager

Deval Patel - QA Supervisor

Dave Lawrence - Inbound Supervisor

Rodney Daniels - Outbound Supervisor

Nelson Arina - Outbound Associate

Sonia Ramirez - Serialization Associate

Alhassan Gbla - Inbound Associate

Clarence Davis - Outbound Associate

Yolanda Murillo - Outbound Associate

4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: True Marker Pharmaceuticals

Physical Address: 4602 E. Elwood St. Suite #11

City: Phoenix, AZ State: Arizona Zip: 85040

Mailing Address (if different from physical address): same as Above

City: _____ State: _____ Zip: _____

Telephone 602-881-9879 Website: www.truemarkerpharma.com

Name of Designated Representative (DR): Davin Deb

Licensing Company Email: compliance@truemarkerpharma.com DR Email: davin@truemarkerpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☐ Controlled Substances	☒ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: non-controlled substances	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Taro Pharmaceuticals
Address: 1 Commerce Dr. City: Cranbury State: NJ Zip: 08512

Name: Gadal Laboratories, Inc
Address: 12178 SW 128th St. City: Miami State: FL Zip: 33186

Name: Samson Pharmaceuticals, Inc.
Address: 5635 Smithway St. Room 2 City: Commerce State: CA Zip: 90040

Name: Dharma Research Inc.
Address: 5220 NW 72nd Ave Unit #15 City: Miami State: FL Zip: 33166

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation

State of Incorporation: Arizona
Parent Company (if any):
Corporation Name: True Marker Pharmaceuticals, Inc.
Mailing Address: 4602 E. Elwood St. Suite #11
City: Phoenix State: AZ Zip: 85040
Telephone: 602-887-9879 Email: compliance@truemarkerpharma.com
Contact Person Name: Davin R. Deb

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

True Marker Pharmaceuticals, Inc

Facility Name

Davin Deb

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/21/25

Date

Board Use Only	Date Received: _____	Amount: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered.				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DAVIN DEB
Print Name of Authorized Person Submitting Application

D. Deb
Original signature of Authorized Person (copies or stamps not accepted)

6/17/25
Date

Board Use Only	Date Received: 6/18/25	Amount: $1000.00

Drug Establishments Current Registration Site

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
True Marker Pharmaceuticals, Inc.	3030341855	119046582	LABEL; MANUFACTURE; PACK	4602 E Elwood St Ste 11, Phoenix, Arizona (AZ) 85040, United States (USA)	12/31/2025



truemarker
PHARMACEUTICALS

Ownership Information

Corporation: True Marker Pharmaceuticals, Inc. (incorporated in Arizona)

Address: 4602 E Elwood St, Ste 11, Phoenix, AZ 85040

Corporate Officer(s)

Name	SSN	Address	Title
Davin Deb	[redacted]		CEO, Secretary, Treasurer, Chairman of the Board of Directors, & DRIC

Shareholder(s)

Name	SSN	Address	% Owned
Davin Deb, Trustee of the LEGACY HEALTHCARE TRUST, dated November 23rd, 2024	[redacted]		100%

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

TRUE MARKER PHARMACEUTICALS, INC.

ACC file number: 23544673

was incorporated under the laws of the State of Arizona on 06/19/2023;

That all annual reports owed to date by said corporation have been filed or delivered for filing, and all annual filing fees owed to date have been paid; and

That, according to the records of the Arizona Corporation Commission, said corporation is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **04/02/2025**

SEAL OF THE ARIZONA CORPORATION COMMISSION
DITAT DEUS
1912

Douglas R. Clark, Executive Director

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 12/05/2024
Receipt Number: 2024193769
Receipt Amount $: 1000.00

Wholesaler - Full Service

PERMIT NO
W003971

EXPIRES
10/31/2026

Issued to : True Marker Pharmaceuticals, Inc.
Davin Deb, Trustee of the LEGACY HEALTHCARE TRUST dated November 23rd, 2024
4602 E ELWOOD STREET SUITE 11 PHOENIX, AZ 85040

True Marker Pharmaceuticals, Inc.
4602 E ELWOOD STREET SUITE 11
PHOENIX, AZ 85040

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : True Marker Pharmaceuticals, Inc.
LICENSE NUMBER : W003971
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 12/05/2024
Receipt Number: 2024193771
Receipt Amount $: 1000.00

Manufacturer - Repackager

PERMIT NO
M002586

EXPIRES
10/31/2026

Issued to : True Marker Pharmaceuticals, Inc.
Davin Deb, Trustee of the LEGACY HEALTHCARE
TRUST dated November 23rd, 2024
4602 E ELWOOD ST STE 11 PHOENIX, AZ 85040

True Marker Pharmaceuticals, Inc.
4602 E ELWOOD ST STE 11
PHOENIX, AZ 85040

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : True Marker Pharmaceuticals, Inc.
LICENSE NUMBER : M002586
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

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- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 101537810

Application/License No. _____

True Marker Pharmaceuticals, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4602 E Elwood Street, Suite 11 Phoenix, AZ 85040 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 12, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 12th day of June, 2025.

APPLICANT/PRINCIPAL

True Marker Pharmaceuticals, Inc.

Authorized Representative

SURETY COMPANY

Merchants Bonding Company (Mutual)
Surety Company's Representative

Cyndi Beilman, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

LP 4229 NV (5/21)

Posted February 20, 2020

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA

County of San Diego }

On June 12, 2025 (Date) before me, Jamie Magnussen (Insert Name of Notary exactly as it appears on the official seal), Notary Public,

personally appeared Cyndi Beilman (Name(s) of Signer(s))

JAMIE MAGNUSSEN
Notary Public - California
San Diego County
Commission # 2517158
My Comm. Expires Apr 13, 2029

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

Witness my hand and official seal.

Signature _____ (Signature of Notary Public)

Place Notary Seal Above

OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of the form to another document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____
☐ Individual
☐ Corporate Officer — Title(s): _____
☐ Partner ☐ Limited ☐ General
☑ Attorney in Fact
☐ Trustee
☐ Guardian or Conservator
☐ Other: _____

Signer is Representing:

RIGHT THUMBPRINT OF SIGNER
Top of thumb here

Signer's Name: _____
☐ Individual
☐ Corporate Officer — Title(s): _____
☐ Partner ☐ Limited ☐ General
☐ Attorney in Fact
☐ Trustee
☐ Guardian or Conservator
☐ Other: _____

Signer is Representing:

RIGHT THUMBPRINT OF SIGNER
Top of thumb here

MERCHANTS BONDING COMPANY™

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, and MERCHANTS NATIONAL INDEMNITY COMPANY , an assumed name of Merchants National Bonding, Inc., (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Cyndi Beilman

their true and lawful Attorney(s)-In-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the By-Laws adopted by the Board of Directors of the Companies.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-In-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship o obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner - Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 12th day of June , 2025 .

MERCHANTS BONDING COMPANY (INCORPORATED -o- 1933) (MUTUAL)
MERCHANTS NATIONAL BONDING, INC. (INCORPORATED -o- 2003)
MERCHANTS NATIONAL INDEMNITY COMPANY (CALIFORNIA)

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor

President

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 12th day of June 2025 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL), MERCHANTS NATIONAL BONDING, INC., and MERCHANTS NATIONAL INDEMNITY COMPANY; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA

Penni Miller
Commission Number 787952
My Commission Expires
January 20, 2027

Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, Elisabeth Sandersfeld, Secretary of MERCHANTS BONDING COMPANY (MUTUAL), MERCHANTS NATIONAL BONDING, INC., and MERCHANTS NATIONAL INDEMNITY COMPANY do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 12th day of June , 2025 .

MERCHANTS BONDING COMPANY (INCORPORATED -o- 1933) (MUTUAL)
MERCHANTS NATIONAL BONDING, INC. (INCORPORATED -o- 2003)
MERCHANTS NATIONAL INDEMNITY COMPANY (CALIFORNIA)

Secretary

POA 0018 (5/25)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler True Marker Pharmaceuticals
Pharmacy/Wholesaler License # (if applicable) WD03971
Physical Address 4602 E. Elwood St. Suite #11
City Phoenix State AZ Zip 85040
Mailing Address (if different from physical address) same as Above
City _____ State _____ Zip _____
Telephone 602-887-4879 Website www.truemarkerpharma.com
Licensing Company Email compliance@truemarkerpharma.com

Section 2: Personal Information

First Davin Middle Roy Last Deb
Alias(es, nicknames, name changes, etc.) N/A
Date of Birth [redacted] SSN or ITI [redacted] Sex ☒ M ☐ F ☐ X
Mailing Address [redacted]
City Mesa State AZ Zip [redacted]
Telephon [redacted] Email davin@truemarkerpharma.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: University of California Riverside			From - To (MM/YY – MM/YY)
Address	City: Riverside	State: CA	Zip
Diploma/Degree obtained, if any: Bachelor's degree			
School Name: American Heritage University			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any: Master's degree			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 12/2014 - Present	Address: [redacted]	City: Mesa	State: AZ	Zip: [redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name: True Maker Pharmaceuticals, Inc.				From - To (MM/YY – MM/YY): 06/2023-Present
Business Address: 4602 E. Elwood St. Suite#11		City: Phoenix	State: AZ	Zip: 85040
Phone: 602-887-4879	Title: CEO, DRIC		Number of Employed Hours: 7,500	
Description of Duties: Pharmacy Management, Quality control, quality assurance, corporate operations				
Business Name: Dsquared Pharmaceuticals				From - To (MM/YY – MM/YY): 11/2014 - 4/2022
Business Address: 4050 E. Cotton Center Blvd Suite# 63		City: Phoenix	State: AZ	Zip: 85040
Phone: 602-466-1310	Title: CEO		Number of Employed Hours: 40,000	
Description of Duties: Pharmacy management, quality control, quality assurance, corporate operations				
Business Name: Pogosyan Corporation				From - To (MM/YY – MM/YY): 08/2011 - 11/2014
Business Address: 200 S. Louise St.		City: Glendale	State: CA	Zip: 91205
Phone:	Title: Chief Operations Officer		Number of Employed Hours: 7,000	
Description of Duties: Pharmacy Management, quality control, quality assurance, corporate operations				
Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				
Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Davin R. Deb, **certify that as the designated representative for** True Marker Pharmaceuticals,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DD I am at least 21 years of age;
3. DD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

DAVIN DEB
Print Name (First, Last)

D-Deb
Original Signature (electronic, copies or stamps not accepted)

6/17/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DAVIN DEB

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, DAVIN DEB, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/29/25

Date

Subscribed and Sworn to before me this 29th day of May, 2025

Raine Sterling

Notary Public Signature

OFFICIAL SEAL
RAINE STERLING
NOTARY PUBLIC - ARIZONA
MARICOPA COUNTY
COMM# 649220
My Comm. Expires June 7, 2027

(Seal)

truemarker
PHARMACEUTICALS

TMP Employee List

C-Level Executive	Davin Deb	CEO/Designated Representative
Business Development	Chris Pogosyan	Dept Head
Sales/Customer Service	Eddie Munoz	Sales Manager
	Levon Pogosyan	Sales Representative
	Holly Green	Sales Representative
	Daisy Frausto	Sales Representative
	Claudia Navarro	Customer Service Rep.
Logistics	Randy Jones	Warehouse Associate
	Stacey Macfarlane	Warehouse Associate
Quality/Regulatory Compliance	Dr. Ra'Sha Porter	Quality/Regulatory Compliance Associate (Dept Head)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit No.	AZ Permit Exp Date	Business Name
WD03971	10/31/2026	True Marker Pharmaceuticals, Inc.

Address

4602 E Elwood Street

Zip	City	State
85040	Phoenix	AZ

Phone	Email	Inspection Date
(602) 687-9879	davin@truemarkerpharma.com	03/28/2025

Designated Representative	DEA #	Inspector Reviewed With
Davin Deb	non dea registrant / n/a	Davin Deb

Inspection Type

Change of Ownership

Inspection Conducted By

Steve Hulbert

ACTIVITIES

1	Controlled Substances	☐ YES	☑ NO
2	Prescription Drugs	☑ YES	☐ NO
3	Nonprescription Drugs	☑ YES	☐ NO
4	Rx Devices	☐ YES	☑ NO
5	Precursor/Regulated Chemicals	☐ YES	☑ NO
6	Veterinary Drugs	☐ YES	☑ NO

FACILITY

1	Physical plant	☑ S	☐ C/P	☐ U	☐ N/A

R4-23-605(J)(1)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

2	Environmental controls HVAC all areas	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-605(J)(1); R4-23-605(J)(5)
3	Security Alarm system - monitored x Titan	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-605(J)(2)
4	Access to drug storage areas Authorized employees	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-605(J)(3)
5	Quarantine area Dedicated location / signage posted	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-605(J)(8)

QUALITY CONTROLS

1	Product criteria	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-601(E); R4-23-605(G)(2)(3); R4-23-605(K)(1)(a)(b)
2	Storage requirements Per manufacturer labeling	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-605(J)(5); R4-23-605(K)(1)(c)
3	Temperature/humidity recording Monitored for temperature & humidity via Dixon system	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-605(K)(1)(d)

4	Written procedures SOP manual maintained	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-605(K)(1)(e)

RECORDKEEPING

1	Acquisition records Electronically maintained - ZoHo	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-601(D); R4-23-605(G)(1)(a)
2	Distribution records Electronically maintained - ZoHo	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-601(D); R4-23-605(G)(1)(a)
3	Recalls SOP 7.0	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-601(D); R4-23-605(H)(1)
4	Returns/outdates SOP 3.01	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-601(D); R4-23-605(H); R4-23-605(I)(1)(3)
5	License/permit records Copy obtained prior to account set up & maintained in ZoHo	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-605(G)(2)(a); R4-23-605(G)(3)(a)
6	Excess purchase reports No CS drug or precursor products	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR 1310.05

7	DSCSA records Maintained w/in One Scan Program	☑ S ☐ C/P ☐ U ☐ N/A	HR 3204-21 USC 301

CONTROLLED SUBSTANCES

1	Security Facility does not receive, stock or distribute controlled drug product	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR 1301.71; 1301.72; 1301.74
2	Limited-access area	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR 1301.72
3	Recordkeeping	☐ S ☐ C/P ☐ U ☑ N/A	ARS 36-2523; ARS 36-2524; R4-23-601(D); R4-23-1003; 21 CFR 1301.74; 1304.04; 21 CFR 1304.21; 21 CFR 1304.22
4	Inventory	☐ S ☐ C/P ☐ U ☑ N/A	ARS 36-2523; R4-23-1003(A)(6); 21 CFR 1304.04; 1304.11

DISTRIBUTION

1	Permittees/practitioners SOP maintained to ensure validation of vendor (supplier - SOP 2.0) and customer (recipient SOP 6.0) accounts for both initial set up and compliance with continued permit requirements	☑ S ☐ C/P ☐ U ☐ N/A	ARS 32-1983; R4-23-605(G)(2)(3)
2	Delivery Deliveries perform by UPS (small) or LTL carrier (large)	☑ S ☐ C/P ☐ U ☐ N/A	ARS 32-1904(A)(4)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

3	Location Delivery made to permitted reciplent address	☑ S	☐ C/P	☐ U	☐ N/A	ARS 32-1983(C); ARS 32-1983(D)
4	Account Prescription drug account set up matches permitted address	☑ S	☐ C/P	☐ U	☐ N/A	ARS 32-1983(E)
5	Cash and carry sales Not allowed	☐ S	☐ C/P	☐ U	☑ N/A	ARS 32-1983(C); R4-23-605(G)(4)

NOTES

Change of ownership inspection - True Marker Pharmaceuticals, Inc. (W003971) - 03/28/2025

Inspection - satisfactory

Close permit W003820 - 03/31/2025

Open permit W003971 - issued to designated representative - 03/31/2025.

Arizona State Board of Pharmacy

MANUFACTURER (DRUG) SECURITY/EQUIPMENT INSPECTION on 03/28/2025 for True Marker Pharmaceuticals, Inc.

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ License #	AZ Permit Expiration Date	Business Name
[redacted]	10/31/2026	True Marker Pharmaceuticals, Inc.

Address		
4402 E Elwood St		
Zip	**City**	**State**
85040	Phoenix	AZ
Phone	**Email**	**Inspection Date**
(602) 687-9870	compliance@truemarkerpharma.com	03/28/2025
Designated Representative	**DEA #**	**DEA Registration**
Devin Deb	non dea registrant / no cs	[redacted]
Inspection Reviewed With:	**Inspection Subject**	
Devin Deb	Change of Ownership	

ACTIVITIES

1	Controlled Substances	☐ YES	☑ NO
2	Prescription Drugs	☑ YES	☐ NO
3	Nonprescription Drugs	☑ YES	☐ NO
4	Rx Devices	☐ YES	☑ NO
5	Precursor/Regulated Chemicals	☐ YES	☑ NO
6	Repackaging	☐ YES	☑ NO

FACILITY

1	Security	☑ S	☐ C/P	☐ U	☐ N/A

ARS 32-1904(B)(3); R4-23-604(B)(7); 21 CFR 211.28(c); 21 CFR 1301.73

Alarm system - monitored by Titan

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

2	Size and space	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-604; 21 CFR 211.42(a)(b)
3	Separate or defined areas: Receipt/identification	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.42(c)(1)
4	Separate or defined areas: Rejected materials	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.42(c)(2)
5	Separate or defined areas: Released materials	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.42(c)(3)
6	Separate or defined areas: In-process materials	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.42(c)(4)
7	Separate or defined areas: Manufacturing and processing operations	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR 211.42(c)(5) Repackaging operations only
8	Separate or defined areas: Packaging and labeling	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.42(c)(6)
9	Separate or defined areas: Quarantine of drug products before release	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.42(c)(7)
10	Separate or defined areas: Storage of drug products after release	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.42(c)(8) Finished repackage products moved to adjacent warehouse area
11	Separate or defined areas: Laboratory operations	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.42(c)(9) Outsourced as needed

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

12	Separate or defined areas: Aseptic processing Not required for repackaging operation as manufactured product container is not opened or disturbed	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR 211.42(c)(10)
13	Penicillin processing None	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR 211.42(d); 211.46(d)
14	Lighting Adequate through out the facility	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.44
15	Ventilation/environmental control systems HVAC all areas	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.46
16	Plumbing City of Phoenix	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.48
17	Sewage and refuse City of Phoenix	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.50; 211.56
18	Washing/bathroom facilities	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.52
19	Physical plant Sanitation compliant	☑ S ☐ C/P ☐ U ☐ N/A	ARS 32-1966(3); 21 CFR 211.56; 211.58

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

EQUIPMENT AND UTENSILS

1	Appropriate design	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.63
2	Construction	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.65
3	Refrigerators/freezers	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR 211.142(b); 21 CFR 211.46
	None required / repackaged products require CRT condictions only		
4	Automated equipment/computer	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.68(b)
5	Filters	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR 211.72
	None required		

STORAGE

1	Components, drug product containers, closures	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.80(b)(c)
2	Packaging and labeling	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.122(d)
	Labels secured in locked cabinet		
3	Drug products	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.142(b)
	OTC and legend repackaging		

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

4	Representative samples Repackaging only - samples retained for reserve	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR 211.84(b); 211.160; 21 CFR 211.165
5	Reserve samples Retained & stored in cabinet at CRT conditions	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.170(a)(b)

QUALITY CONTROLS

1	Adequate laboratory facilities Minimal laboratory testing needed / firm will send to outside lab when needed	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR 211.22
2	Written procedures and recordkeeping	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-604(K); 21 CFR 211. 21; CFR 1304.22

DISTRIBUTION

1	Distribution records Maintained electronically - ZoHo	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-601(D); R4-23-1003(A); 21 CFR 211.196
2	Stock distribution Maintained electronically - ZoHo	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-604(H); 21 CFR 211.150(a)

MANUFACTURING RECORDS

1	Master production records Hardcopy master repackaging record - maintained	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-604(K); 21 CFR 211.186(a)(b)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

2	Batch records Hardcopy batch repackaging record - maintained	☑ S ☐ C/P ☐ U ☐ N/A 21 CFR 211.134; 21CFR 211.188(a)(b); 21 CFR 211.192

CONTROLLED SUBSTANCES

1	Security Firm does not hold a DEA registration / firm does not receive, handle or distribute controlled drug product	☐ S ☐ C/P ☐ U ☑ N/A 21 CFR 1301.71(a); 1301.72
2	In-process substance security	☐ S ☐ C/P ☐ U ☑ N/A 21 CFR 1301.73
3	Limited-access area	☐ S ☐ C/P ☐ U ☑ N/A 21 CFR 1301.73; 211.28(c)

NOTES

Change of ownership inspection - True Marker Pharmaceuticals, Inc. (M002586) - 03/28/2025

Drug & Supplement Repackaging Operation

Hours of operation - Mon-Fri (09:00 - 16:30) Sat/Sun - closed

FDA labeler ID 83592
FDA facility ID 3030341855

Inspection - satisfactory

Close permit M002346 - 03/31/2025

Open permit M002586 - issued to designated representative - 03/31/2025.

truemarker
PHARMACEUTICALS

TMP STATE LICENSE LIST

State	Licensing Organization	License Type	Permit No	Issued Date	Expiration Date
Arizona	Arizona State Board of Pharmacy	Resident Wholesaler (Full Service)	W003971	3/31/2025	10/31/2026
Arizona	Arizona State Board of Pharmacy	Manufacturer - Repackager	M002586	3/31/2025	10/31/2026
Arkansas	Arkansas State Board of Pharmacy	Wholesale Ditributor of Prescription (Legend) Drugs	WD06138	4/9/2025	12/31/2026
California	California State Board of Pharmacy	Nonresident Wholesaler License	OSD 8585	4/30/2025	4/1/2026
Colorado	Colorado Board of Pharmacy	Out-of-State Wholesaler (WHO)	WHO.0008819	6/6/2025	10/31/2026
Connecticut	Department of Consumer Protection	Wholesaler of Drugs, Medical Devices, and/or Cosmetics Outside of the State of Connecticut	CWS.0005636	4/4/2025	6/30/2026
Idaho	Division of Occupational & Professional Licenses	Wholesale Distributor License	4471568	6/16/2025	12/31/2025
Kentucky	Kentucky Board of Pharmacy	Wholesaler	W07652	6/2/2025	9/30/2025
Louisiana	Louisiana Board of Drug & Device Distributors	Distributor of Legend Drugs or Devices	11577	4/16/2025	12/31/2025
Michigan	Licensing and Regulatory Affairs	Wholesaler Distributor	5306008224	5/21/2025	5/21/2027
Mississippi	Mississippi Board of Pharmacy	Wholesaler Distributor	19100	6/16/2025	12/31/2025
New Hampshire	New Hampshire Board of Pharmacy	Prescription Drug/Device Manufacturer/Wholesaler/Broker/Distributor	8315	5/12/2025	5/12/2027
New Jersey	New Jersey Department of Health, Consumer, Enviromental & Occupational Health Services	Drug or Medical Device Manufacturing or Wholesale Drug or Medical Device Business	5006508	4/18/2024	1/31/2026
New York	New York State Board of Pharmacy	Non-Resident Establishment Registered Wholesaler of Drugs and/or Devices	40788	1/31/2024	12/31/2026
North Carolina	Department of Agriculture & Consumer Srvcs Food & Drug Protection Divs	Wholesaler	2064	4/10/2024	12/31/2025
Pennsylvania	Department of Health-Drug, Device & Cosmetic	Distributor	3000010737	4/7/2025	4/30/2026
Texas	Texas Department of Health Services	Rx Out of State Wholesaler	1003808	3/14/2024	1/22/2026
Virginia	Virginia Dept of Health Professions BOP	Non-Resident Wholesale Drug Distributor	219002153	5/1/2025	2/28/2026
Virginia	Virginia Dept of Health Professions BOP	Non-Resident Manufacturer	238000320	6/12/2025	2/28/2026
West Virginia	West Virginia Board of Pharmacy	Non-Resident Wholesale Drug Distributor	WD0560727	4/8/2025	6/30/2026
West Virginia	West Virginia Board of Pharmacy	Non-Resident Manufacturer	MR0552706	4/8/2025	6/30/2026

4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: TSC Life US Inc.

Physical Address: 6400 S. Fiddlers Green Circle, Suite 305

City: Greenwood Village State: CO Zip: 80111

Mailing Address (if different from physical address): 6400 S Fiddlers Green Circle Suite 305

City: Greenwood Village State: CO Zip: 80111

Telephone: 773-520-4980 Website: https://www.tsc-life.com/

Name of Designated Representative (DR): Christopher Duffie

Licensing Company Email: chris.duffie@tsc-life.com DR Email: chris.duffie@tsc-life.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☒ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No suppliers sold, dispensed or distributed within last year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: CO

Parent Company (if any): The Surgical Company Holding B.V.

Corporation/Organization Name: TSC Life US Inc.

Mailing Address: 6400 S Fiddlers Green Circle Suite 305

City: Greenwood Village State: CO Zip: 80111

Telephone: 773-520-4980 Email: chris.duffie@tsc-life.com

Contact Person Name: Christopher Duffie

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

TSC Life US Inc.
Facility Name

Christopher Duffie
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2/5/25
Date

Board Use Only	Date Received: 7/8/25	Amount: $1000 - CK 3804

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
TSC Life
Bedrijvenpark Twente Noord 48
Almelo Overijssel, NL 7602 KR
Registration Number: 3021073836
FEI Number*: 3021073836
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
THE SURGICAL COMPANY INTERNATIONAL BV[6]
Beeldschermweg 6F
AMERSFOORT, Utrecht NL 3821 AH
Owner/Operator Number: 9101201[7]

Official Correspondent:
Federica Federici
Beeldschermweg 6F
AMERSFOORT, Utrecht NL 3821 AH
Phone: 31-6-19163910

US Agent:
Chris Duffie
TSC Life US Inc.
6400 S Fiddlers Green Cir Ste 305
Greenwood Village, CO US 80111
Phone: 773 5204980 Ext
Email: Fda.Tsclife-Us@Tsc-Group.Com

√ verified 7/16/25 M.H

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9101201&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9101201&OwnerOperator

Page Last Updated: 05/05/2025

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

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1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
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4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

TSC LIFE

Description of Operations

TSC Life US Inc. is a Virtual Manufacturer. TSC Life US Inc.'s products are manufactured by a Contract Manufacturer and will be distributed to hospital pharmacies by their Third-Party Logistics Provider, LifeScience Logistics, LLC , who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturers to produce our product:

The Surgical Company International B.V.
Bedrijvenpark Twente Noord 48, Almelo, 7602 KR
FDA Establishment Number: 31029240

Contact Person: Ewoud Welten
Contact Number: +31 33 450 72 50

Axess Vision Technology SAS
6 Zone de la Liodière, rue de la Flottière, Joué-lès-Tours, 37300
FDA Establishment Number: 488295759

Contact Person: Ewoud Welten
Contact Number: +31 33 450 72 50

TSC Life US Inc's. CMO's manufacture and package TSC Life US Inc.'s product. At no time do the CMO's own the product, contract with TSC Life US Inc.'s customers, invoice, nor sell a TSC Life US Inc. product. TSC Life US Inc.'s products not Controlled Substances.

FDA Device Registration Number: 3030478437

Third Party Logistic information:
For distribution into the commercial supply channels, LifeScience Logistics, LLC acts as TSC Life US Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of TSC Life US Inc.'s product-throughout the United States. LifeScience Logistics, LLC's address is:

LifeScience Logistics, LLC
1105 East Northfeld Drive
Kayla Plocar
817-374-0582

TSC Life US Inc. has 1 employee working on site during normal business hours.

TSC Life US Inc.'s hours of operation are 9:00 am – 5:00pm Monday through Friday.

TSC Life US Inc.'s records are stored at The Surgical Company International B.V. and Axess Vision Technology.

TSC Life US Inc.'s facility square footage is 64 sq ft.

Company Information

Company Name: TSC Life US Inc.
Address: 6400 S Fiddlers Green Circle Suite 305
City, State, Zip: Greenwood Village, CO 80111
Phone: 773-520-4980
Website: https://www.tsc-life.com/
E-mail: letsconnect@tsc-life.com

FEIN: 3030478437
State of Formation: Colorado
Date Incorporated: 02/16/2022
File Number: 6627474

Ownership Information

TSC Life US Inc. is 100% owned by The Surgical Company Holding B.V.

Parent Company Address: Bedrijvenpark Twente Noord 48, Almelo, 7602 KR
Parent Company Phone: +1 773 520 4980
Parent Company FEIN: N/A

Officers

Christopher John Duffie, VP Commercial US
Business Address: 6400 S. Fiddlers Green Circle, Suite 305, Greenwood Village CO 80111
Business Phone: 773-520-4980

Daphne Geerke Maria Zwartjes, VP Regulatory Affairs Quality Assurance
Business Address: Beeldschermweg 6F, Amersfoort, Netherlands 3821 AH
Business Phone: +31 33 450 7250

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "TSC LIFE US INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE NOT HAVING BEEN CANCELLED OR DISSOLVED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF INCORPORATION, FILED THE SEVENTEENTH DAY OF FEBRUARY, A.D. 2022, AT 4:43 O`CLOCK P.M.

CERTIFICATE OF AMENDMENT, CHANGING ITS NAME FROM "TSC ENDOVISION USA, INC." TO "TSC LIFE US INC.", FILED THE SEVENTEENTH DAY OF JANUARY, A.D. 2024, AT 2:20 O`CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID CORPORATION, "TSC LIFE US INC.".

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

6627474 8310

SR# 20251413954

Authentication: 203369137

Date: 04-06-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "TSC LIFE US INC." WAS INCORPORATED ON THE SEVENTEENTH DAY OF FEBRUARY, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203369137

Date: 04-06-25

6627474 8310

SR# 20251413954

You may verify this certificate online at corp.delaware.gov/authver.shtml

State Of Delaware

Entity Details

10/29/2024 11:47:32AM

File Number: 6627474
Incorporation Date / Formation Date: 2/17/2022
Entity Name: TSC LIFE US INC.
Entity Kind: Corporation
Entity Type: General
Residency: Domestic
State: DELAWARE
Status: Good Standing
Status Date: 2/28/2024

Registered Agent Information

Name: THE CORPORATION TRUST COMPANY
Address: CORPORATION TRUST CENTER 1209 ORANGE ST
City: WILMINGTON
Country:
State: DE
Postal Code: 19801
Phone: 302-658-7581

Tax Information

Last AnnualReport Filed: 2023
Tax Due: $ 0
Annual Tax Assessment: $175
Total Authorized Shares: 1000

Filing History (Last 5 Filings)

Seq	Description	No of Pages	Filing Date mm/dd/yyyy	Filing Time	Effective Date mm/dd/yyyy
1	Amendment Name TSC ENDOVISION USA, INC.	1	20240117	142000	20240117
2	Stock Corporation	2	20220217	164300	20220217

TSC Life US Inc. is not currently licensed in their resident state of Colorado. The Colorado State Board of Pharmacy does not license device virtual manufacturers. Please see attached email from a representative of the Colorado State Board of Pharmacy confirming the licensure is not available to virtual manufacturers of medical devices.

Confirmation that CO does not license Medical Device Facilities.

From: stephanie.diaz@state.co.us <stephanie.diaz@state.co.us> **On Behalf Of** DPO_Licensing - DORA, DORA
Sent: Tuesday, April 2, 2024 3:23 PM
To: Nichole Frame <Nichole.Frame@twolabs.com>
Cc: donna.bame@state.co.us
Subject: Re: Rx Medical Devices without Drugs or Drug Components - Confirming No license required

[External]

Good day -

This is still a true statement.

Regards,

Customer Care Team

P 303.894.7800 | F 303.894.7693
1560 Broadway, Suite 1350, Denver, CO 80202
dora_dpo_licensing@state.co.us | www.dpo.colorado.gov

CONFIDENTIALITY NOTICE: This message is intended only for the use of the individual to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not an intended recipient you are not authorized to disseminate, distribute or copy this e-mail. Please notify the sender immediately if you have received this e-mail by mistake and delete this e-mail and any attachments from your system.

On Tue, Apr 2, 2024 at 7:16 AM Nichole Frame <Nichole.Frame@twolabs.com> wrote:

Good day,

I am reaching out today to confirm that the below communication is still accurate or if there has been a change in policy since August of 2023. Please confirm if there is/is not new licensing requirement for Rx Devices with neither drugs nor drug Components.

From: donna.bame@state.co.us on behalf of DPO_Licensing - DORA, DORA
To: Cheryl Midian
Subject: Re: Medical Device Licensure Question
Date: Thursday, August 17, 2023 5:55:24 PM
Attachments: image001.png
image002.png

[External]

A business that ships drugs into Colorado requires a license, not medical devices.

Confirmation that CO does not license Medical Device Facilities.

Customer Care Team
P 303.894.7800 | F 303.894.7693
1560 Broadway, Suite 1350, Denver, CO 80202
dora_dpo_licensing@state.co.us | www.dpo.colorado.gov
CONFIDENTIALITY NOTICE: This message is intended only for the use of the individual to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not an intended recipient you are not authorized to disseminate, distribute or copy this e-mail. Please notify the sender immediately if you have received this e-mail by mistake and delete this e-mail and any attachments from your system.

Thank you for your time and assistance.
Respectfully,
Nichole Frame
Licensing Analyst
Commercial-Regulatory
TwoLabs PHARMA SERVICES
110 Riverbend Ave., Suite 100 | Powell, OH | 43065
mobile 304.270.7571 | **hours** M. – F. 7:30 AM – 4:00 PM
website | **email** | **LinkedIn**

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/03/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. 8940 Lyra Drive Suite 250 Columbus, OH 43240	PHONE (A/C, No, Ext):	FAX (A/C, No):
	E-MAIL ADDRESS: client.requests@aon.com	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
TSC Life US Inc. 6400 S Fiddlers Green Circle Greenwood Village, CO 80111	INSURER A: ACE Property & Casualty Insurance Co.	20699
	INSURER B: Hartford Casualty Insurance Co.	29424
	INSURER C: Federal Insurance Company	20281
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			D97150321	06/03/2025	06/03/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 1,000,000 $ 1,000,000 $ 5,000 $ 1,000,000 $ 2,000,000 $ Excluded $
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			D97150321	06/03/2025	06/03/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ 1,000,000 $ $ $ $
A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			D97150333	06/03/2025	06/03/2026	EACH OCCURRENCE AGGREGATE [ ]	$ 4,000,000 $ 4,000,000 $
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] (Mandatory In NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		01WECAR4P8U	04/04/2025	04/04/2026	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C	Product Liability			36072325EUC	06/03/2025	06/03/2026	Agg./Each Occ.	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

TSC Life US Inc.
6400 S Fiddlers Green Circle
Greenwood Village, CO 80111

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBJI1637

Application/License No. _____

TSC LIFE US, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 6400 S Fiddlers Green Circle, Suite 305 Greenwood Village, CO 80111 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 20, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 20th day of March, 2025.

APPLICANT/PRINCIPAL
TSC LIFE US, INC.

Authorized Representative

SURETY COMPANY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

SIGNED and SEALED in the presence of:

Witness Richard Casas

Witness

Witness Ann Formhals

Countersigned by:

N/A
Nevada Resident Agent

Melena Gonzales
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID 20234015472
MY COMMISSION EXPIRES April 24, 2027

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK SERVICES CENTRAL INC
Agency Code: 83-553702

- ☒ **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- ☒ **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- ☒ **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- ☐ **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :
Derek J. Elston, Jennifer L. Jakaitis, Richard Casas, Aaron D. Griffin, Bartlomiej Siepierski, Aerie Walton of CHICAGO, Illinois

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of March 20th, 2025

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG TSC Life US Inc. MDEG License # (if applicable) _____

Physical Address 6400 S. Fiddlers Green Circle, Suite 305

City Greenwood Village State CO Zip 80111

Mailing Address (if different from physical address) 6400 S Fiddlers Green Circle Suite 305

City Greenwood Village State CO Zip 80111

Telephone 773-520-4980 Website https://www.tsc-life.com/

Licensing Company Email chris.duffie@tsc-life.com

Section 2: Personal Information

First Christopher Middle John Last Duffie

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 6400 S Fiddlers Green Circle Suite 305

City Greenwood Village State CO Zip 80111

Telephone 773-520-4980 Email chris.duffie@tsc-life.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Illinois		09/92 – 12/96	
Address	**City**	**State**	**Zip**
901 W Illinois St	Urbana	IL	61801
Diploma/Degree obtained, if any			
Bach. Science, Engineering			
School Name		**From - To (MM/YY – MM/YY)**	
Barrington High School		09/88 – 05/92	
Address	**City**	**State**	**Zip**
616 W Main St	Barrington	IL	60010
Diploma/Degree obtained, if any			
HS Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/20/2010 Current	[redacted]	Castle Pines	CO	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
TSC Life US Inc.			11/23- Present	
Business Address		**City**	**State**	**Zip**
6400 S. Fiddlers Green Circle, Suite 305		Greenwood Village	CO	80111
Phone	**Title**		**Number of Employed Hours**	
773-520-4980	VP Commercial US		2600	
Description of Duties				
At TSC Life US Inc., I have become familiar with the policies and procedures for drug distribution including storage, temperature control, security, inventory, authorized trade partners, customer returns, recalls & withdrawals, and final product disposition.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		x
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		x

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Duffie, **certify that as the MDEG Administrator for**

TSC Life US Inc.,

that I (initial that you have read and meet the following requirements):

1. CD Have a high school diploma or its equivalent;
2. CD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Duffie
Print Name (First, Last)

CHRISTOPHER DUFFIE
Original Signature (electronic, copies or stamps not accepted)

2/5/25
Date

Board Use Only	Date Received: 7/8/25

CHRIS DUFFIE

[redacted]

QUALIFICATION SUMMARY

Results-oriented, strategic thinker with extensive global sales, sales management, and general management experience. Strong leadership and strategic abilities with specific emphasis on building teams that are prepared, accountable, and focused on winning. Expert in developing and managing relationships with key opinion leaders. Skilled at working effectively within a complex matrix, leading cross-functional planning, decision-making processes, and project initiatives. Passionate about optimizing commercial organizations and developing teammates to drive sustainable growth.

PROFESSIONAL EXPERIENCE

TSC Life, Inc, Colorado **Nov, 2023 - Present**
VP Commercial US
- Build, lead and develop the capabilities and talent for TSC Life's commercial entry into the US Market.

HOLOGIC, LOUISVILLE, CO **Nov, 2021 – Sept, 2023**
Global Director of Advanced Energy
- Leading the integration of the Bolder Surgical laparoscopic technology into Hologic's strategic plan.
- Maintained responsibility for global commercial and growth objectives post-acquisition.
- Scaled the domestic sales team and grew the portfolio's revenue by 55%.
- Managed all OUS distribution activities and drove 34% growth in total revenue.

BOLDER SURGICAL, LOUISVILLE, CO **June, 2018 – Nov, 2021**
(Acquired by Hologic – November 2021)
Vice President of Global Sales
- Member of the leadership team that formed the initial relationship with Hologic and navigated the diligence process that resulted in a $160M acquisition.
- Adapted leadership direction to attain significant sales targets during the pandemic, achieved launch objectives; and delivered 56% revenue growth in 2021over 2018.
- Expanded distribution partnerships within Europe and select Asian and Middle Eastern markets more than doubling global revenue.
- Created and implemented a new sales incentive program aligned to company growth expectations.
- Reorganized away from a hybrid distribution model, redesigned desired candidate profile, and upgraded talent on the domestic sales team.

PHILIPS HEALTHCARE – IMAGE GUIDED THERAPY, COLORADO SPRINGS, CO **Aug, 2017 – June, 2018**
Segment Leader and General Manager – Lead Management, Denver, CO
- Responsible for the strategy, execution, and the P&L of the global Lead Management business; directly responsible for North American Sales, Global Marketing, and segment Research and Development.
- Led the integration effort for Lead Management business into Philip's expanding Electrophysiology franchise.
- Created and began execution of a 5-year Strategic Plan with a cadence of new product innovation aligned to strategic goals.
- 2018: Met post-acquisition revenue and growth goals while overperforming on budget and profitability targets.

SPECTRANETICS CORPORATION, COLORADO SPRINGS, CO **March, 2015 – Aug, 2017**
(Acquired by Philips Healthcare – August 2017)
Vice President of Sales – Lead Management, Denver, CO (December 2016 – December 2017)
Western Area Vice President – Lead Management, Denver, CO (December 2015 – December 2016)
- Provided strategic leadership and direction to build and sustain a world-class sales organization focused on

launching new cardiovascular lead management products, expanding market penetration, winning new customers, delivering solutions, and achieving targeted revenue growth with capital and disposable products.

- Exceeded revenue goals for new product introduction each fiscal year
- Managed a team of 6 Regional Sales Directors and 58 Territory Sales Managers
- 2015: 9% growth; 98% to plan; 157% to new product plan (responsible for 3 quarters)
- 2016: 10% growth, 101% to plan; 146% to new product plan
- 2017: 9% growth; 104% to plan; 145% to new product plan

IMACOR, INC., GARDEN CITY, NY **May, 2014 – March, 2015**

Regional Sales Director, Denver, CO

- Established partnerships with hospitals to utilize disruptive miniaturized ultrasound technology to manage the hemodynamic function of complex patients in the critical care environment.
- Responsible for all aspects of business for the Western United States including the management and development of clinical and sales personnel, development of regional thought leaders, and the revenue growth of the capital and disposable product portfolio.

INTUITIVE SURGICAL, SUNNYVALE, CA **Oct, 2006 – Jan, 2014**

Sales Director, Denver, CO (July 2010 – January 2014)

- Responsible for 5 Clinical Sales Managers and 26 Clinical Sales Representatives in 7 states.
- Strategically realigned territories across the region to best position the area for growth.
- Collaborated with colleagues from across the organization to create and implement a Sales Leadership program to better prepare high capacity and high performing representatives for management responsibilities.
- 2011: 39% procedural growth and 101.4% to quota; $53.7M in total revenue
- 2012: 30% procedural growth and 100.1% to quota; $80.1M in total revenue. Ranked 4th of 17.
- 2013: 28% procedural growth and 103.2% to quota; $101.3M in total revenue. Ranked 3rd of 19.

Sales Manager, Chicago, IL (January 2009 – June 2010)

- Responsible for 5 Clinical Sales Representatives in Illinois and Iowa.
- Mentored and developed two Clinical Sales Representatives to promotion to Clinical Sales Manager positions.
- 2009: 54% procedural growth and 102.2% to quota; $16.2M in total revenue.
- 1st half 2010: 101.5% to quota; led the nation in existing customer capital sales.

Sales Representative, Chicago, IL (October 2006 – December 2008)

- "Student of the Program" at Intuitive Surgical's 6-week sales training program in Sunnyvale.
- Developed the first robotic thoracic program in the Midwest, delivering the fastest growth of robotic lung procedures in the country.
- Successfully trained and guided over 40 surgeons through a clinical pathway to adopt robotics into their practice.
- Promoted to Field Sales Trainer in 2008.
- 2007: 164% procedural growth and 108.4% to quota.
- 2008: 114% procedural growth and 99.6% to quota.

DATASCOPE CORPORATION – MAHWAH, NJ **March, 2004 – Oct, 2006**

Sales Representative – Patient Monitoring Division, Chicago, IL

- Finished 2005 at 102% to plan.
- Finished 2006 at 101% to plan; 210% to plan in targeted categories

THE TRANE COMPANY – LA CROSSE, WI **Jan, 1997 – March, 2004**

Capital Equipment Sales Engineer – Commercial Systems Group, Providence, RI and Chicago, IL

EDUCATION

University of Illinois at Urbana-Champaign, College of Engineering
Bachelor of Science, General Engineering, 1996
Secondary Field of Study: Marketing

COMMUNITY

Littleton Hockey Association – Youth Hockey Coach, 2015-2022

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler TSC Life US Inc.
Pharmacy/Wholesaler License # (if applicable)
Physical Address 6400 S. Fiddlers Green Circle, Suite 305
City Greenwood Village State CO Zip 80111
Mailing Address (if different from physical address) 6400 S Fiddlers Green Circle Suite 305
City Greenwood Village State CO Zip 80111
Telephone 773-520-4980 Website https://www.tsc-life.com/
Licensing Company Email chris.duffie@tsc-life.com

Section 2: Personal Information

First Christopher Middle John Last Duffie
Alias(es, nicknames, name changes, etc.)
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X
Mailing Address 6400 S. Fiddlers Green Circle, Suite 305
City Greenwood Village State CO Zip 80111
Telephone 773-520-4980 Email chris.duffie@tsc-life.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Illinois		09/92 – 12/96	
Address	**City**	**State**	**Zip**
901 W Illinois St	Urbana	IL	61801
Diploma/Degree obtained, if any			
Bach. Science, Engineering			

School Name		From - To (MM/YY – MM/YY)	
Barrington High School		09/88 – 05/92	
Address	**City**	**State**	**Zip**
616 W Main St	Barrington	IL	60010
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/10- Present	[redacted]	Castle Pines	CO	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
TSC Life US Inc.			11/23- Present
Business Address	**City**	**State**	**Zip**
6400 S. Fiddlers Green Circle, Suite 305	Greenwood Village	CO	80111
Phone	**Title**	**Number of Employed Hours**	
773-520-4980	VP Commercial US	2600	

Description of Duties

At TSC Life US Inc.. I have become familiar with the policies and procedures for drug distribution including storage, temperature control, security, inventory, authorized trade partners, customer returns, recalls & withdrawals, and final product disposition.

Business Name			From - To (MM/YY – MM/YY)
Hologic			11/21-09/23
Business Address	**City**	**State**	**Zip**
331 S 104th St Suite 200	Louisville	CO	80027
Phone	**Title**	**Number of Employed Hours**	
866-683-1743	Global Director of Advanced Energy	3814	

Description of Duties

Resume

Business Name			From - To (MM/YY – MM/YY)
Bolder Surgical			06/18-11/21
Business Address	**City**	**State**	**Zip**
331 S 104th St #200	Louisville	CO	80027
Phone	**Title**	**Number of Employed Hours**	
866-683-1743	Vice President of Global Sales	7106	

Description of Duties

Resume

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Duffie, **certify that as the designated representative for**

TSC Life US Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CD I am at least 21 years of age;
3. CD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Duffie
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/5/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Duffie

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/5/25

Date

Please have this section completed in the presence of a Notary Public.

State of Colorado, ss. County of Douglas

I, Christopher Duffie, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/5/25

Date

Subscribed and Sworn to before me this 5th day of February 2025

Notary Public Signature

HOLLY HOLSMAN
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID 20164015343
MY COMMISSION EXPIRES 04/21/2028

(Seal)

TSC LIFE

Colorado Office Employee List:

1. Christopher Duffie

4GG

164910

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☒ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WHT.MW00281	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Vitalcare Health Services, Inc. DBA: Vitalcare Health Services

Physical Address: 5301 Longley Lane, Bldg E, Unit 189 & 190

City: Reno State: NV Zip: 89511

Mailing Address (if different from physical address): 6251 Chancellor Dr Ste 119

City: Orlando State: FL Zip: 32809

Telephone: (775) 828-9589 Website:

Name of Designated Representative (DR): Todd Carlblom

Licensing Company Email: provider.services@rotech.com DR Email: tcarlblom@rotech.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Sister Location		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

NA

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: FL

Parent Company (if any): Rotech Healthcare Inc.

Corporation/Organization Name: Vitalcare Health Services, Inc.

Mailing Address: 6251 Chancellor Dr Ste 119

City: Orlando State: FL Zip: 32809

Telephone: (407) 822-4600 Email: provider.services@rotech.com

Contact Person Name: Suzy Martinez

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond** form at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond** form at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **"Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing "Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8).				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Vitalcare Health Services, Inc.

Facility Name

Penny Lohman - Director of Provider Services

Print Name of Authorized Person Submitting Application

Penny Lohman

Original signature of Authorized Person (copies or stamps not accepted)

2/27/2025

Date

Board Use Only	Date Received: _____	Amount: _____

Certificate of Compliance

Record of FDA Electronic Registration as Drug Manufacturer for

Firm Name	Facility Establishment Identifier	Data Universal Numbering System Number	Business Operations	Address	Expiration Date
VITALCARE HEALTH SERVICES	1000522896	956721187	MANUFACTURE; TRANSFILL	5301 LONGLEY LANE BLDG E UNITS 189 & 190, RENO, Nevada (NV) 89511, United States (USA)	12/31/2025

See http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm for the official FDA Electronic Drug Registration database.

This certificate and the FDA Drug Establishment Registration expires 31 December 2025

ROTECH HEALTHCARE INC.

Owners of Rotech Healthcare Inc.

Capital Research and Management Company (privately owned company) owns 46.5% of Rotech's equity
Address: 333 South Hope Street, 55th Floor
Los Angeles, CA 90071
Tax ID: 951411037

Silver Point Finance, LLC (privately owned company) owns 32.7% of Rotech's equity
Address: Two Greenwich Plaza, 1st
Floor Greenwich, CT 06830
TaxID: 223849636

Venor Capital Management L.P. (privately owned company) owns 20.8% of Rotech's equity
Address: 7 Times Square, Suite 4303
New York, NY 10036
TaxID: 043816218

Capital Research and Management Company, Silver Point Finance, LLC and Venor Capital Management L.P. hold the shares of Rotech Healthcare Inc. common stock; they also are privately owned companies. Rotech Healthcare Inc. does not have any visibility to the officers or directors of these privately owned companies.

The individuals with decision-making authority for Rotech Healthcare Inc. are our CEO Robin L Menchen and our CFO Nam Phan, both have 0% ownership.

Vitalcare Health Services, Inc. is a 100% wholly owned subsidiary of Rotech Healthcare Inc. located at
6251 Chancellor Drive, Suite 119, Orlando, FL 32809

OFFICERS FOR ALL SUBSIDIARIES OWNED BY ROTECH HEALTHCARE INC

Robin L. Menchen, Chief Executive Officer

Home Address: [redacted]

Office No. (407) 822-4600 [redacted]

Nam Phan, CFO

Home Address: [redacted]

State of Florida
Department of State

I certify from the records of this office that VITALCARE HEALTH SERVICES, INC. is a corporation organized under the laws of the State of Florida, filed on August 28, 1992.

The document number of this corporation is V60573.

I further certify that said corporation has paid all fees due this office through December 31, 2024, that its most recent annual report/uniform business report was filed on April 26, 2024, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Seventeenth day of March, 2025

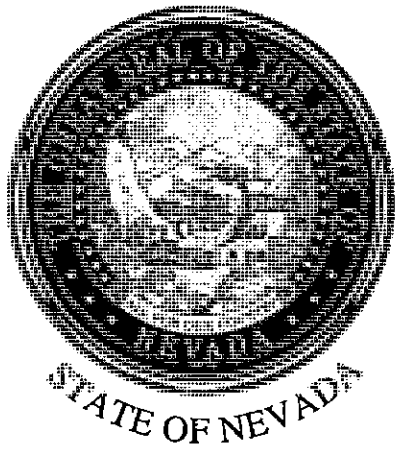
Secretary of State

Tracking Number: 7437869060CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

VITALCARE HEALTH SERVICES, INC.

Organizational Documents on File	Filing Date
Amendment	01/13/2014
Amendment	04/14/1998
Foreign Qualification	03/29/1993

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence VITALCARE HEALTH SERVICES, INC., as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 03/29/1993, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/30/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202501305397793
You may verify this certificate online at
https://www.nvsilverflume.gov/home

Nevada State Board Of Pharmacy

(Firm mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 09/27/2024
Amount: $ 525.00
Permit #: MW00281

VITALCARE HEALTH SERVICES
5301 Longley Lane
Bldg. E, Unit 189 & 190
RENO NV 89511

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Permit #
MW00281
Active

Medical Devices Equipment Gas
Effective Date:11/01/2024
Expires:10/31/2026

VITALCARE HEALTH SERVICES
5301 Longley Lane
Bldg. E, Unit 189 & 190
RENO NV 89511

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Medical Devices Equipment Gas

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENCED

Permit Type: Medical Devices Equipment Gas
Permit #: MW00281
Effective Date: 11/01/2024

Expires: 10/31/2026
STATUS: Active

VITALCARE HEALTH SERVICES
5301 Longley Lane
Bldg. E, Unit 189 & 190
RENO NV 89511

NONTRANSFERABLE

POST THIS PERMIT PROMINENTLY IN A CONSPICUOUS PLACE

City of Reno

BUSINESS LICENSE

VITALCARE HEALTH SERVICES INC

DBA: VITALCARE HEALTH SERVICES INC

SUZY L MARTINEZ

5301 LONGLEY LN UNIT 189
RENO, NV 89511

LICENSE TYPE: DIST/MFG/WHS

LICENSE #: **R126920A-LIC**

EXPIRES: **12/31/2025**

ANNUAL LICENSE

In accordance with the provisions of Reno Municipal Code Titles 4 and 5, the above named is hereby granted a City of Reno business license and is authorized to conduct the business activity listed. This license is valid until the expiration date unless suspended, revoked or cancelled and shall not be transferred or assigned.

DIRECTOR OF BUSINESS LICENSING

CITY CLERK

This license must be displayed in a conspicuous place pursuant to RMC Sec. 4.04.180(3). You may verify this business license online at www.onenv.us.

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

VITALCARE HEALTH SERVICES, INC.

Nevada Business Identification # NV19931039119
Expiration Date: 03/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 03/13/2024.

Certificate Number: B202403134460614
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State

ROTEHEA-01 KARENPETERS

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 6/4/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER NFP Property & Casualty Services, Inc. 159 Wolf Road Suite 200 Albany, NY 12205	CONTACT NAME: Karen A Peters PHONE (A/C, No, Ext): (518) 244-4298 FAX (A/C, No): (518) 244-4262 E-MAIL ADDRESS: karen.peters@nfp.com
INSURED Rotech Healthcare Inc. 6251 Chancellor Drive, Suite 119 Orlando, FL 32809	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : State National Insurance Company Inc — 12831 INSURER B : Indemnity Insurance Company of North America — 43575 INSURER C : ACE American Insurance Company — 22667 INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			VGM D1024 G6289-6	6/1/2025	6/1/2026	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Incidental Medical P						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:						EBL Aggregate	$ 1,000,000
B	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$ 2,000,000
	X ANY AUTO			ISA H1082509A	6/1/2025	6/1/2026	BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	UMBRELLA LIAB X OCCUR			VGM UM1024 6697-6	6/1/2025	6/1/2026	EACH OCCURRENCE	$ 10,000,000
	X EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 10,000,000
	DED RETENTION $						Except Auto	$ 5,000,000
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			WLP C72631687	6/1/2025	6/1/2026	X PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
A	E&O/Professional Lia			VGM D1024 G6289-6	6/1/2025	6/1/2026	Each Claim	1,000,000
A				VGM D1024 G6289-6	6/1/2025	6/1/2026	Aggregate	3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Job Lawson # 164910
Evidence of Insurance for Rotech Healthcare Inc. and Subsidiaries.

CERTIFICATE HOLDER

Vitalcare Health Services, Inc.
Vitalcare Health Services
5301 Longley Lane, Bldg E
Reno, NV 89509

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Matt Thill

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800011503

Application/License No. _____

VitalCare Health Services, Inc dba VitalCare Health Services (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5301 Longley Lane, Bldg. E, Unit 189 & 190, Reno, NV 89511 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 601 Carlson Parkway, Minnetonka, MN 55345 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 7, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 7th day of February, 2025.

APPLICANT/PRINCIPAL

COMPANY
VitalCare Health Services, Inc dba VitalCare Health Services

Authorized Representative

Robin L. Menchen,
Chief Executive Officer

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY

Atlantic Specialty Insurance Company

Surety Company's Representative

Renee A. Manny, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A

Nevada Resident Agent

Posted February 20, 2020

STATE OF Florida)
COUNTY OF Orange)

Bond No. 800011503

CORPORATION

On this 14th day of February, 2025 before me personally came Robin L. Menchen to me known, being sworn by me, did depose and say that he/she resides in Magnolia, TX that he/she is the Chief Executive Officer of Rotech Healthcare Inc. the corporation described in and which executed the foregoing instrument; that he/she knows the said seal of such corporation; that the seal affixed to said instrument is such corporate seal; and that it was so affixed by the order of the Board of Directors of said corporation, and that he/she signed his/her name thereto by like order.

Sworn to and acknowledged on the above date, Penny L. Lohman.

Notary Public State of Florida
Penny L. Lohman
My Commission HH 143943
Expires 08/28/2028

STATE OF NEW YORK)
COUNTY OF ALBANY)

SURETY

On this 7th day of February, 2025 before me personally came Renee A. Manny to me known resides in Rensselaer, NY and duly sworn and says that he/she is the Attorney-in-fact of Atlantic Specialty Insurance Company and knows the corporate seal and that it was affixed thereto by authority of the Power of Attorney of said Company; of which a certified copy is attached; and that he/she signed said instrument as an Attorney-in-Fact of said Company by like authority.

Sworn to and acknowledged on the above date, Jennifer S. Vanat.

JENNIFER S. VANAT
Notary Public, State of New York
Qualified in Columbia County
Reg # 01VA6135808
Commission Expires Oct. 24, 2025

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Casey LaChapelle, David W. Cooper, Jennifer Susan Vanat, Kevin J. Garrity, Maddalena Bucciero, Mark C. Nickel, Renee A. Manny, Thomas R. Tyrrell**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 7th day of February, 2025.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

intact specialty solutions

Atlantic Specialty Insurance Company

Period Ended 12/31/2023

Dollars displayed in thousands

Admitted Assets	
Investments:	
Bonds	$ 2,666,141
Preferred Stocks	-
Common Stocks	765,847
Mortgage Loans	-
Real Estate	-
Contract Loans	-
Derivatives	-
Cash, Cash Equivalents & Short Term Investments	194,124
Other Investments	9,571
Total Cash & Investments	3,635,684
Premiums and Considerations Due	338,312
Reinsurance Recoverable	127,403
Receivable from Parent, Subsidiary or Affiliates	17,691
All Other Admitted Assets	96,457
Total Admitted Assets	4,215,546

Liabilities and Surplus	
Liabilities	
Loss Reserves	$ 1,191,377
Loss Adjustment Expense Reserves	401,505
Total Loss & LAE Reserves	1,592,881
Unearned Premium Reserve	806,718
Total Reinsurance Liabilities	45,997
Commissions, Other Expenses, and Taxes due	78,425
Derivatives	-
Payable to Parent, Subs or Affiliates	-
All Other Liabilities	810,774
Total Liabilities	3,334,795
Capital and Surplus	
Common Capital Stock	9,001
Preferred Capital Stock	-
Surplus Notes	-
Unassigned Surplus	254,805
Other Including Gross Contributed	616,946
Capital & Surplus	880,751
Total Liabilities and C&S	4,215,546

State of Minnesota
County of Hennepin

I, Kara L.B. Barrow, Secretary of Atlantic Specialty Insurance Company do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said Company, on the 31st day of December, 2023, according to the best of my information, knowledge and belief.

Secretary

Subscribed and sworn to, before me, a Notary Public of the State of Minnesota on this 3rd day of May, 2024.

Notary Public

KERRI RIECHERS
Notary Public
Minnesota
My Commission Expires January 31, 2025

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Vitalcare Health Services MDEG License # (if applicable) MW00.281

Physical Address 5301 Longley Lane, Bldg E, Ste. 189-190

City Reno State NV Zip 89434

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 775-828-9581 Website rotech.com

Licensing Company Email tcarlblo@rotech.com

Section 2: Personal Information

First Todd Middle Robert Last Carlblom

Alias(es, nicknames, name changes, etc.) None

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Sparks State NV Zip [redacted]

Telephon [redacted] Email tcarlblo@rotech.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Barnesville Highschool			09/1985 – 05/1987
Address	**City**	**State**	**Zip**
302 3rd St. SE	Barnesville	MN	56514
Diploma/Degree obtained, if any			
Diploma			

School Name			From - To (MM/YY – MM/YY)
Alexandria Technical College			09/1996 – 05/1998
Address	**City**	**State**	**Zip**
1601 Jefferson Street	Alexandria	MN	56308
Diploma/Degree obtained, if any			
AAS of Law Enforcement			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2002 – Present	[redacted]	Sparks	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Vitalcare Health Services			From - To (MM/YY – MM/YY): 01/2000 to Present
Business Address: 5301 Longley Lane, Bldg. E, Ste. 189-190	City: Reno	State: NV	Zip: 89511
Phone: 775-828-9589	Title: District Transfill Manager		Number of Employed Hours: +50,000 hours
Description of Duties: Manage the production & distribution of medical grade oxygen and the repair & distribution of durable medical equipment.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) _____ Date _____

I, Todd Carlblom, certify that as the MDEG Administrator for VitalCare Health Services,

that I (initial that you have read and meet the following requirements):

1. TC Have a high school diploma or its equivalent;
2. TC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. TC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. TC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Todd Carlblom
Print Name (First, Last)

Todd R. Carl
Original Signature (electronic, copies or stamps not accepted)

4/29/25
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Vital Care Health Services

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5301 Longley Lane, Bldg. E, Ste. 189-190

City Reno State NV Zip 89511

Mailing Address (if different from physical address) 6251 Chancellor Dr., Ste. 119

City Orlando State FL Zip 32809

Telephone 775-828-9589 Website Rotech.com

Licensing Company Email _____

Section 2: Personal Information

First Todd Middle Robert Last Carlblom

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Sparks State NV Zip [redacted]

Telephone [redacted] Email tcarlblo@rotech.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Alexandria Technical College			From - To (MM/YY – MM/YY): 09/96 - 05/98
Address: 1601 Jefferson Street	City: Alexandria	State: MN	Zip: 56308
Diploma/Degree obtained, if any: AAS of Law Enforcement			
School Name: Barnesville High School			From - To (MM/YY – MM/YY): 09/83 - 05/89
Address: 302 3rd St. SE	City: Barnesville	State: MN	Zip: 56514
Diploma/Degree obtained, if any: Diploma			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/02 - Present	[redacted]	Sparks	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Vitalcare Health Services			01/2000 to Present
Business Address	**City**	**State**	**Zip**
5301 Longley Lane, Bldg. E, Ste. 134-190	Reno	NV	89511
Phone	**Title**	**Number of Employed Hours**	
775-828-9589	District Transfill Manager	+52,000 hours	
Description of Duties			
Manage the production & distribution of medical grade oxygen and the repair & distribution of durable medical equipment.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Todd Carlblom, **certify that as the designated representative for**

Vital Care Health Services,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TC I am at least 21 years of age;
3. TC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Todd Carlblom

Print Name (First, Last)

Todd R. Carlblom

Original Signature (electronic, copies or stamps not accepted)

2/24/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Todd Carlblom

Print Name (First, Last)

Todd R. Carlblom — 2/24/25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Todd Carlblom, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Todd R. Carlblom — 2/24/25

Original Signature — **Date**

Subscribed and Sworn to before me this 24 day of February 2025

Noe Silva Guzman

Notary Public Signature

NOE SILVA GUZMAN
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 06-21-26
Certificate No: 22-3660-02

(Seal)

ROTECH HEALTHCARE INC.

MEMO

To: Nevada Board of Pharmacy

From: Vitalcare Health Services, Inc.

Date: 3/17/2025

Re: List of Employees

Below is the list of employees currently at the Reno, NV transfill.

Luis Gomez
Todd Carlblom

Medical Gases, Equipment and Gases (MDEG) Information	
Date Completed:	01/06/2024
MDEG Name:	Vitalcare Healthservices, INC
MDEG License #:	MW00281
MDEG Address:	5301 Longley Lane, Bldg E, Ste. 189-190, Reno, NV 89511
MDEG Telephone #:	775-828-9589
MDEG Fax #:	NA
MDEG Email:	tcarlblo@rotech.com
MDEG Administrator Name:	Todd Carlblom
MDEG Administrator Start Date:	01/24/2000

List all personnel – (Make copies of this page if additional space is needed)			
#	Name (First, Last)	License/Registration # (If applicable)	Position
1	Todd Carlblom		District Transfill Manager
2	Luis Gomez		Transfill Delivery Driver
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

Products and Services Provided	Yes	No
Assistive Equipment		✓
Respiratory Equipment	✓	
Medical Gases	✓	
Life-Sustaining Equipment		✓
Enteral Services and Equipment		✓
Orthotics and Prosthetics		✓
Stockings		✓
Insulin Pumps		✓

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Wholesaler, Manufacturer, Warehouse

Section 1: General Information	
Inspection Date:	1/14/2025
Licensee Name:	VITALCARE HEALTH SERVICES
Licensee Address:	5301 LONGLEY LN BLDG E #189 & 190, RENO NV 89511
Licensee Phone:	775-828-9589
Licensee NVBOP License #:	MW00281
Designated Representative:	TODD CARLBLOM
Accreditation Company/Expiration Date	N/A
E-mail to be utilized for inspection f/u:	tcarlblo@rotech.com
Name of Employee present for Inspection:	LUIS GOMEZ
Name of NVBOP Inspector:	MUI LEE

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: INSPECTION FORM IS COMPLETE AND READY FOR REVIEW	☒	☐
2.	Personnel List complete and accurate. Comments:	☒	☐
3.	Policy and procedures for screening and hiring employees with access to controlled substances and dangerous drugs complete and accurate. Comments: ALL EMPLOYEES ARE BACKGROUND AND DRUG TESTED	☒	☐
4.	Dangerous drugs are stored per the manufacturer's guidelines. Comments: ---------- N/A---------- NO DANGEROUS DRUG	☐	☒
5.	Facility meets security requirements as defined in NVBOP regulations . Comments:	☒	☐
6.	All records maintained for a minimum of 3 years. Comments:	☒	☐
7.	Facility has a procedure in place for monitoring for outdated or adulterated drugs. Comments: ---------- N/A---------- NO EXPIRATION DATE	☐	☒
8.	Security of the controlled substance cage meets NVBOP regulations. Comments: ---------- N/A---------- NO CONTROLLED SUBSTANCES	☐	☒

9.	Facility has documentation of monthly pest control. Comments: ONLY ON AS NEEDED BASIS	☐	☒
10.	Facility is clean and maintained in an orderly manner. Dedicated clean/dirty/quarantine areas located in warehouse. Comments: AREAS ARE PROPERLY MARKED	☒	☐
11.	Facility has a process in place to document cleaning and testing of all rental equipment. Comments: NO SEPARATE LOG FOR CLEANING, ALL PRODUCTS IN FACILITY ARE FOR REPAIR AND CLEANING IS PART OF THE PROCESS	☒	☐
12.	Facility has repair log available for review and meets all NVBOP regulations. Comments: REPAIR/PART REPLACEMENT LOG REVIEWED	☒	☐
13.	Facility has system in place to monitor for any product recalls. Comments: RECALLS ARE DONE BY CORPORATE AND THIS FACILITY IS FOR REPAIR ONLY	☒	☐

Section 3: Required Follow-Up - The following items were identified as issues which require a response from the facility manager.

Description of Issue	Response due date
- PLEASE SEND IN APPLICATION FOR WHOLESALER LICENSE INSTEAD OF RENEWING THIS LICENSE AS THIS LICENSE GROUP IS OBSOLETED	ASAP
- MAKE SURE NOT TO HAVE FOOD AROUND WORKING AREA	NEXT INSPECTION

Additional Comments:

- LICENSE POSTED AND CURRENT
- HANDWASHING SIGN POSTED IN RESTROOM
- SINK WITH HOT/COLD WATER
- PATIENT READY AND EMPTY TANK SIGNS POSTED
- NO FULL OXYGEN TANK STORED IN FACILITY, ALL ARE FILLED AND DELIVERED AS NEEDED
- OXYGEN ANALYZER CALIBRATION LOG REVIEWED
- LIABILITY INSURANCE IS GOOD TILL 6/1/2025
- THIS IS A REPAIR FACILITY ONLY SERVICING FACILITY IN SPARKS, NV
- OXYGEN IS SUPPLIED BY AIRGAS
- SDS BOOK IS AVAILABLE

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

John Castaldo – jcastaldo@pharmacy.nv.gov
Leo Basch – lbasch@pharmacy.nv.gov
Joe Dodge – j.dodge@pharmacy.nv.gov

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – m.lee@pharmacy.nv.gov
Jenine Davis – jmdavis@pharmacy.nv.gov

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

Recoverable Signature

X _____

Signature of Employee Present for Inspection

Signed by: b55d7188-f5cd-400d-b052-f22b285ce302

4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH 02662	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Animal Health International, Inc.

Physical Address: 1908 Rockefeller Drive

City: Ceres State: CA Zip: 95307

Mailing Address (if different from physical address): Attn: Regulatory Licensing 1031 Mendota Heights Road

City: Saint Paul State: MN Zip: 55120

Telephone: (209) 538-2750 Website: https://www.animalhealthinternational.com/

Name of Designated Representative (DR): Jason Divird

Licensing Company Email: facilitylicensing@pattersoncompanies.com DR Email: jason.divird@animalhealthinternational.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class I & Class II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Universities/Research		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/14/2020	5/4/2020	VA	Abingdon	Washington

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DVAW120CR000007-001	United States District Court, Western District of Virginia

Reason/Charge
Violation of 21 U.S.C. § 331(a), 333(a)(1), and 352(f)(1) - Introduction of Misbranded Drugs into Interstate Commerce

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

Original Signature (electronic, copies or stamps not accepted)

4-23-25
Date

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

FEB 14 2020

JULIA C. DUDLEY, CLERK
BY: DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20-cr-00007
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

PLEA AGREEMENT

ANIMAL HEALTH INTERNATIONAL, INC. (EIN: 84-0575063) ("AHI") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this Plea Agreement are as follows:

1. CHARGE TO WHICH AHI IS PLEADING GUILTY AND WAIVER OF RIGHTS

AHI will enter a plea of guilty to Count One of the Information charging it with violating Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) in the Western District of Virginia by introducing and delivering for introduction, and causing the introduction and delivery for introduction, into interstate commerce of veterinary prescription drugs that were misbranded.

AHI understands, and the parties agree and stipulate, the maximum statutory penalty is a fine of $14,855,856 (fourteen million eight hundred fifty-five thousand eight hundred fifty-six dollars), pursuant to Title 18, United States Code, Section 3571(d), and a period of probation of five (5) years, pursuant to Title 18, United States Code, Section 3561(c)(2). In addition, AHI's assets are subject to forfeiture. AHI understands fees may be imposed to pay for probation and there will be a $125 (one hundred twenty-five dollars) special assessment for Count One, pursuant to Title 18, United States Code, Section 3013(a)(1)(B)(iii). AHI's attorneys have informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before AHI could be found guilty as charged.

AHI admits and agrees that all of the statements and allegations in the Information are true and correct.

AHI acknowledges AHI has had all of its rights explained to it. AHI expressly recognizes that, as a corporation, AHI may have the following constitutional rights and by voluntarily pleading guilty AHI knowingly waives and gives up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses.

The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

AHI is pleading guilty as described above because AHI is in fact guilty and because AHI believes it is in its best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for its plea of guilty. AHI agrees all of the matters set forth in the Information are true and correct.

AHI understands the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree the 2018 version of the United States Sentencing Commission Guidelines Manual ("U.S.S.G.") is the appropriate Guidelines Manual to utilize. According to U.S.S.G. § 8C2.1, the organizational fine provisions do not apply to the count of conviction in this case, which is a misdemeanor under 21 U.S.C. § 333(a)(1).

The parties agree and stipulate:

a. the fine shall be $5,000,000 (five million dollars);
b. AHI shall pay $1,000,000 (one million dollars) to the Virginia Department of Health Professions ("DHP") in recognition of direct assistance provided by DHP to the United States during the investigation;
c. AHI shall forfeit $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars); and
d. AHI shall serve a term of probation of one to three years, as determined by the Court.

The Court will determine what terms and length of probation are appropriate and the parties will be free to argue for which terms and length of probation they believe are appropriate. AHI understands and agrees if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum may be imposed.

The parties agree if the Court refuses to accept this Plea Agreement with the agreed-upon sentence, AHI will be free to withdraw its guilty plea. In the event the Court refuses to accept this Plea Agreement and AHI withdraws its guilty plea within ten days of being notified of the Court's refusal, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410. Under these circumstances, the United States will move to dismiss the Information without prejudice and the United States may file any charges it could have filed in the absence of the plea agreement. AHI agrees to toll the statute of limitations between the date of the plea and the filing of any such charges.

3. FINANCIAL OBLIGATIONS

AHI agrees and understands any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept this Plea Agreement with the agreed-upon sentence and, as a result, AHI withdraws its guilty plea. If the Court rejects this Plea Agreement and AHI withdraws its guilty plea, the United States will return all money paid by AHI, without

interest, not more than thirty (30) days after AHI withdraws its guilty plea and notifies the United States Attorney's Office for the Western District of Virginia ("USAO"), in writing, it wishes to have the money returned.

In addition, in accordance with 18 U.S.C. § 3572(d)(3), AHI will notify the Court of any material change in AHI's economic circumstances that might affect AHI's ability to pay any amounts payable under this Plea Agreement.

a. Payments

Within 7 days of the entry of AHI's guilty plea, AHI will make the following disbursements:

(1) $125 (one hundred twenty-five dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the special assessment.

(2) $5,000,000 (five million dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the fine;

(3) $1,000,000 (one million dollars) to the Virginia Department of Health Professions. These funds must be remitted in the form of certified funds made payable to the "Treasurer of Virginia." The comment section of the check should note "DHP-Enforcement" in recognition of direct assistance provided to the United States during the investigation; and

(4) $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) made payable to the United States Marshals Service, as directed by the USAO as payment of a forfeiture money judgment.

b. Forfeiture

AHI agrees to the entry of a forfeiture money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency ("Forfeiture Money Judgment") pursuant to 21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c). AHI agrees that the value of the quantities of prescription drugs which were misbranded in violation of 21 U.S.C. § 331(a) totaled at least $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency.

AHI acknowledges and agrees the quantities of the drugs which were misbranded in violation of 21 U.S.C. § 331(a) cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, AHI agrees the government is entitled to forfeit as substitute assets any other assets of AHI up to the value of the now missing directly forfeitable assets, pursuant to

21 U.S.C. § 853(p). Payment in full of the Forfeiture Money Judgment shall satisfy any and all forfeiture obligations that AHI may have as a result of this guilty plea. AHI consents to the entry of an Order of Forfeiture pursuant to Rule 32.2 of the Federal Rules of Criminal Procedure forfeiting the above-referenced Forfeiture Money Judgment.

AHI agrees to sign any documentation necessary and to cooperate fully with the United States to accomplish the forfeiture. AHI agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of these funds to the United States.

AHI agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. AHI agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgement in any administrative or judicial proceeding.

AHI understands and agrees forfeiture of this property is proportionate to the degree and nature of the offense. AHI freely and knowingly waives any and all constitutional and statutory challenges to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including, but not limited to, that the forfeiture constitutes an excessive fine or punishment. AHI further understands and agrees this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty or other monetary judgment that may be imposed by the court.

c. Restitution

The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no restitution will be ordered.

4. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, AHI withdraws its plea, AHI agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny it committed the crime to which it has pled guilty; (4) comply with any reasonable request of the United States Attorney's Office and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement.

Neither AHI, nor its corporate parent (Patterson Companies, Inc. ["Patterson"]), will (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If Patterson or AHI makes a public statement that in whole or in part contradicts any such statement or provision, AHI may avoid being in violation of this Plea Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by Patterson's and AHI's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) Patterson or AHI websites. Notwithstanding the above, Patterson and AHI may avail themselves of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by

any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

5. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, AHI agrees AHI will not appeal the conviction or sentence imposed. AHI is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). AHI expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. AHI understands the United States expressly reserves all of its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, AHI may file a cross appeal of that same sentence. AHI agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this Plea Agreement.

6. INFORMATION ACCESS WAIVER

AHI agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a. However, if a third party obtains any records pertaining to the investigation or prosecution of this case under the Freedom of Information Act, AHI shall have the right to request copies of such disclosed records.

7. ADMISSIBILITY OF STATEMENTS

AHI understands any statements made on its behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against AHI by the United States in this or any other proceeding. AHI knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other proceeding. If, and only if, the Court rejects this Plea Agreement, and, as a result, AHI withdraws its plea, AHI will not be bound by the waivers set forth in this section of the Plea Agreement.

8. COMPLETION OF PROSECUTION

Pursuant to Fed. R. Crim. P. 11(c)(l)(A), so long as AHI complies with all of its obligations under this Plea Agreement, the United States agrees, other than the charge in the attached Information, it shall not further criminally prosecute AHI for any additional federal criminal

charges or forfeiture action with respect to any offenses set forth in the Information or Non-Prosecution Agreement with Patterson (Attached as Attachment B).

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

9. LIMITATION OF PLEA AGREEMENT

This Plea Agreement is limited to the United States Department of Justice and does not bind any other federal, state, or local authority.

10. COMPLIANCE AND REMEDIAL MEASURES

AHI agrees to comply with the Corporate Compliance Program Agreement attached hereto as Attachment C.

11. COOPERATION

AHI acknowledges that its ongoing and future cooperation is important and a material fact underlying the United States' decision to enter into this Plea Agreement. AHI agrees to continue to cooperate fully and actively with the United States regarding any matter, including, but not limited to, matters involving (a) current and former AHI personnel, and (b) other entities who operate in the same commercial segment as AHI and/or Patterson during the Term of the Non-Prosecution Agreement with Patterson, provided however that any cooperation in an ongoing investigation or prosecution shall continue until such investigation or prosecution is concluded.

Nothing in this Plea Agreement shall be construed to require Patterson or AHI to waive any attorney-client privilege or work-product protection.

12. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THIS PLEA AGREEMENT

AHI understands if: (1) AHI attempts to withdraw its plea (in the absence of the Court refusing to accept this Plea Agreement); (2) AHI fails to comply with any provision of this Plea Agreement; (3) AHI's conviction is set aside, for any reason; and/or (4) AHI fails to execute all required paperwork prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement titled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, AHI will still be bound by its obligations under this Plea Agreement. AHI hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of this Plea Agreement. AHI hereby waives any statute of limitations argument as to any such charges.

13. EFFECTIVE REPRESENTATION

AHI has discussed the terms of this Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, AHI has no dissatisfaction or complaint with its attorneys' representation. AHI agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint AHI may have with its attorneys' representation.

14. EFFECT OF AHI'S SIGNATURE

AHI understands its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. AHI understands the United States has not accepted AHI's offer until the authorized representative of the United States has signed this Plea Agreement.

15. GENERAL UNDERSTANDINGS

AHI understands a presentence investigation will be conducted and sentencing recommendations independent of the USAO will be made by the presentence preparer.

AHI understands the United States and AHI retain the right, notwithstanding any provision in this Plea Agreement, to inform the probation office and the Court of all facts, to address the Court with respect to the nature and seriousness of the offense and the offender, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, and to respond to any statements made to the Court.

AHI willingly stipulates there is a sufficient factual basis for the Court to accept the plea.

AHI understands this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

AHI has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. AHI understands its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. AHI understands AHI will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing, the Non-Prosecution Agreement with Patterson (attached as Attachment B), the Corporate Compliance Program Agreement (attached as Attachment C), and the Agreed Order of Forfeiture (attached as Attachment D) are the complete and only agreements between the United States and AHI concerning resolution of this matter. In addition, AHI has no objection to the filing of the Information.

The agreements and documents listed in this section set forth the entire understanding between the parties and constitute the complete agreement between the United States Attorney for the Western District of Virginia and AHI and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and AHI. AHI consents to public disclosure of all of the agreements and other documents referenced in this section.

AHI has consulted with its attorneys and fully understands its rights. AHI has read this Plea Agreement and carefully reviewed every part of it with its attorneys. AHI understands this Plea Agreement and AHI voluntarily agrees to it. Being aware of all of the possible consequences of its plea, AHI has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer ("Officer") below.

The Officer, by signing below, hereby certifies to the following:

(1) The Officer is fully authorized to enter into this Plea Agreement on behalf of AHI;

(2) The Officer has read the entire Plea Agreement and documents referenced herein and discussed them with AHI's Board of Directors;

(3) AHI understands all the terms of this Plea Agreement and those terms correctly reflect the results of plea negotiations;

(4) AHI is fully satisfied with AHI's attorneys' representation during all phases of this case;

(5) AHI is freely and voluntarily pleading guilty in this case;

(6) AHI is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea; and

(7) AHI understands it is waiving its right to appeal the judgment and conviction in this case.

AHI acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Officer. A copy of a certification by AHI's Board of Directors authorizing the Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of AHI is attached as Attachment A.

Date: 2/13/2020 Keri M. Tolman

Authorized Corporate Officer
AHI

Counsel has fully explained to the Board of Directors of AHI the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the Sentencing Guidelines; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and documents referenced herein with the client, through its Officer. AHI understands the terms and conditions of this Plea Agreement, and AHI's decision to enter into this Plea Agreement is knowing and voluntary. AHI's execution of and entry into the Plea Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED
2/11/2020
JULIA C. DUDLEY, CLERK
BY: LOTTIE LUNSFORD
DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No. 1:20CR00007**
v.	)	
	)	**Violations: 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)**
ANIMAL HEALTH INTERNATIONAL, INC.	)	

INFORMATION

INTRODUCTION

1. Defendant Animal Health International, Inc. ("AHI") is a Colorado corporation with its principal place of business in Colorado. AHI is comprised of two legacy organizations, Lextron, Inc. ("Lextron") and Walco International, Inc. ("Walco"). In June 2011, Lextron acquired all outstanding stock of the parent company of Walco and changed its name to AHI. Walco continued operations as a subsidiary of AHI until December 2011 when Animal Health Holdings, Inc. and each of its wholly-owned subsidiaries, including Walco, were merged with and into AHI and no longer had separate corporate existences. AHI, and its predecessor entities, dispense, distribute and sell, among other products, veterinary prescription drugs to customers in the production animal industry across the United States. Specifically, AHI obtains prescription drugs for production animals from manufacturers for further distribution to veterinarians, farms, feedlots, and other distribution facilities.

2. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulates the distribution and labeling of all drugs, including animal drugs, shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C § 301, *et seq.* ("FDCA"). Veterinary prescription drugs are drugs intended for use by animals that, because of their toxicity or other potentiality for harmful

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effect, or the method of their use, or the collateral measures necessary for their use, are not safe for animal use except under the professional supervision of a licensed veterinarian. 21 U.S.C. § 353(f)(1)(A).

3. Under the FDCA, a drug is misbranded if, among other things, its labeling does not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). Adequate directions for use is defined as "directions under which the *layman* can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5 (emphasis added). Prescription veterinary drugs by definition can only safely be used under the professional supervision of a licensed veterinarian and therefore they must qualify for an exemption to this requirement in order to move in interstate commerce. These exemptions are set out in 21 C.F.R. Part 201, Subpart D ("Exemptions from Adequate Directions for Use").

4. Veterinary prescription drugs are exempt from the requirement that their labeling contain adequate directions for use if they meet all enumerated conditions, including that they be distributed through a closed supply chain in which every entity that possesses a prescription drug must have legal authorization to do so. *See* 21 C.F.R. § 201.105 (a)(1) (a veterinary prescription drug must be in the possession of: a person lawfully engaged in the manufacture, transportation, storage or wholesale distribution of drugs; a retail pharmacy or other person authorized under state law to dispense veterinary prescription drugs; or a licensed veterinarian for use in the course of his professional practice). Moreover, the veterinary prescription drug must be dispensed in accordance with 21 U.S.C. § 353(f), i.e., pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian's professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105 (a)(2).

5. The FDCA's restrictions on veterinary prescription drugs are not primarily to protect animals from the potential harms of prescription drugs, but are to protect the human food supply from unsafe drug residues in the edible tissues of animals sold for slaughter. Common causes of illegal residues include: (1) exceeding the drug's approved dose; (2) using a shorter withdrawal period than what is stated on the drug's label (if a higher than approved dose is given, the labeled withdrawal period may not be enough to allow the drug in the edible tissues to deplete to levels that are at or below the tolerance); (3) using a drug in an extra-label manner (for indications and dosages outside the approved labeling) without a veterinarian's involvement; (4) giving a drug not approved for that species; and (5) using an unapproved route of administration. Drug residues in the nation's drug supply are concerning because: (1) they may contribute to antibiotic resistance in the human population, rendering human drugs less effective to treat human disease and contributing to the mutations of "superbugs"; and (2) they may cause allergic reactions in individuals with certain drug allergies.

6. Certain legacy customers of AHI, namely Marlin Webb and Billy K. Groce, were not properly licensed to receive, transport, store, distribute, or dispense veterinary prescription drugs in the Commonwealth of Virginia from January 2012 through April 2015.

7. Webb was the store manager of a cooperative in Hillsville, Virginia. The cooperative was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Webb operated a side business from the cooperative's location in which he illegally circumvented the FDA's regulation of veterinary prescription drugs by illegally obtaining from Billy K. Groce and AHI and reselling veterinary prescription drugs using unlawful prescriptions written by a veterinarian who was licensed in Tennessee but who was not properly licensed to

practice veterinary medicine in Virginia and who did not have a veterinarian-patient relationship with the animals in question. That veterinarian died in 2015.

8. Groce was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Groce operated an unlicensed veterinary prescription drug distribution business. Groce worked with the same veterinarian as did Webb.

9. Webb and Groce obtained veterinary prescription drugs from AHI in interstate commerce without valid prescriptions, and, on many occasions, with no prescription at all.

10. On April 29, 2015, the government executed search warrants at locations in Virginia and Tennessee associated with Groce and Webb. In 2016 and 2017, respectively, Groce and Webb pled guilty to illegally conspiring to defraud the FDA by obtaining and distributing veterinary prescription drugs from July 2009 through April 29, 2015 in a manner that circumvented the FDA's regulation of veterinary prescription drugs.

11. Groce and Webb were legacy customers of, among others, Lextron and Walco, and continued to be customers after the companies merged to form AHI in 2012 until May 2015. Neither Lextron, Walco, nor AHI performed adequate customer diligence processes, nor adequately trained sales representatives to raise questions regarding Groce's, Webb's or the veterinarian's activities in Virginia and Tennessee. For example, Groce operated a business that stored and distributed veterinary prescription drugs out of a storefront called "Goin' Postal" and his personal residence. Neither of those locations resembled a veterinarian establishment and should have raised questions for sales representatives who personally visited them. After learning of search warrants executed on each of the customers' locations, AHI took some steps to block the sale of veterinary prescription drugs to these customers on May 4, 2015.

12. Furthermore, between January 2012 and May 2015, AHI did not maintain the proper licenses to ship from its Memphis, Tennessee, facility into Virginia or from its Wolcott, Indiana, facility into Virginia or Tennessee, but, despite this deficiency, shipped products from those locations to Virginia and Tennessee.

13. All veterinary prescription drugs distributed by AHI to Groce and Webb were misbranded because, neither recipient was licensed to possess or distribute veterinary prescription drugs, and the prescribing veterinarian was not properly licensed to practice veterinary medicine in Virginia and consequently none of the drugs he caused to be dispensed were prescribed pursuant to lawful orders.

14. From the illegal shipments to and on behalf of Groce and Webb, AHI received $7,427,928 (seven million four hundred twenty-seven thousand nine hundred twenty-eight dollars) and made a profit of $558,309 (five hundred fifty-eight thousand three hundred nine dollars) by unlawfully distributing veterinary prescription drugs to or on behalf of Groce and Webb.

15. From 2012 through on or about 2018, AHI caused additional misbranded veterinary prescription drug shipments to be made throughout the United States by distributing veterinary prescription drugs from its wholesale locations directly to end users in states where such shipments were illegal and, in some instances, by shipping veterinary prescription drugs to locations in states in which AHI did not have legal authority to make such shipments. AHI obtained not less than $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) from such shipments. Its profits from such shipments were a small percentage of the amount received.

COUNT ONE

Introduction of Misbranded Drugs into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)

The United States Attorney charges that:

16. The Information is realleged and incorporated by reference into this Count.

17. From about January 2012 to April 2015, in the Western District of Virginia, Animal Health Incorporated ("AHI") introduced and delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce, of veterinary prescription drugs that were misbranded in that the drugs' labeling did not bear adequate directions for the use of such drugs.

18. The offense conduct included, but was not limited to, the following:

a. AHI distributed veterinary prescription drugs directly to Billy K. Groce and Marlin Webb, notwithstanding that neither Groce nor Webb was legally authorized to possess or distribute the drugs; and

b. AHI distributed veterinary prescription drugs to customers of Billy K. Groce and Marlin Webb without a lawful prescription having been issued for those drugs.

19. Since these veterinary prescription drugs were not lawfully distributed or prescribed, they failed to qualify for the exemption from the requirement that they bear labeling containing adequate directions for lay use. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1).

NOTICE OF FORFEITURE

20. Upon conviction of the offense alleged in this Information, AHI shall forfeit to the United States veterinary prescription drugs that were misbranded or became misbranded as a result of AHI's conduct, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

21. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of $46,802,203 pursuant to 21 U.S.C. § 853(p).

DATED: February 11, 2020

Randy Ramseyer
for THOMAS T. CULLEN
United States Attorney

NON-PROSECUTION AGREEMENT

1. The United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") and Patterson Companies, Inc. ("Patterson"), and any and all current and former affiliated entities including, but not limited to, Animal Health International, Inc. ("AHI") (collectively referred to as the "Company") enter into this Non-Prosecution Agreement ("Agreement") to resolve the investigation by the USAO-WDVA of the Company related to possible violations of federal laws relating to the licensing, dispensing, distribution, or sale of veterinary prescription drugs.

2. This Agreement, in conjunction with the Plea Agreement with AHI ("Plea Agreement"), resolves all of the Company's potential federal criminal liability for the offenses covered herein and in the Plea Agreement.

3. The USAO-WDVA enters into this Agreement based on the individual circumstances presented by this case including:

a. Patterson's cooperation with the USAO-WDVA investigation since June 2018, and AHI's subsequent cooperation under the direction of Patterson, as well as the Company's continued cooperation under the direction of the Special Investigation Committee of the Board of Directors of Patterson ("SIC") which was formed in April 2019. Since 2018, the Company has conducted a thorough and robust internal investigation; proactively brought information to the USAO-WDVA's attention, remediated noncompliant activity and implemented control enhancements, including certain licensing, dispensing, distribution and related sales practices company-wide; made factual presentations to the USAO-WDVA; timely and fully produced all requested documents; entered into agreements tolling relevant statutes of limitations; and collected, analyzed, and organized voluminous data and information for the USAO-WDVA.

b. Patterson's voluntary disclosure to the USAO-WDVA of non-compliant licensing, dispensing, distribution, and sales at AHI and Patterson beyond AHI's conduct set forth in the Information and Plea Agreement, and its timely efforts to remediate non-compliant activity and enhance controls and processes to mitigate against future reoccurrence. The additional non-compliant activity involved wholesale distribution of veterinary prescription drugs: (i) without verifying the continued validity of all practitioners' licenses in the receiving state; (ii) without verifying that an alternate location requested by the customer was authorized by state law to receive veterinary prescription drugs; (iii) without verifying that veterinarians licensed in Virginia were also associated with a veterinary establishment registered with the Virginia Board of Veterinary Medicine, (iv) without valid licensure to ship to the state to which the drugs were shipped, and/or (v) to end users in states where drop shipments by wholesalers to end users is not allowed. The additional non-compliant activity was due to prior weaknesses and inconsistencies among AHI and Patterson regulatory functions and processes, as well as system challenges presented by the Company's enterprise resource planning implementation. The Company has since taken extensive

proactive steps to enhance its regulatory function, capabilities and support to guide the business and other control functions on regulatory compliance matters. It has also enhanced its regulatory system controls to address the issues disclosed in the investigation and to verify that veterinary prescription drugs are shipped from facilities with required state licenses and to customers and locations authorized by state law to receive veterinary prescription drugs. Consistent with its approach to the USAO-WDVA, Patterson also disclosed the pending federal investigation to state regulators in all 50 states and continues to engage with state regulators, as appropriate, on matters related to the USAO-WDVA investigation.

c. The Company's enhanced regulatory compliance processes and commitment to implement a compliance program that meets the minimum elements set forth in Attachment C to the Plea Agreement ("Corporate Compliance Program Agreement").

d. The Company's agreement to comply with the terms of the Agreement and Plea Agreement.

e. AHI's admission to and the Company's agreement with the facts and allegations set forth in the Plea Agreement.

f. Although the investigation did not involve controlled substances, the Company's recognition that diversion of controlled substances, including drugs of the type that are prescribed and dispensed by veterinarians, such as buprenorphine and hydrocodone, should be a concern of all distributors and dispensers of those drugs and the Company's ongoing commitment to be proactive in deterring diversion and identifying and notifying authorities of suspicious ordering.

4. The Company agrees it will not take any tax deduction or seek or accept directly or indirectly reimbursement or indemnification from any source for any payments made pursuant to the Plea Agreement.

5. No money paid by the Company will be returned, and the Company expressly agrees to release any and all claims it may have to the money. The Company will not file any claim or otherwise contest the payment of money set forth in this Plea Agreement, and it will not assist anyone in asserting a claim to the money.

6. Nothing in this Agreement or any related documents is an admission by the United States that the amounts paid by the Company are the maximum amounts that could be recovered from the Company in the absence of an accepted plea agreement. If the Company does not comply with all of its obligations under this Agreement, the United States is not precluded from arguing or presenting evidence that the total amount to be paid by the Company should be higher.

7. The Company's obligations under this Agreement shall have a term of 42 months from the date on which the Agreement is executed (the "Term").

8. During the Term, the Company will fully cooperate with the USAO-WDVA.

9. During the Term, the Company shall undertake and abide by the terms of the Corporate Compliance Program Agreement in Attachment C to the Plea Agreement.

10. If the Company complies with all of the terms of this Agreement and the Plea Agreement, the USAO-WDVA will not prosecute the Company for any criminal conduct occurring prior to the entering of this agreement concerning:

a. The subject matter of the Information to which AHI is pleading guilty; or

b. Facts disclosed by the Company to the USAO prior to entering this agreement related to the Company's licensing, dispensing, distribution, or sale of veterinary prescription drugs.

11. However, if the USAO-WDVA, in its sole discretion, determines the Company (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement or (b) violated any provision of this Agreement, then the USAO-WDVA will not be bound to their agreement not to prosecute the Company for the matters covered in paragraph 10. Should the USAO-WDVA determine that the Company has violated any provision of this Agreement, the USAO-WDVA shall provide prompt written notice to the Company addressed to its General Counsel, and to its outside counsel, Amy Conway-Hatcher, Baker Botts LLP, 1299 Pennsylvania Avenue NW, Washington, DC, or to any successor the Company may designate, of the alleged violation and provide the Company with a 45 (forty-five) day period from the date of receipt of notice in which to make a presentation to the USAO-WDVA to demonstrate that no violation occurred, or, to the extent applicable, that the violation should not result in adverse action, including because the violation has been cured by the Company. In the event of a violation, the Company will not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other rule or law, that any statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible in any proceeding brought by the Department of Justice. If, as a result of a violation, the United States charges the Company, the Company hereby waives any statute of limitations defense for any offense not time-barred by the applicable statute of limitations on the date this Agreement is signed, including time protected as the result of existing agreements to toll the applicable statute of limitations.

12. The Company will not, through its present or future directors, officers, employees, agents, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If the Company makes a public statement that in whole or in part contradicts any such statement or provision, the Company may avoid being in violation of this Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by the Company's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) the Company's

websites. Notwithstanding the above, the Company may avail itself of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

13. The terms of this Agreement bind the USAO-WDVA and other divisions of the Department of Justice (collectively referred to as the "United States"), except that they do not bind the Tax Division of the Department of Justice or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities. The USAO-WDVA will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

14. The Company and the United States may disclose this Agreement and any other documents used to effectuate the objectives of this Agreement to the public.

15. Nothing in this Agreement resolves, in any way, any liability of any individual.

16. This Agreement and the Plea Agreement set forth all the terms of the agreement between the Company and the USAO-WDVA. No amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the USAO-WDVA, the attorneys for the Company, and a duly authorized representative of the Company.

The Company acknowledges its acceptance of this Agreement by the signature of its counsel and Officer. A copy of a resolution by the Company's Board of Directors authorizing the Officer to execute this Agreement and all other documents to resolve this matter on behalf of the Company is attached as Addendum 1.

Date: February 12, 2020

Mark S. Walchirk
Authorized Corporate Officer
Patterson Companies, Inc.

Counsel has fully explained to the Board of Directors of the Company the facts and circumstances of the investigation and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein with the client, through its Officer. The Company understands the terms and conditions of this Agreement, and the Company's decision to enter into this Agreement is knowing and voluntary. The Company's execution of and entry into this Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI and Patterson Companies, Inc.

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

EXHIBIT A

RESOLUTION OF THE
BOARD OF DIRECTORS
OF
PATTERSON COMPANIES, INC.

NON-PROSECUTION AGREEMENT

WHEREAS, the Company, together with outside counsel reporting to the Special Investigation Committee of the Board ("SIC Counsel"), has been in discussions with the U.S. Attorney's Office for the Western District of Virginia ("USAO-WDVA") to resolve its investigation into Animal Health International, Inc. by, among other things, having the Company enter into a Non-Prosecution Agreement (the "Agreement");

WHEREAS, SIC Counsel has advised the Board of the terms of the Agreement and the consequences of entering into the Agreement; and

WHEREAS, the Board has determined that it is in the best interest of the Company to enter into the Agreement.

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby approves the Agreement and authorizes any executive officer of the Company (the "Authorized Officers") and SIC Counsel to execute and deliver the Agreement on behalf of the Company, with such changes thereto as the Authorized Officers may approve, such approval to be conclusively evidenced by the execution of the changed Agreement.

RESOLVED FURTHER, that the Authorized Officers and SIC Counsel are hereby authorized and directed to execute and deliver all other documents necessary to carry out the provisions of the Agreement.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to acknowledge on behalf of the Company that the Agreement and related documents fully set forth the agreement made between the Company and the USAO-WDVA, and that no additional promises or representations have been made to the Company by any officials of the USAO-WDVA in connection with the Agreement and related documents, other than those set forth in therein.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to make any payments required in connection with the Agreement.

RESOLVED FURTHER, that each Authorized Officer is authorized and empowered, in the name and on behalf of the Company, to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such documents, certificates and instruments as they may deem appropriate in order to effectuate fully the purpose of the foregoing resolutions, and that any actions taken heretofore and hereafter to accomplish such purposes be, and they hereby are approved, ratified and confirmed.

CERTIFICATE OF SECRETARY

I, Les B. Korsh, herby certify that I am now, and at all times mentioned herein have been, the duly elected, qualified, and acting Secretary of **PATTERSON COMPANIES, INC.**, a Minnesota corporation (the "Corporation") and, as such officer, I have access to the records of the Company, which records of the Company reflect that:

1. RESOLUTIONS. Attached hereto as **Exhibit A** is a true and correct copy of resolutions that have been duly adopted by the Board of Directors of the Corporation on February 4, 2020, in compliance with, and not in contravention of, the articles of organization and bylaws of the Corporation; none of such resolutions have been repealed or modified in any respect, and all of such resolutions are in full force and effect on and as of the date hereof, and constitute the only action taken by the Board of Directors of the Corporation with respect to the subject matter hereof.

IN WITNESS WHEREOF, I duly executed this Certificate this 10th day of February, 2020.

Les B. Korsh
Secretary of Patterson Companies, Inc.

CORPORATE COMPLIANCE PROGRAM AGREEMENT

The following Patterson Companies, Inc. ("Patterson" or the "Company") Corporate Compliance Program Agreement ("Corporate Compliance Program Agreement") has been prepared pursuant to the Non-Prosecution Agreement dated this same date between Patterson and the United States Attorney's Office for the Western District of Virginia ("USAO-WDVA"). Compliance with all the terms and standards of the Corporate Compliance Program Agreement is a condition of the Non-Prosecution Agreement and shall continue for the Term of the Non-Prosecution Agreement ("Term").

Applicability and Purpose

1. This Corporate Compliance Program Agreement shall be incorporated into the Non-Prosecution Agreement by reference, and compliance with the terms of the Corporate Compliance Program Agreement will be a condition of the Non-Prosecution Agreement. The USAO-WDVA acknowledges that the Company has already implemented many of these terms as of the date of the resolution.

2. Any proposed modifications to this Corporate Compliance Program Agreement must be made in writing and signed by the Company and the designated signatory for the USAO-WDVA.

3. The Corporate Compliance Program Agreement does not in any way release the Company from complying with any applicable federal or state statutes and/or regulations, and does not limit the imposition of any sanctions, penalties or any other actions available under those state or federal statutes and regulations.

The Corporate Compliance Program Agreement

4. The Company and the USAO-WDVA agree that the Company shall undertake the following voluntary compliance measures. The Corporate Compliance Program Agreement does and will continue to contain policies and procedures designed to prevent, detect, and correct violations of federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* and FDA requirements. These policies and procedures shall be designed to ensure that the Company complies with, among other things, the FDCA's prohibitions against causing the introduction into interstate commerce of a drug that is misbranded or otherwise violates the FDCA.

5. *Compliance Officer.* Prior to the effective date of the Non-Prosecution Agreement, the Company established the position of Chief Compliance Officer ("Compliance Officer") and appointed an individual to serve in the role on an interim basis until such time as the Company can fill the role on a permanent basis. The Company shall maintain a Compliance Officer for the Term. During the Term, the Compliance Officer shall be authorized to oversee compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA, FDA requirements, and the requirements of the Corporate

Compliance Program Agreement. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures and practices designed to address compliance with the requirements set forth in this Corporate Compliance Program Agreement, with federal and state statutes and/or regulations concerning federal prescription drug distribution and FDA requirements. The Compliance Officer shall be a member of senior management of the Company, and shall report directly to the Chief Executive Officer of the Company. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Patterson Company's Board of Directors (hereinafter the "Board") or any authorized committee thereof, and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the Company as well as for any obligations created under the Corporate Compliance Program Agreement. Any non-compliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in the Corporate Compliance Program Agreement.

6. *Compliance Committee.* Prior to the effective date of the Non-Prosecution Agreement, the Company formed a Compliance Committee (hereafter "Compliance Committee") which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the compliance program. The Company shall maintain the Compliance Committee for the Term. The Compliance Committee shall include, at a minimum, the Compliance Officer and other members of senior management necessary to meet the requirements of the Corporate Compliance Program Agreement (e.g., senior executives of relevant departments, such as legal, regulatory, audit, human resources, and operations.) The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Company's risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

7. *Board of Directors Compliance Obligations.* Prior to the effective date of the Non-Prosecution Agreement, the Board formed a committee responsible for overseeing the Company's compliance program ("Board Committee"). The Company shall maintain the Board Committee for the Term. The Board Committee shall consist of no less than three (3) non-employee directors, including at least one (1) member of the Special Investigation Committee formed in response to the USAO-WDVA investigation for a minimum of twelve (12) months from the date of this Non-Prosecution Agreement. The Board Committee shall oversee the Company's compliance program, including at a minimum:

a. the Company's obligations under the Corporate Compliance Program Agreement

b. receiving updates about adoption and implementation of policies, procedures and practices designed to ensure compliance with the FDCA and FDA requirements, and

c. evaluating the effectiveness of the compliance program.

8. The Company shall continue to evaluate its current business to ensure that it is not currently receiving, distributing or handling misbranded or unapproved federal prescription drugs. Should the Company find it is receiving, distributing, or handling misbranded or unapproved federal prescription drugs, it shall take necessary steps to remediate any such conduct.

9. The Company shall continue to enhance its current training program to ensure that pertinent employees are familiar with the requirements of the FDCA and FDA requirements that could potentially apply to the Company's conduct.

10. The Company will put in place processes to (a) encourage employees to report suspected non-compliant activities by the Company, customers, or others and to (b) acknowledge or otherwise recognize employees for reporting confirmed non-compliant activity, as appropriate.

11. The Company will maintain, or as necessary establish, policies and procedures designed to ensure effective investigation of any complaints and/or potential deficiencies relating to compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA and FDA requirements. Such policies and procedures shall include, but are not limited to:

a. Training and providing guidance to all pertinent employees as to the requirement to report all information regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to the Compliance Officer, who in turn will review and determine whether corrective actions are required; and

b. Tracking allegations and remediation action plans regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to identify issues that may require corrective actions.

12. Within 60 days of the end of the Company's fiscal year, the Company's Chief Executive Officer will certify, under oath, to (a) the United States Attorney's Office during the Term and (b) the United States Probation Office for any period during which Animal Health International, Inc. is on probation, that (1) the Company fully complied with all federal laws and regulations pursuant to the Food, Drug, and Cosmetic Act ("FDCA") in the preceding year (or, in the instance of the first such certification, the period from execution of the Non-Prosecution Agreement through the end of the Company's fiscal year 2020), or in the alternative, (2) list all non-compliant activity and the steps taken by the company to remedy such non-compliant activity. Any listing of non-compliant activity shall not be considered by the government or the Probation Officer as a per se violation of the terms of probation or the Non-Prosecution Agreement. Instead, other factors will be taken into account, including whether the conduct violated policies the Company has adopted, whether the Company provided training addressing the subject matter of the reported conduct, whether it was an isolated or systemic occurrence, the Company's response, and any remedial actions taken after the Company learned of the conduct reported.

Non-Compliance

13. The Corporate Compliance Program Agreement is part of the Non-Prosecution Agreement and adherence to it will be an enforceable condition. Deliberate, intentional or knowing failure to comply with any part of the Corporate Compliance Program Agreement is a violation of the Non-Prosecution Agreement.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.**
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before 7 days from the date of entry of a guilty plea, the defendant will voluntarily remit payment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant upon entry, and shall be made a part of the sentence and included in the judgment.

ENTERED THIS _____ DAY OF _____, 2020.

_____

UNITED STATES DISTRICT JUDGE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached disclosure statement.

Original Signature (electronic, copies or stamps not accepted)

4/23/25
Date

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Animal Health International, Inc. (AHI) Disclosure Statement

a. On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement and a fine, and AHI paid $41,250.

b. On April 18, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Visalia, California Veterinary Food- Animal Drug Retailer license for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

c. On June 18, 2013, the Missouri Division of Professional Regulation issued a drug distributor license to Animal Health International, Inc.'s (AHI) Salina, Kansas facility. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

d. On August 30, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failing to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

e. On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no misconduct allegations beyond the conduct in Arkansas, which led to the non-disciplinary order and fine.

f. In March 2017, the Colorado Board of Pharmacy issued a letter of admonishment to Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license following allegations that it failed to timely submit an application detailing a change in designated representative. AHI was required to pay the costs associated with the Board's order.

g. On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

h. On July 20, 2020, Animal Health International, Inc. (AHI) in Boaz, AL entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an

administrative fine of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The facility in Boaz, Alabama facility, subject to discipline was AHI's Boaz, Alabama, wholesale drug distributor license.

i. On July 20, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas, wholesale drugdistributor license.

j. On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license. This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

k. On December 31, 2024, Animal Health International's Sioux Center, Iowa Wholesale Distributor facility entered into a Consent Order with the Illinois Department of Financial and Professional Regulation in which the facility's Illinois Wholesale Distributor license was reprimanded and fined $10,000. This action was based entirely on the Department of Justice case against AHI related to distribution activities predating current ownership. The Federal case was reported to State Boards during the investigation in July 2019 and again in February 2020 once the case was resolved.

l. On January 9, 2025, Animal Health International's ("AHI") Ceres, California Wholesale Distributor Facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 6 days in 2016, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

m. On January 9, 2025, Animal Health International's ("AHI") Roanoke, Texas Wholesale Distributor facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 165 days in 2014, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil

penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

n. On January 9, 2025, Animal Health International's ("AHI") Twin Falls, Idaho pharmacy entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 3 days in 2016, the pharmacy dispensed prescriptions into Oregon without an active pharmacy license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $3,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. Please note that the activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice case was reported to the state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. A copy of the Oregon Consent Order is enclosed. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054
Name: Elanco US Inc.
Address: 2500 Innovation Way N City: Greenfield State: IN Zip: 46140
Name: Boehringer Ingelheim
Address: 900 Ridgebury Rd City: Ridgefield State: CT Zip: 06877
Name: Huvepharma, Inc.
Address: 525 Westpark Drive, Suite 230 City: Peachtree City State: GA Zip: 30269

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Colorado
Parent Company (if any): Patterson Companies, Inc.
Corporation/Organization Name: Animal Health International, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: (651) 686-1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Animal Health International, Inc.

Facility Name

Kevin Barry

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4/23/25

Date

Board Use Only	Date Received: 5/19/25	Amount: $100.00

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515
State of Incorporation:	Minnesota

ANIMAL HEALTH INTERNATIONAL, INC. – Officer List

Corporate Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Phone Number:	970-353-2000
FEIN #:	84-0575063
State of Incorporation:	Colorado (5/16/1967)

Robert J. Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Steven M. Cunningham	**President**
Business Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Business Phone:	970-353-2000
Email:	Facilitylicensing@pattersoncompanies.com

Kevin M. Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Leslie B. Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Animal Health International, Inc.

is a

Corporation

formed or registered on 05/16/1967 under the law of Colorado, has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 19871193550 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 05/06/2025 that have been posted, and by documents delivered to this office electronically through 05/08/2025 @ 06:42:52 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 05/08/2025 @ 06:42:52 in accordance with applicable law. This certificate is assigned Confirmation Number 17280636 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

BOARD OF PHARMACY

LICENSING DETAILS FOR: WLS 6864

NAME: ANIMAL HEALTH INTERNATIONAL INC

LICENSE TYPE: WHOLESALER

LICENSE STATUS: CLEAR

ADDRESS

1908 ROCKEFELLER DR
CERES CA 95307
STANISLAUS COUNTY

ISSUANCE DATE

APRIL 20, 2016

EXPIRATION DATE

APRIL 1, 2026

CURRENT DATE / TIME

FEBRUARY 12, 2025
6:19:22 AM

LICENSE RELATIONSHIPS

NAME: ANIMAL HEALTH INTERNATIONAL INC

LICENSE/REGISTRATION TYPE: VETERINARY FOOD-ANIMAL DRUG RETAILER

LICENSE NUMBER: 152 **PRIMARY STATUS:** CLEAR

ADDRESS :
1908 ROCKEFELLER DR
CERES CA 95307
STANISLAUS COUNTY

NAME: MONTES RODRIGUEZ, FERNANDO

LICENSE/REGISTRATION TYPE: DESIGNATED REPRESENTATIVE (VETERINARY FOOD-ANIMAL DRUG RETAILER)

LICENSE NUMBER: 26169 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/07/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400 CN102114303-Stnd-GAWU-24-25	CONTACT NAME: Marsh | U.S. Operations & Technology PHONE (A/C, No, Ext): 866-966-4664 FAX (A/C, No): E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com
INSURED Animal Health International, Inc. and Subsidiaries 822 7th Street, Suite 740 Greeley, CO 80631	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Starr Indemnity & Liability Company — 38318 INSURER B : Starr Specialty Insurance Company — 16109 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** CHI-010764188-03 **REVISION NUMBER:** 1

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	0
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	10,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	4,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY			1000198195241 (AOS)	11/01/2024	11/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	3,000,000
A	X ANY AUTO			1000198196241 (MA)	11/01/2024	11/01/2025	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
A	X UMBRELLA LIAB X OCCUR			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	5,000,000
	DED X RETENTION $ 25,000							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			100 0005556 (AOS)	11/01/2024	11/01/2025	X PER STATUTE OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A		100 0005558 (FL,MA)	11/01/2024	11/01/2025	E.L. EACH ACCIDENT	$	1,000,000
B	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			100 0005559 (WI)	11/01/2024	11/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance

CERTIFICATE HOLDER

Animal Health International, Inc.
and Subsidiaries
822 7th Street, Suite 740
Greeley, CO 80631

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K15388249

Application/License No. _____

Animal Health International, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1908 Rockefeller Drive, Ceres, CA 95307 (Address of Applicant/Principal), as PRINCIPAL, and Westchester Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 436 Walnut Street, Philadelphia, PA 19106 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 17, 2019 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 17th day of April, 2019.

APPLICANT/PRINCIPAL
Animal Health International, Inc.

Authorized Representative

SURETY COMPANY
Westchester Fire Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

BONNIE K. RAMIREZ
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID 20054017910
MY COMM EXP. May 4, 2021

Countersigned by:

N/A
Nevada Resident Agent

Cynthia L. Choren
Vice President

Marsh USA Inc.
701 Market Street
St. Louis, Missouri 63101
314 342 2661 Fax 314 342 2618
Cynthia.L.Choren@marsh.com
www.marsh.com

Delivered via Federal Express (Tracking #7749 9544 1202)

April 17, 2019

Ms. Kasey Cannon
Licensing Coordinator
Animal Health International, Inc.
822 7th Street
Suite 650
Greeley, CO 80631

Subject:
$100,000 Nevada Pharmaceutical Wholesaler Surety Bond
Bond No. K15388249

Dear Kasey:

We are pleased to enclose the above captioned bond as you requested. Prior to filing this bond with the Obligee, please complete the following items:

1) Bond signed by authorized officer
2) Officer's name and title inserted below signature
3) Officer's signature witnessed by two (2) individuals
4) Corporate seal affixed

If you have any questions regarding this bond, please do not hesitate to give me a call.

Sincerely,

Cindy

Cynthia L. Choren
Vice President

Enclosure

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Animal Health International, Inc. MDEG License # (if applicable): _____

Physical Address: 1908 Rockefeller Drive

City: Ceres State: CA Zip: 95307

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: (209) 538-2750 Website: https://www.animalhealthinternational.com/

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Jason Middle: Richard Last: Divird

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Ceres State: CA Zip: [redacted]

Telephone: [redacted] Email: jason.divird@animalhealthinternational.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years [illegible] Guard or a reserve component of the Armed Forces of the United States and separated fr[illegible] nditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the [illegible] Commissioned Corps of the National Oceanic and Atmospheric Admini[illegible] f a commissioned officer while on active duty in defense of t[illegible] rvice under conditions other than dishonorable? (Mark "Yes" if dischar[illegible]		✓

Section 4: Federally Mandated Requirement (NRS 425.520, N[illegible]	Yes	No
1. Are you the subject of a court order for the support of a child[illegible]		✓
2. Are you in compliance with the order or the plan approved by th[illegible] or other public agency enforcing the order for the repayment of the amount owed pursu[illegible] rder?		

DR / Administrator
ok
for Mark K

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Modesto Junior College		08/95 - 05/98	
Address	City	State	Zip
435 College Avenue	Modesto	CA	95350
Diploma/Degree obtained, if any			
Business Management			

School Name		From - To (MM/YY – MM/YY)	
Grace Davis Hight School		08/89 - 06/93	
Address	City	State	Zip
1200 W Rumble Rd	Modesto	CA	95350
Diploma/Degree obtained, if any			
High School diploma v			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/10 - Current	[redacted]	Modesto	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International, Inc.			10/2012 - Present	
Business Address		**City**	**State**	**Zip**
1908 Rockefeller Drive		Ceres	CA	95307
Phone	**Title**		**Number of Employed Hours**	
(559) 920-6678	Operations Manager		Approx. 25,000	
Description of Duties				
Responsibilities include managing a fleet of eight CDL drivers. Knowledge of DOT/HAZMAT regulations. Conduct daily/weekly/monthly safety audits, Payroll, Route scheduling & SAP operating system.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/23/2025
Date

I, Jason Richard Divird, **certify that as the MDEG Administrator for**

Animal Health International, Inc.,

that I (initial that you have read and meet the following requirements):

1. JD Have a high school diploma or its equivalent;
2. JD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jason Divird
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/23/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Animal Health International, Inc.

Pharmacy/Wholesaler License # (if applicable): WH02662

Physical Address: 1908 Rockefeller Drive

City: Ceres State: CA Zip: 95307

Mailing Address (if different from physical address): 1031 Mendota Heights Road

City: Saint Paul State: MN Zip: 55120

Telephone: (209) 538-2750 Website: https://www.animalhealthinternational.com/

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Jason Middle: Richard Last: Divird

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: 553-57-0595 Sex: ☑ M ☐ F ☐ X

Mailing Address: 1908 Rockefeller Drive

City: Ceres State: CA Zip: 95307

Telephone: [redacted] Email: jason.divird@animalhealthinternational.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Modesto Junior College		08/95 - 05/98	
Address	**City**	**State**	**Zip**
435 College Avenue	Modesto	CA	95350
Diploma/Degree obtained, if any			
Business Management			

School Name		From - To (MM/YY – MM/YY)	
Grace Davis Hight School		08/89 - 06/93	
Address	**City**	**State**	**Zip**
1200 W Rumble Rd	Modesto	CA	95350
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/10 - Current	[redacted]	Modesto	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International, Inc.			10/2012 - Present	
Business Address		**City**	**State**	**Zip**
1908 Rockefeller Drive		Ceres	CA	95307
Phone	**Title**		**Number of Employed Hours**	
(559) 920-6678	559-920-6678		Approx. 25,000	
Description of Duties				
Responsibilities include managing a fleet of eight CDL drivers. Knowledge of DOT/HAZMAT regulations. Conduct daily/weekly/monthly safety audits, Payroll, Route scheduling & SAP operating system.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/6/2025
Date

I, Jason Richard Divird, **certify that as the designated representative for**

Animal Health International, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JRD I am at least 21 years of age;
3. JRD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JRD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JRD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JRD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JRD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jason Divird

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/6/2025

Date

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jason Divird

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/6/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Stanislaus

I, Jason Divird, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/6/2025

Date

Subscribed and Sworn to before me this 6 day of May, 2025

Notary Public Signature

RITU BHULLER
COMM. # 2406903
NOTARY PUBLIC - CALIFORNIA
STANISLAUS COUNTY
COMM. EXPIRES JUNE 4, 2026

(Seal)

Animal Health INTERNATIONAL
a Patterson company

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Ceres, CA – Employee List

Legal Name (Last, First)

Henry, Simon
Walker, George
Cervantes Valdez, Consuelo
Negri, Michael L
Cline, David Michael
Santos, Daniel
Cupples, Douglas James
McCart, Brian Samuel
Old, Antonia
Avila, Emily Darlene
Jackson, Deja Monique
Hagens, Ashley Ann
Hudson, Mark Michael
Montes Rodríguez, Fernando
Alley, Kasandra
Garrett, Barry
Mayoral, Humberto
Pulido, Jesus
Divird, Jason Richard
Vieira, Brian
Kennedy, Rhett
Kidder, Russell
Moorhouse, Sarah
Alexander, Blake
Borges, Michael
Hetrick, Clacy Erin
Estrada, Magdaleno
Ramos, Juan A
Rotermund, Jonathan
Kern, Erika
Candido, Richelle
Lopes, Joshua
Mello, Christina
Cocio, Gabriel
Vaz, John

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH 03587	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Animal Health International, Inc.

Physical Address: 1906 East Cedar Avenue

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address): 1031 Mendota Heights Road

City: Saint Paul State: MN Zip: 55120

Telephone: _____ Website: https://www.animalhealthinternational.com/home

Name of Designated Representative (DR): Matthew Harris

Licensing Company Email: facilitylicensing@pattersoncompa DR Email: Matthew.Harris@animalhealthinternational.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class I & Class II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Universities/Research		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/14/2020		VA	Abingdon	Washington
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
DVAW120CR00007-001		United States District Court, Wetern District of Virginia Abingdon		
Reason/Charge				
Violation of Title 21, US Code, Sections 221(1), 333(a)(1), and (352)(f)(l)				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Animal Health International, Inc.			N/A	
Name of Business/Industry/Entity				
Animal Health International, Inc.				

Provide explanation below:

On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

FEB 14 2020

JULIA C. DUDLEY, CLERK
BY: DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20-cr-00007
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

PLEA AGREEMENT

ANIMAL HEALTH INTERNATIONAL, INC. (EIN: 84-0575063) ("AHI") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this Plea Agreement are as follows:

1. CHARGE TO WHICH AHI IS PLEADING GUILTY AND WAIVER OF RIGHTS

AHI will enter a plea of guilty to Count One of the Information charging it with violating Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) in the Western District of Virginia by introducing and delivering for introduction, and causing the introduction and delivery for introduction, into interstate commerce of veterinary prescription drugs that were misbranded.

AHI understands, and the parties agree and stipulate, the maximum statutory penalty is a fine of $14,855,856 (fourteen million eight hundred fifty-five thousand eight hundred fifty-six dollars), pursuant to Title 18, United States Code, Section 3571(d), and a period of probation of five (5) years, pursuant to Title 18, United States Code, Section 3561(c)(2). In addition, AHI's assets are subject to forfeiture. AHI understands fees may be imposed to pay for probation and there will be a $125 (one hundred twenty-five dollars) special assessment for Count One, pursuant to Title 18, United States Code, Section 3013(a)(1)(B)(iii). AHI's attorneys have informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before AHI could be found guilty as charged.

AHI admits and agrees that all of the statements and allegations in the Information are true and correct.

AHI acknowledges AHI has had all of its rights explained to it. AHI expressly recognizes that, as a corporation, AHI may have the following constitutional rights and by voluntarily pleading guilty AHI knowingly waives and gives up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses.

The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

AHI is pleading guilty as described above because AHI is in fact guilty and because AHI believes it is in its best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for its plea of guilty. AHI agrees all of the matters set forth in the Information are true and correct.

AHI understands the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree the 2018 version of the United States Sentencing Commission Guidelines Manual ("U.S.S.G.") is the appropriate Guidelines Manual to utilize. According to U.S.S.G. § 8C2.1, the organizational fine provisions do not apply to the count of conviction in this case, which is a misdemeanor under 21 U.S.C. § 333(a)(1).

The parties agree and stipulate:

a. the fine shall be $5,000,000 (five million dollars);
b. AHI shall pay $1,000,000 (one million dollars) to the Virginia Department of Health Professions ("DHP") in recognition of direct assistance provided by DHP to the United States during the investigation;
c. AHI shall forfeit $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars); and
d. AHI shall serve a term of probation of one to three years, as determined by the Court.

The Court will determine what terms and length of probation are appropriate and the parties will be free to argue for which terms and length of probation they believe are appropriate. AHI understands and agrees if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum may be imposed.

The parties agree if the Court refuses to accept this Plea Agreement with the agreed-upon sentence, AHI will be free to withdraw its guilty plea. In the event the Court refuses to accept this Plea Agreement and AHI withdraws its guilty plea within ten days of being notified of the Court's refusal, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410. Under these circumstances, the United States will move to dismiss the Information without prejudice and the United States may file any charges it could have filed in the absence of the plea agreement. AHI agrees to toll the statute of limitations between the date of the plea and the filing of any such charges.

3. FINANCIAL OBLIGATIONS

AHI agrees and understands any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept this Plea Agreement with the agreed-upon sentence and, as a result, AHI withdraws its guilty plea. If the Court rejects this Plea Agreement and AHI withdraws its guilty plea, the United States will return all money paid by AHI, without

interest, not more than thirty (30) days after AHI withdraws its guilty plea and notifies the United States Attorney's Office for the Western District of Virginia ("USAO"), in writing, it wishes to have the money returned.

In addition, in accordance with 18 U.S.C. § 3572(d)(3), AHI will notify the Court of any material change in AHI's economic circumstances that might affect AHI's ability to pay any amounts payable under this Plea Agreement.

a. Payments

Within 7 days of the entry of AHI's guilty plea, AHI will make the following disbursements:

(1) $125 (one hundred twenty-five dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the special assessment.

(2) $5,000,000 (five million dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the fine;

(3) $1,000,000 (one million dollars) to the Virginia Department of Health Professions. These funds must be remitted in the form of certified funds made payable to the "Treasurer of Virginia." The comment section of the check should note "DHP-Enforcement" in recognition of direct assistance provided to the United States during the investigation; and

(4) $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) made payable to the United States Marshals Service, as directed by the USAO as payment of a forfeiture money judgment.

b. Forfeiture

AHI agrees to the entry of a forfeiture money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency ("Forfeiture Money Judgment") pursuant to 21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c). AHI agrees that the value of the quantities of prescription drugs which were misbranded in violation of 21 U.S.C. § 331(a) totaled at least $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency.

AHI acknowledges and agrees the quantities of the drugs which were misbranded in violation of 21 U.S.C. § 331(a) cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, AHI agrees the government is entitled to forfeit as substitute assets any other assets of AHI up to the value of the now missing directly forfeitable assets, pursuant to

21 U.S.C. § 853(p). Payment in full of the Forfeiture Money Judgment shall satisfy any and all forfeiture obligations that AHI may have as a result of this guilty plea. AHI consents to the entry of an Order of Forfeiture pursuant to Rule 32.2 of the Federal Rules of Criminal Procedure forfeiting the above-referenced Forfeiture Money Judgment.

AHI agrees to sign any documentation necessary and to cooperate fully with the United States to accomplish the forfeiture. AHI agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of these funds to the United States.

AHI agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. AHI agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgement in any administrative or judicial proceeding.

AHI understands and agrees forfeiture of this property is proportionate to the degree and nature of the offense. AHI freely and knowingly waives any and all constitutional and statutory challenges to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including, but not limited to, that the forfeiture constitutes an excessive fine or punishment. AHI further understands and agrees this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty or other monetary judgment that may be imposed by the court.

c. Restitution

The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no restitution will be ordered.

4. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, AHI withdraws its plea, AHI agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny it committed the crime to which it has pled guilty; (4) comply with any reasonable request of the United States Attorney's Office and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement.

Neither AHI, nor its corporate parent (Patterson Companies, Inc. ["Patterson"]), will (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If Patterson or AHI makes a public statement that in whole or in part contradicts any such statement or provision, AHI may avoid being in violation of this Plea Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by Patterson's and AHI's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) Patterson or AHI websites. Notwithstanding the above, Patterson and AHI may avail themselves of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by

any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

5. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, AHI agrees AHI will not appeal the conviction or sentence imposed. AHI is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). AHI expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. AHI understands the United States expressly reserves all of its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, AHI may file a cross appeal of that same sentence. AHI agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this Plea Agreement.

6. INFORMATION ACCESS WAIVER

AHI agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a. However, if a third party obtains any records pertaining to the investigation or prosecution of this case under the Freedom of Information Act, AHI shall have the right to request copies of such disclosed records.

7. ADMISSIBILITY OF STATEMENTS

AHI understands any statements made on its behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against AHI by the United States in this or any other proceeding. AHI knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other proceeding. If, and only if, the Court rejects this Plea Agreement, and, as a result, AHI withdraws its plea, AHI will not be bound by the waivers set forth in this section of the Plea Agreement.

8. COMPLETION OF PROSECUTION

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), so long as AHI complies with all of its obligations under this Plea Agreement, the United States agrees, other than the charge in the attached Information, it shall not further criminally prosecute AHI for any additional federal criminal

charges or forfeiture action with respect to any offenses set forth in the Information or Non-Prosecution Agreement with Patterson (Attached as Attachment B).

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

9. LIMITATION OF PLEA AGREEMENT

This Plea Agreement is limited to the United States Department of Justice and does not bind any other federal, state, or local authority.

10. COMPLIANCE AND REMEDIAL MEASURES

AHI agrees to comply with the Corporate Compliance Program Agreement attached hereto as Attachment C.

11. COOPERATION

AHI acknowledges that its ongoing and future cooperation is important and a material fact underlying the United States' decision to enter into this Plea Agreement. AHI agrees to continue to cooperate fully and actively with the United States regarding any matter, including, but not limited to, matters involving (a) current and former AHI personnel, and (b) other entities who operate in the same commercial segment as AHI and/or Patterson during the Term of the Non-Prosecution Agreement with Patterson, provided however that any cooperation in an ongoing investigation or prosecution shall continue until such investigation or prosecution is concluded.

Nothing in this Plea Agreement shall be construed to require Patterson or AHI to waive any attorney-client privilege or work-product protection.

12. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THIS PLEA AGREEMENT

AHI understands if: (1) AHI attempts to withdraw its plea (in the absence of the Court refusing to accept this Plea Agreement); (2) AHI fails to comply with any provision of this Plea Agreement; (3) AHI's conviction is set aside, for any reason; and/or (4) AHI fails to execute all required paperwork prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement titled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, AHI will still be bound by its obligations under this Plea Agreement. AHI hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of this Plea Agreement. AHI hereby waives any statute of limitations argument as to any such charges.

13. EFFECTIVE REPRESENTATION

AHI has discussed the terms of this Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, AHI has no dissatisfaction or complaint with its attorneys' representation. AHI agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint AHI may have with its attorneys' representation.

14. EFFECT OF AHI'S SIGNATURE

AHI understands its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. AHI understands the United States has not accepted AHI's offer until the authorized representative of the United States has signed this Plea Agreement.

15. GENERAL UNDERSTANDINGS

AHI understands a presentence investigation will be conducted and sentencing recommendations independent of the USAO will be made by the presentence preparer.

AHI understands the United States and AHI retain the right, notwithstanding any provision in this Plea Agreement, to inform the probation office and the Court of all facts, to address the Court with respect to the nature and seriousness of the offense and the offender, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, and to respond to any statements made to the Court.

AHI willingly stipulates there is a sufficient factual basis for the Court to accept the plea.

AHI understands this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

AHI has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. AHI understands its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. AHI understands AHI will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing, the Non-Prosecution Agreement with Patterson (attached as Attachment B), the Corporate Compliance Program Agreement (attached as Attachment C), and the Agreed Order of Forfeiture (attached as Attachment D) are the complete and only agreements between the United States and AHI concerning resolution of this matter. In addition, AHI has no objection to the filing of the Information.

The agreements and documents listed in this section set forth the entire understanding between the parties and constitute the complete agreement between the United States Attorney for the Western District of Virginia and AHI and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and AHI. AHI consents to public disclosure of all of the agreements and other documents referenced in this section.

AHI has consulted with its attorneys and fully understands its rights. AHI has read this Plea Agreement and carefully reviewed every part of it with its attorneys. AHI understands this Plea Agreement and AHI voluntarily agrees to it. Being aware of all of the possible consequences of its plea, AHI has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer ("Officer") below.

The Officer, by signing below, hereby certifies to the following:

(1) The Officer is fully authorized to enter into this Plea Agreement on behalf of AHI;

(2) The Officer has read the entire Plea Agreement and documents referenced herein and discussed them with AHI's Board of Directors;

(3) AHI understands all the terms of this Plea Agreement and those terms correctly reflect the results of plea negotiations;

(4) AHI is fully satisfied with AHI's attorneys' representation during all phases of this case;

(5) AHI is freely and voluntarily pleading guilty in this case;

(6) AHI is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea; and

(7) AHI understands it is waiving its right to appeal the judgment and conviction in this case.

AHI acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Officer. A copy of a certification by AHI's Board of Directors authorizing the Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of AHI is attached as Attachment A.

Date: 2/13/2020

Authorized Corporate Officer
AHI

Counsel has fully explained to the Board of Directors of AHI the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the Sentencing Guidelines; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and documents referenced herein with the client, through its Officer. AHI understands the terms and conditions of this Plea Agreement, and AHI's decision to enter into this Plea Agreement is knowing and voluntary. AHI's execution of and entry into the Plea Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED
2/11/2020
JULIA C. DUDLEY, CLERK
BY: LOTTIE LUNSFORD
DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No. 1:20CR00007**
v.	)	
	)	**Violations: 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)**
ANIMAL HEALTH INTERNATIONAL, INC.	)	

INFORMATION

INTRODUCTION

1. Defendant Animal Health International, Inc. ("AHI") is a Colorado corporation with its principal place of business in Colorado. AHI is comprised of two legacy organizations, Lextron, Inc. ("Lextron") and Walco International, Inc. ("Walco"). In June 2011, Lextron acquired all outstanding stock of the parent company of Walco and changed its name to AHI. Walco continued operations as a subsidiary of AHI until December 2011 when Animal Health Holdings, Inc. and each of its wholly-owned subsidiaries, including Walco, were merged with and into AHI and no longer had separate corporate existences. AHI, and its predecessor entities, dispense, distribute and sell, among other products, veterinary prescription drugs to customers in the production animal industry across the United States. Specifically, AHI obtains prescription drugs for production animals from manufacturers for further distribution to veterinarians, farms, feedlots, and other distribution facilities.

2. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulates the distribution and labeling of all drugs, including animal drugs, shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C § 301, *et seq.* ("FDCA"). Veterinary prescription drugs are drugs intended for use by animals that, because of their toxicity or other potentiality for harmful

effect, or the method of their use, or the collateral measures necessary for their use, are not safe for animal use except under the professional supervision of a licensed veterinarian. 21 U.S.C. § 353(f)(1)(A).

3. Under the FDCA, a drug is misbranded if, among other things, its labeling does not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). Adequate directions for use is defined as "directions under which the *layman* can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5 (emphasis added). Prescription veterinary drugs by definition can only safely be used under the professional supervision of a licensed veterinarian and therefore they must qualify for an exemption to this requirement in order to move in interstate commerce. These exemptions are set out in 21 C.F.R. Part 201, Subpart D ("Exemptions from Adequate Directions for Use").

4. Veterinary prescription drugs are exempt from the requirement that their labeling contain adequate directions for use if they meet all enumerated conditions, including that they be distributed through a closed supply chain in which every entity that possesses a prescription drug must have legal authorization to do so. *See* 21 C.F.R. § 201.105 (a)(1) (a veterinary prescription drug must be in the possession of: a person lawfully engaged in the manufacture, transportation, storage or wholesale distribution of drugs; a retail pharmacy or other person authorized under state law to dispense veterinary prescription drugs; or a licensed veterinarian for use in the course of his professional practice). Moreover, the veterinary prescription drug must be dispensed in accordance with 21 U.S.C. § 353(f), i.e., pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian's professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105 (a)(2).

5. The FDCA's restrictions on veterinary prescription drugs are not primarily to protect animals from the potential harms of prescription drugs, but are to protect the human food supply from unsafe drug residues in the edible tissues of animals sold for slaughter. Common causes of illegal residues include: (1) exceeding the drug's approved dose; (2) using a shorter withdrawal period than what is stated on the drug's label (if a higher than approved dose is given, the labeled withdrawal period may not be enough to allow the drug in the edible tissues to deplete to levels that are at or below the tolerance); (3) using a drug in an extra-label manner (for indications and dosages outside the approved labeling) without a veterinarian's involvement; (4) giving a drug not approved for that species; and (5) using an unapproved route of administration. Drug residues in the nation's drug supply are concerning because: (1) they may contribute to antibiotic resistance in the human population, rendering human drugs less effective to treat human disease and contributing to the mutations of "superbugs"; and (2) they may cause allergic reactions in individuals with certain drug allergies.

6. Certain legacy customers of AHI, namely Marlin Webb and Billy K. Groce, were not properly licensed to receive, transport, store, distribute, or dispense veterinary prescription drugs in the Commonwealth of Virginia from January 2012 through April 2015.

7. Webb was the store manager of a cooperative in Hillsville, Virginia. The cooperative was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Webb operated a side business from the cooperative's location in which he illegally circumvented the FDA's regulation of veterinary prescription drugs by illegally obtaining from Billy K. Groce and AHI and reselling veterinary prescription drugs using unlawful prescriptions written by a veterinarian who was licensed in Tennessee but who was not properly licensed to

practice veterinary medicine in Virginia and who did not have a veterinarian-patient relationship with the animals in question. That veterinarian died in 2015.

8. Groce was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Groce operated an unlicensed veterinary prescription drug distribution business. Groce worked with the same veterinarian as did Webb.

9. Webb and Groce obtained veterinary prescription drugs from AHI in interstate commerce without valid prescriptions, and, on many occasions, with no prescription at all.

10. On April 29, 2015, the government executed search warrants at locations in Virginia and Tennessee associated with Groce and Webb. In 2016 and 2017, respectively, Groce and Webb pled guilty to illegally conspiring to defraud the FDA by obtaining and distributing veterinary prescription drugs from July 2009 through April 29, 2015 in a manner that circumvented the FDA's regulation of veterinary prescription drugs.

11. Groce and Webb were legacy customers of, among others, Lextron and Walco, and continued to be customers after the companies merged to form AHI in 2012 until May 2015. Neither Lextron, Walco, nor AHI performed adequate customer diligence processes, nor adequately trained sales representatives to raise questions regarding Groce's, Webb's or the veterinarian's activities in Virginia and Tennessee. For example, Groce operated a business that stored and distributed veterinary prescription drugs out of a storefront called "Goin' Postal" and his personal residence. Neither of those locations resembled a veterinarian establishment and should have raised questions for sales representatives who personally visited them. After learning of search warrants executed on each of the customers' locations, AHI took some steps to block the sale of veterinary prescription drugs to these customers on May 4, 2015.

12. Furthermore, between January 2012 and May 2015, AHI did not maintain the proper licenses to ship from its Memphis, Tennessee, facility into Virginia or from its Wolcott, Indiana, facility into Virginia or Tennessee, but, despite this deficiency, shipped products from those locations to Virginia and Tennessee.

13. All veterinary prescription drugs distributed by AHI to Groce and Webb were misbranded because, neither recipient was licensed to possess or distribute veterinary prescription drugs, and the prescribing veterinarian was not properly licensed to practice veterinary medicine in Virginia and consequently none of the drugs he caused to be dispensed were prescribed pursuant to lawful orders.

14. From the illegal shipments to and on behalf of Groce and Webb, AHI received $7,427,928 (seven million four hundred twenty-seven thousand nine hundred twenty-eight dollars) and made a profit of $558,309 (five hundred fifty-eight thousand three hundred nine dollars) by unlawfully distributing veterinary prescription drugs to or on behalf of Groce and Webb.

15. From 2012 through on or about 2018, AHI caused additional misbranded veterinary prescription drug shipments to be made throughout the United States by distributing veterinary prescription drugs from its wholesale locations directly to end users in states where such shipments were illegal and, in some instances, by shipping veterinary prescription drugs to locations in states in which AHI did not have legal authority to make such shipments. AHI obtained not less than $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) from such shipments. Its profits from such shipments were a small percentage of the amount received.

COUNT ONE

Introduction of Misbranded Drugs into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)

The United States Attorney charges that:

16. The Information is realleged and incorporated by reference into this Count.

17. From about January 2012 to April 2015, in the Western District of Virginia, Animal Health Incorporated ("AHI") introduced and delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce, of veterinary prescription drugs that were misbranded in that the drugs' labeling did not bear adequate directions for the use of such drugs.

18. The offense conduct included, but was not limited to, the following:

a. AHI distributed veterinary prescription drugs directly to Billy K. Groce and Marlin Webb, notwithstanding that neither Groce nor Webb was legally authorized to possess or distribute the drugs; and

b. AHI distributed veterinary prescription drugs to customers of Billy K. Groce and Marlin Webb without a lawful prescription having been issued for those drugs.

19. Since these veterinary prescription drugs were not lawfully distributed or prescribed, they failed to qualify for the exemption from the requirement that they bear labeling containing adequate directions for lay use. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1).

NOTICE OF FORFEITURE

20. Upon conviction of the offense alleged in this Information, AHI shall forfeit to the United States veterinary prescription drugs that were misbranded or became misbranded as a result of AHI's conduct, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

21. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of $46,802,203 pursuant to 21 U.S.C. § 853(p).

DATED: February 11, 2020

Randy Ramseyer
for THOMAS T. CULLEN
United States Attorney

NON-PROSECUTION AGREEMENT

1. The United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") and Patterson Companies, Inc. ("Patterson"), and any and all current and former affiliated entities including, but not limited to, Animal Health International, Inc. ("AHI") (collectively referred to as the "Company") enter into this Non-Prosecution Agreement ("Agreement") to resolve the investigation by the USAO-WDVA of the Company related to possible violations of federal laws relating to the licensing, dispensing, distribution, or sale of veterinary prescription drugs.

2. This Agreement, in conjunction with the Plea Agreement with AHI ("Plea Agreement"), resolves all of the Company's potential federal criminal liability for the offenses covered herein and in the Plea Agreement.

3. The USAO-WDVA enters into this Agreement based on the individual circumstances presented by this case including:

a. Patterson's cooperation with the USAO-WDVA investigation since June 2018, and AHI's subsequent cooperation under the direction of Patterson, as well as the Company's continued cooperation under the direction of the Special Investigation Committee of the Board of Directors of Patterson ("SIC") which was formed in April 2019. Since 2018, the Company has conducted a thorough and robust internal investigation; proactively brought information to the USAO-WDVA's attention, remediated noncompliant activity and implemented control enhancements, including certain licensing, dispensing, distribution and related sales practices company-wide; made factual presentations to the USAO-WDVA; timely and fully produced all requested documents; entered into agreements tolling relevant statutes of limitations; and collected, analyzed, and organized voluminous data and information for the USAO-WDVA.

b. Patterson's voluntary disclosure to the USAO-WDVA of non-compliant licensing, dispensing, distribution, and sales at AHI and Patterson beyond AHI's conduct set forth in the Information and Plea Agreement, and its timely efforts to remediate non-compliant activity and enhance controls and processes to mitigate against future reoccurrence. The additional non-compliant activity involved wholesale distribution of veterinary prescription drugs: (i) without verifying the continued validity of all practitioners' licenses in the receiving state; (ii) without verifying that an alternate location requested by the customer was authorized by state law to receive veterinary prescription drugs; (iii) without verifying that veterinarians licensed in Virginia were also associated with a veterinary establishment registered with the Virginia Board of Veterinary Medicine, (iv) without valid licensure to ship to the state to which the drugs were shipped, and/or (v) to end users in states where drop shipments by wholesalers to end users is not allowed. The additional non-compliant activity was due to prior weaknesses and inconsistencies among AHI and Patterson regulatory functions and processes, as well as system challenges presented by the Company's enterprise resource planning implementation. The Company has since taken extensive

proactive steps to enhance its regulatory function, capabilities and support to guide the business and other control functions on regulatory compliance matters. It has also enhanced its regulatory system controls to address the issues disclosed in the investigation and to verify that veterinary prescription drugs are shipped from facilities with required state licenses and to customers and locations authorized by state law to receive veterinary prescription drugs. Consistent with its approach to the USAO-WDVA, Patterson also disclosed the pending federal investigation to state regulators in all 50 states and continues to engage with state regulators, as appropriate, on matters related to the USAO-WDVA investigation.

c. The Company's enhanced regulatory compliance processes and commitment to implement a compliance program that meets the minimum elements set forth in Attachment C to the Plea Agreement ("Corporate Compliance Program Agreement").

d. The Company's agreement to comply with the terms of the Agreement and Plea Agreement.

e. AHI's admission to and the Company's agreement with the facts and allegations set forth in the Plea Agreement.

f. Although the investigation did not involve controlled substances, the Company's recognition that diversion of controlled substances, including drugs of the type that are prescribed and dispensed by veterinarians, such as buprenorphine and hydrocodone, should be a concern of all distributors and dispensers of those drugs and the Company's ongoing commitment to be proactive in deterring diversion and identifying and notifying authorities of suspicious ordering.

4. The Company agrees it will not take any tax deduction or seek or accept directly or indirectly reimbursement or indemnification from any source for any payments made pursuant to the Plea Agreement.

5. No money paid by the Company will be returned, and the Company expressly agrees to release any and all claims it may have to the money. The Company will not file any claim or otherwise contest the payment of money set forth in this Plea Agreement, and it will not assist anyone in asserting a claim to the money.

6. Nothing in this Agreement or any related documents is an admission by the United States that the amounts paid by the Company are the maximum amounts that could be recovered from the Company in the absence of an accepted plea agreement. If the Company does not comply with all of its obligations under this Agreement, the United States is not precluded from arguing or presenting evidence that the total amount to be paid by the Company should be higher.

7. The Company's obligations under this Agreement shall have a term of 42 months from the date on which the Agreement is executed (the "Term").

8. During the Term, the Company will fully cooperate with the USAO-WDVA.

9. During the Term, the Company shall undertake and abide by the terms of the Corporate Compliance Program Agreement in Attachment C to the Plea Agreement.

10. If the Company complies with all of the terms of this Agreement and the Plea Agreement, the USAO-WDVA will not prosecute the Company for any criminal conduct occurring prior to the entering of this agreement concerning:

a. The subject matter of the Information to which AHI is pleading guilty; or

b. Facts disclosed by the Company to the USAO prior to entering this agreement related to the Company's licensing, dispensing, distribution, or sale of veterinary prescription drugs.

11. However, if the USAO-WDVA, in its sole discretion, determines the Company (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement or (b) violated any provision of this Agreement, then the USAO-WDVA will not be bound to their agreement not to prosecute the Company for the matters covered in paragraph 10. Should the USAO-WDVA determine that the Company has violated any provision of this Agreement, the USAO-WDVA shall provide prompt written notice to the Company addressed to its General Counsel, and to its outside counsel, Amy Conway-Hatcher, Baker Botts LLP, 1299 Pennsylvania Avenue NW, Washington, DC, or to any successor the Company may designate, of the alleged violation and provide the Company with a 45 (forty-five) day period from the date of receipt of notice in which to make a presentation to the USAO-WDVA to demonstrate that no violation occurred, or, to the extent applicable, that the violation should not result in adverse action, including because the violation has been cured by the Company. In the event of a violation, the Company will not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other rule or law, that any statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible in any proceeding brought by the Department of Justice. If, as a result of a violation, the United States charges the Company, the Company hereby waives any statute of limitations defense for any offense not time-barred by the applicable statute of limitations on the date this Agreement is signed, including time protected as the result of existing agreements to toll the applicable statute of limitations.

12. The Company will not, through its present or future directors, officers, employees, agents, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If the Company makes a public statement that in whole or in part contradicts any such statement or provision, the Company may avoid being in violation of this Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by the Company's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) the Company's

websites. Notwithstanding the above, the Company may avail itself of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

13. The terms of this Agreement bind the USAO-WDVA and other divisions of the Department of Justice (collectively referred to as the "United States"), except that they do not bind the Tax Division of the Department of Justice or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities. The USAO-WDVA will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

14. The Company and the United States may disclose this Agreement and any other documents used to effectuate the objectives of this Agreement to the public.

15. Nothing in this Agreement resolves, in any way, any liability of any individual.

16. This Agreement and the Plea Agreement set forth all the terms of the agreement between the Company and the USAO-WDVA. No amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the USAO-WDVA, the attorneys for the Company, and a duly authorized representative of the Company.

The Company acknowledges its acceptance of this Agreement by the signature of its counsel and Officer. A copy of a resolution by the Company's Board of Directors authorizing the Officer to execute this Agreement and all other documents to resolve this matter on behalf of the Company is attached as Addendum 1.

Date: February 12, 2020

Mark S. Walchirk
Authorized Corporate Officer
Patterson Companies, Inc.

Counsel has fully explained to the Board of Directors of the Company the facts and circumstances of the investigation and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein with the client, through its Officer. The Company understands the terms and conditions of this Agreement, and the Company's decision to enter into this Agreement is knowing and voluntary. The Company's execution of and entry into this Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI and Patterson Companies, Inc.

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

EXHIBIT A

RESOLUTION OF THE
BOARD OF DIRECTORS
OF
PATTERSON COMPANIES, INC.

NON-PROSECUTION AGREEMENT

WHEREAS, the Company, together with outside counsel reporting to the Special Investigation Committee of the Board ("SIC Counsel"), has been in discussions with the U.S. Attorney's Office for the Western District of Virginia ("USAO-WDVA") to resolve its investigation into Animal Health International, Inc. by, among other things, having the Company enter into a Non-Prosecution Agreement (the "Agreement");

WHEREAS, SIC Counsel has advised the Board of the terms of the Agreement and the consequences of entering into the Agreement; and

WHEREAS, the Board has determined that it is in the best interest of the Company to enter into the Agreement.

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby approves the Agreement and authorizes any executive officer of the Company (the "Authorized Officers") and SIC Counsel to execute and deliver the Agreement on behalf of the Company, with such changes thereto as the Authorized Officers may approve, such approval to be conclusively evidenced by the execution of the changed Agreement.

RESOLVED FURTHER, that the Authorized Officers and SIC Counsel are hereby authorized and directed to execute and deliver all other documents necessary to carry out the provisions of the Agreement.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to acknowledge on behalf of the Company that the Agreement and related documents fully set forth the agreement made between the Company and the USAO-WDVA, and that no additional promises or representations have been made to the Company by any officials of the USAO-WDVA in connection with the Agreement and related documents, other than those set forth in therein.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to make any payments required in connection with the Agreement.

RESOLVED FURTHER, that each Authorized Officer is authorized and empowered, in the name and on behalf of the Company, to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such documents, certificates and instruments as they may deem appropriate in order to effectuate fully the purpose of the foregoing resolutions, and that any actions taken heretofore and hereafter to accomplish such purposes be, and they hereby are approved, ratified and confirmed.

CERTIFICATE OF SECRETARY

I, Les B. Korsh, herby certify that I am now, and at all times mentioned herein have been, the duly elected, qualified, and acting Secretary of **PATTERSON COMPANIES, INC.**, a Minnesota corporation (the "Corporation") and, as such officer, I have access to the records of the Company, which records of the Company reflect that:

1. RESOLUTIONS. Attached hereto as **Exhibit A** is a true and correct copy of resolutions that have been duly adopted by the Board of Directors of the Corporation on February 4, 2020, in compliance with, and not in contravention of, the articles of organization and bylaws of the Corporation; none of such resolutions have been repealed or modified in any respect, and all of such resolutions are in full force and effect on and as of the date hereof, and constitute the only action taken by the Board of Directors of the Corporation with respect to the subject matter hereof.

IN WITNESS WHEREOF, I duly executed this Certificate this 10th day of February, 2020.

Les B. Korsh
Secretary of Patterson Companies, Inc.

CORPORATE COMPLIANCE PROGRAM AGREEMENT

The following Patterson Companies, Inc. ("Patterson" or the "Company") Corporate Compliance Program Agreement ("Corporate Compliance Program Agreement") has been prepared pursuant to the Non-Prosecution Agreement dated this same date between Patterson and the United States Attorney's Office for the Western District of Virginia ("USAO-WDVA"). Compliance with all the terms and standards of the Corporate Compliance Program Agreement is a condition of the Non-Prosecution Agreement and shall continue for the Term of the Non-Prosecution Agreement ("Term").

Applicability and Purpose

1. This Corporate Compliance Program Agreement shall be incorporated into the Non-Prosecution Agreement by reference, and compliance with the terms of the Corporate Compliance Program Agreement will be a condition of the Non-Prosecution Agreement. The USAO-WDVA acknowledges that the Company has already implemented many of these terms as of the date of the resolution.

2. Any proposed modifications to this Corporate Compliance Program Agreement must be made in writing and signed by the Company and the designated signatory for the USAO-WDVA.

3. The Corporate Compliance Program Agreement does not in any way release the Company from complying with any applicable federal or state statutes and/or regulations, and does not limit the imposition of any sanctions, penalties or any other actions available under those state or federal statutes and regulations.

The Corporate Compliance Program Agreement

4. The Company and the USAO-WDVA agree that the Company shall undertake the following voluntary compliance measures. The Corporate Compliance Program Agreement does and will continue to contain policies and procedures designed to prevent, detect, and correct violations of federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* and FDA requirements. These policies and procedures shall be designed to ensure that the Company complies with, among other things, the FDCA's prohibitions against causing the introduction into interstate commerce of a drug that is misbranded or otherwise violates the FDCA.

5. *Compliance Officer.* Prior to the effective date of the Non-Prosecution Agreement, the Company established the position of Chief Compliance Officer ("Compliance Officer") and appointed an individual to serve in the role on an interim basis until such time as the Company can fill the role on a permanent basis. The Company shall maintain a Compliance Officer for the Term. During the Term, the Compliance Officer shall be authorized to oversee compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA, FDA requirements, and the requirements of the Corporate

Compliance Program Agreement. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures and practices designed to address compliance with the requirements set forth in this Corporate Compliance Program Agreement, with federal and state statutes and/or regulations concerning federal prescription drug distribution and FDA requirements. The Compliance Officer shall be a member of senior management of the Company, and shall report directly to the Chief Executive Officer of the Company. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Patterson Company's Board of Directors (hereinafter the "Board") or any authorized committee thereof, and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the Company as well as for any obligations created under the Corporate Compliance Program Agreement. Any non-compliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in the Corporate Compliance Program Agreement.

6. *Compliance Committee.* Prior to the effective date of the Non-Prosecution Agreement, the Company formed a Compliance Committee (hereafter "Compliance Committee") which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the compliance program. The Company shall maintain the Compliance Committee for the Term. The Compliance Committee shall include, at a minimum, the Compliance Officer and other members of senior management necessary to meet the requirements of the Corporate Compliance Program Agreement (e.g., senior executives of relevant departments, such as legal, regulatory, audit, human resources, and operations.) The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Company's risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

7. *Board of Directors Compliance Obligations.* Prior to the effective date of the Non-Prosecution Agreement, the Board formed a committee responsible for overseeing the Company's compliance program ("Board Committee"). The Company shall maintain the Board Committee for the Term. The Board Committee shall consist of no less than three (3) non-employee directors, including at least one (1) member of the Special Investigation Committee formed in response to the USAO-WDVA investigation for a minimum of twelve (12) months from the date of this Non-Prosecution Agreement. The Board Committee shall oversee the Company's compliance program, including at a minimum:

a. the Company's obligations under the Corporate Compliance Program Agreement

b. receiving updates about adoption and implementation of policies, procedures and practices designed to ensure compliance with the FDCA and FDA requirements, and

c. evaluating the effectiveness of the compliance program.

8. The Company shall continue to evaluate its current business to ensure that it is not currently receiving, distributing or handling misbranded or unapproved federal prescription drugs. Should the Company find it is receiving, distributing, or handling misbranded or unapproved federal prescription drugs, it shall take necessary steps to remediate any such conduct.

9. The Company shall continue to enhance its current training program to ensure that pertinent employees are familiar with the requirements of the FDCA and FDA requirements that could potentially apply to the Company's conduct.

10. The Company will put in place processes to (a) encourage employees to report suspected non-compliant activities by the Company, customers, or others and to (b) acknowledge or otherwise recognize employees for reporting confirmed non-compliant activity, as appropriate.

11. The Company will maintain, or as necessary establish, policies and procedures designed to ensure effective investigation of any complaints and/or potential deficiencies relating to compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA and FDA requirements. Such policies and procedures shall include, but are not limited to:

a. Training and providing guidance to all pertinent employees as to the requirement to report all information regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to the Compliance Officer, who in turn will review and determine whether corrective actions are required; and

b. Tracking allegations and remediation action plans regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to identify issues that may require corrective actions.

12. Within 60 days of the end of the Company's fiscal year, the Company's Chief Executive Officer will certify, under oath, to (a) the United States Attorney's Office during the Term and (b) the United States Probation Office for any period during which Animal Health International, Inc. is on probation, that (1) the Company fully complied with all federal laws and regulations pursuant to the Food, Drug, and Cosmetic Act ("FDCA") in the preceding year (or, in the instance of the first such certification, the period from execution of the Non-Prosecution Agreement through the end of the Company's fiscal year 2020), or in the alternative, (2) list all non-compliant activity and the steps taken by the company to remedy such non-compliant activity. Any listing of non-compliant activity shall not be considered by the government or the Probation Officer as a per se violation of the terms of probation or the Non-Prosecution Agreement. Instead, other factors will be taken into account, including whether the conduct violated policies the Company has adopted, whether the Company provided training addressing the subject matter of the reported conduct, whether it was an isolated or systemic occurrence, the Company's response, and any remedial actions taken after the Company learned of the conduct reported.

Non-Compliance

13. The Corporate Compliance Program Agreement is part of the Non-Prosecution Agreement and adherence to it will be an enforceable condition. Deliberate, intentional or knowing failure to comply with any part of the Corporate Compliance Program Agreement is a violation of the Non-Prosecution Agreement.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	Criminal No.
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before 7 days from the date of entry of a guilty plea, the defendant will voluntarily remit payment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant upon entry, and shall be made a part of the sentence and included in the judgment.

ENTERED THIS _____ DAY OF _____, 2020.

_____

UNITED STATES DISTRICT JUDGE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Please see attached disclosure statement.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Animal Health International, Inc. (AHI) Disclosure Statement

a. On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement and a fine, and AHI paid $41,250.

b. On April 18, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Visalia, California Veterinary Food- Animal Drug Retailer license for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

c. On June 18, 2013, the Missouri Division of Professional Regulation issued a drug distributor license to Animal Health International, Inc.'s (AHI) Salina, Kansas facility. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

d. On August 30, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failing to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

e. On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no misconduct allegations beyond the conduct in Arkansas, which led to the non-disciplinary order and fine.

f. In March 2017, the Colorado Board of Pharmacy issued a letter of admonishment to Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license following allegations that it failed to timely submit an application detailing a change in designated representative. AHI was required to pay the costs associated with the Board's order.

g. On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

h. On July 20, 2020, Animal Health International, Inc. (AHI) in Boaz, AL entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an

administrative fine of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The facility in Boaz, Alabama facility, subject to discipline was AHI's Boaz, Alabama, wholesale drug distributor license.

i. On July 20, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas, wholesale drugdistributor license.

j. On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license. This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

k. On December 31, 2024, Animal Health International's Sioux Center, Iowa Wholesale Distributor facility entered into a Consent Order with the Illinois Department of Financial and Professional Regulation in which the facility's Illinois Wholesale Distributor license was reprimanded and fined $10,000. This action was based entirely on the Department of Justice case against AHI related to distribution activities predating current ownership. The Federal case was reported to State Boards during the investigation in July 2019 and again in February 2020 once the case was resolved.

l. On January 9, 2025, Animal Health International's ("AHI") Ceres, California Wholesale Distributor Facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 6 days in 2016, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

m. On January 9, 2025, Animal Health International's ("AHI") Roanoke, Texas Wholesale Distributor facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 165 days in 2014, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil

penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

n. On January 9, 2025, Animal Health International's ("AHI") Twin Falls, Idaho pharmacy entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 3 days in 2016, the pharmacy dispensed prescriptions into Oregon without an active pharmacy license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $3,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. Please note that the activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice case was reported to the state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. A copy of the Oregon Consent Order is enclosed. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054
Name: Elanco US Inc
Address: 2500 Innovation Way N City: Greenfield State: IN Zip: 46140
Name: Boehringer Ingelheim
Address: 900 Ridgebury Rd City: Ridgefield State: CT Zip: 06877
Name: Huvepharma, Inc.
Address: 525 Westpark Drive, Suite 230 City: Peachtree City State: GA Zip: 30269

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Colorado
Parent Company (if any): Patterson Companies, Inc.
Corporation/Organization Name: Animal Health International, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Animal Health International, Inc.

Facility Name

Kevin M Barry

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/6/25

Date

Board Use Only	Date Received: 5/9/25	Amount: $100.00 CC

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner **owning more than 10% of the business** stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

Animal Health INTERNATIONAL
A Patterson Company

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515
State of Incorporation:	Minnesota

ANIMAL HEALTH INTERNATIONAL, INC. – Officer List

Corporate Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Phone Number:	970-353-2000
FEIN #:	84-0575063
State of Incorporation:	Colorado (5/16/1967)

Robert J. Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Steven M. Cunningham	**President**
Business Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Business Phone:	970-353-2000
Email:	Facilitylicensing@pattersoncompanies.com

Kevin M. Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Leslie B. Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Animal Health International, Inc.

is a

Corporation

formed or registered on 05/16/1967 under the law of Colorado, has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 19871193550 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 05/06/2025 that have been posted, and by documents delivered to this office electronically through 05/08/2025 @ 06:42:52 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 05/08/2025 @ 06:42:52 in accordance with applicable law. This certificate is assigned Confirmation Number 17280636 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal License

Wholesale Drug Permit

License No. WLS 6863
Receipt No. 00197168

Valid Until: 4/1/2026

ANIMAL HEALTH INTERNATIONAL INC
1906 EAST CEDAR
ONTARIO, CA 91761

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/07/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400 CN102114303-Sind-GAWU-24-25	**CONTACT NAME:** Marsh	U.S. Operations & Technology **PHONE (A/C, No, Ext):** 866-966-4664 **FAX (A/C, No):** **E-MAIL ADDRESS:** Minneapolis.CertRequest@marsh.com
INSURED Animal Health International, Inc. and Subsidiaries 822 7th Street, Suite 740 Greeley, CO 80631	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Starr Indemnity & Liability Company — 38318 **INSURER B :** Starr Specialty Insurance Company — 16109 **INSURER C :** **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CHI-010764188-03 **REVISION NUMBER:** 1

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 0
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 10,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 4,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY			1000198195241 (AOS)	11/01/2024	11/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$ 3,000,000
A	X ANY AUTO			1000198196241 (MA)	11/01/2024	11/01/2025	BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE	$ 5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 5,000,000
	DED X RETENTION $ 25,000							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			100 0005556 (AOS)	11/01/2024	11/01/2025	X PER STATUTE OTH-ER	
B	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N	N/A		100 0005558 (FL,MA)	11/01/2024	11/01/2025	E.L. EACH ACCIDENT	$ 1,000,000
B	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			100 0005559 (WI)	11/01/2024	11/01/2025	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits	See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance

CERTIFICATE HOLDER

Animal Health International, Inc.
and Subsidiaries
822 7th Street, Suite 740
Greeley, CO 80631

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K41888441

Application/License No. _____

Animal Health International, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1906 East Cedar Avenue, Ontario, CA 91761 (Address of Applicant/Principal), as PRINCIPAL, and Federal Insurance Company (Surety Company), a corporation organized under the laws of the state of Indiana (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 202B Halls Mill Road, Whitehouse Station, NJ 08889-3454 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 25, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25 day of February, 2025.

APPLICANT/PRINCIPAL
Animal Health International, Inc.

Authorized Representative

SURETY COMPANY
Federal Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness JoAnn R. Frank

Witness Brittany D. Stuckel

Countersigned by:

N/A
Nevada Resident Agent

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Cynthia L. Choren

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024.**

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this February 25, 2025

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903- 3493 Fax (908) 903- 3656 e-mail: surety@chubb.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Animal Health International, Inc. MDEG License # (if applicable): _____

Physical Address: WLS 6863

City: 1906 East Cedar Avenue State: CA Zip: 91761

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 970-656-1957 Website: https://www.animalhealthinternational.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Matthew Middle: _____ Last: Harris

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Addre[redacted]

City: Menifee State: CA Zi[redacted]

Telephone[redacted] Email: Matthew.Harris@animalhealthinternational.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Murrieta Valley High School		08/05-08/09	
Address	**City**	**State**	**Zip**
42200 Nighthawk Way	Murrieta	CA	92562
Diploma/Degree obtained, if any			
Graduated 2009			

School Name		From - To (MM/YY – MM/YY)	
California State University, Fullerton		08/10-08/12	
Address	**City**	**State**	**Zip**
800 N State College Blvd	Fullerton	CA	92831
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/23-PRESENT	[redacted]	Menifee	CA	[redacted]
06/18-11/23		Murrieta	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Animal Health International, Inc.			From - To (MM/YY – MM/YY): 05/2019 - Present
Business Address: 1906 East Cedar Street	City: Ontario	State: CA	Zip: 91761
Phone: 626-542-8063	Title: Operations Supervisor		Number of Employed Hours: 12,360
Description of Duties: Managing day to day operation			

Business Name: Animal Health International, Inc.			From - To (MM/YY – MM/YY): 10/10-05/19
Business Address: 1906 East Cedar Street	City: Ontario	State: CA	Zip: 91761
Phone: 626-542-8063	Title: Material Handler		Number of Employed Hours: Same as Above
Description of Duties: Shipping, receiving, inventory control.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/23/25
Date

I, Matthew Harris, **certify that as the MDEG Administrator for**

Animal Health International, Inc.,

that I (initial that you have read and meet the following requirements):

1. MH Have a high school diploma or its equivalent;
2. MH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Harris

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/23/25

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Animal Health International, Inc.

Pharmacy/Wholesaler License # (if applicable): WLS 6863

Physical Address: 1906 East Cedar Avenue

City: 1906 East Cedar Avenue State: CA Zip: 91761

Mailing Address (if different from physical address): 1031 Mendota Heights Road

City: Saint Paul State: MN Zip: 55120

Telephone: 970-656-1957 Website: www.animalhealthinternational.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Matthew Middle: Douglas Last: Harris

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Menifee State: CA Zip: [redacted]

Telephone: [redacted] Email: Matthew.Harris@animalhealthinternational.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Murrieta Valley High School		08/05-08/09	
Address	**City**	**State**	**Zip**
42200 Nighthawk Way	Murrieta	CA	92562
Diploma/Degree obtained, if any			
Diploma - Graduated 2009			

School Name		From - To (MM/YY – MM/YY)	
California State University, Fullerton		2010 - 2012	
Address	**City**	**State**	**Zip**
800 N State College Blvd	Fullerton	CA	92831
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/23-Present	[redacted]	Menifee	CA	
6/18-11/23		Murrieta	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International, Inc.			5/2019 - Present	
Business Address		**City**	**State**	**Zip**
1906 East Cedar Street		Ontario	CA	91761
Phone	**Title**		**Number of Employed Hours**	
626-542-8063	Operations Supervisor		12,360	
Description of Duties				
.Managing day to day operations				

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International, Inc.			2010 - Present	
Business Address		**City**	**State**	**Zip**
1906 East Cedar Street		Ontario	CA	91761
Phone	**Title**		**Number of Employed Hours**	
626-542-8063	Material Handler		AVAVC	
Description of Duties				
Shipping, receiving, inventory control.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Matthew Harris, **certify that as the designated representative for**

Animal Health International, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MH I am at least 21 years of age;
3. MH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Matthew Harris

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/27/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Harris

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/27/25

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Bernardino

I, Matthew Harris, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/28/25

Date

Subscribed and Sworn to before me this 28 day of February 2025.

Laura Silva

Notary Public Signature

LAURA SILVA
COMM. #2363346
Notary Public - California
San Bernardino County
My Comm. Expires June 29, 2025

(Seal)

Animal Health INTERNATIONAL
a Patterson Company

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Employee List

1906 East Cedar Avenue
Ontario, CA 91761
License Number: WH03587

Salazar, Larry T
Silva, William
Maxwell, Holly Marie
Smith, Russell Loyd
Prestsater, Vanessa
Dean, Lyndsi D
Harris, Matthew Douglas
Swager, Dan R
Harris, Norman
Vandermeer, Rick
Grisley Jr, John
Enriquez Jr, Frank Xavier
Lopez, Monique

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02465	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Animal Health International, Inc.

Physical Address: 804 Henrietta Creek Road

City: Roanoke State: TX Zip: 76262

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 970-584-5206 Website: https://www.animalhealthinternational.com/home

Name of Designated Representative (DR): Sergio Gutierrez

Licensing Company Email: facilitylicensing@pattersoncompa DR Email: Sergio.Gutierrez@animalhealthinternational.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies ■ Practitioners ■ Hospitals ■ Wholesalers ■ Veterinarians ■ Others: Universities/Research	■ Dangerous Drugs ■ Controlled Substances ☐ [a]Medical devices, equipment, supplies, gases ■ Others: Class I & Class II Medical Devices	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ■ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/14/2020		VA	Abingdon	Washington

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DVAW120CR00007-001	United States District Court, Wetern District of Virginia Abingdon

Reason/Charge
Violation of Title 21, US Code, Sections 221(1), 333(a)(1), and (352)(f)(l)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

CLERKS OFFICE U.S. DISTRICT COURT
AT ABINGDON, VA
FILED

FEB 14 2020

JULIA C. DUDLEY, CLERK
BY: DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20-cr-00007
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

PLEA AGREEMENT

ANIMAL HEALTH INTERNATIONAL, INC. (EIN: 84-0575063) ("AHI") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this Plea Agreement are as follows:

1. CHARGE TO WHICH AHI IS PLEADING GUILTY AND WAIVER OF RIGHTS

AHI will enter a plea of guilty to Count One of the Information charging it with violating Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) in the Western District of Virginia by introducing and delivering for introduction, and causing the introduction and delivery for introduction, into interstate commerce of veterinary prescription drugs that were misbranded.

AHI understands, and the parties agree and stipulate, the maximum statutory penalty is a fine of $14,855,856 (fourteen million eight hundred fifty-five thousand eight hundred fifty-six dollars), pursuant to Title 18, United States Code, Section 3571(d), and a period of probation of five (5) years, pursuant to Title 18, United States Code, Section 3561(c)(2). In addition, AHI's assets are subject to forfeiture. AHI understands fees may be imposed to pay for probation and there will be a $125 (one hundred twenty-five dollars) special assessment for Count One, pursuant to Title 18, United States Code, Section 3013(a)(1)(B)(iii). AHI's attorneys have informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before AHI could be found guilty as charged.

AHI admits and agrees that all of the statements and allegations in the Information are true and correct.

AHI acknowledges AHI has had all of its rights explained to it. AHI expressly recognizes that, as a corporation, AHI may have the following constitutional rights and by voluntarily pleading guilty AHI knowingly waives and gives up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses.

The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

AHI is pleading guilty as described above because AHI is in fact guilty and because AHI believes it is in its best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for its plea of guilty. AHI agrees all of the matters set forth in the Information are true and correct.

AHI understands the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree the 2018 version of the United States Sentencing Commission Guidelines Manual ("U.S.S.G.") is the appropriate Guidelines Manual to utilize. According to U.S.S.G. § 8C2.1, the organizational fine provisions do not apply to the count of conviction in this case, which is a misdemeanor under 21 U.S.C. § 333(a)(1).

The parties agree and stipulate:

a. the fine shall be $5,000,000 (five million dollars);
b. AHI shall pay $1,000,000 (one million dollars) to the Virginia Department of Health Professions ("DHP") in recognition of direct assistance provided by DHP to the United States during the investigation;
c. AHI shall forfeit $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars); and
d. AHI shall serve a term of probation of one to three years, as determined by the Court.

The Court will determine what terms and length of probation are appropriate and the parties will be free to argue for which terms and length of probation they believe are appropriate. AHI understands and agrees if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum may be imposed.

The parties agree if the Court refuses to accept this Plea Agreement with the agreed-upon sentence, AHI will be free to withdraw its guilty plea. In the event the Court refuses to accept this Plea Agreement and AHI withdraws its guilty plea within ten days of being notified of the Court's refusal, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410. Under these circumstances, the United States will move to dismiss the Information without prejudice and the United States may file any charges it could have filed in the absence of the plea agreement. AHI agrees to toll the statute of limitations between the date of the plea and the filing of any such charges.

3. FINANCIAL OBLIGATIONS

AHI agrees and understands any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept this Plea Agreement with the agreed-upon sentence and, as a result, AHI withdraws its guilty plea. If the Court rejects this Plea Agreement and AHI withdraws its guilty plea, the United States will return all money paid by AHI, without

interest, not more than thirty (30) days after AHI withdraws its guilty plea and notifies the United States Attorney's Office for the Western District of Virginia ("USAO"), in writing, it wishes to have the money returned.

In addition, in accordance with 18 U.S.C. § 3572(d)(3), AHI will notify the Court of any material change in AHI's economic circumstances that might affect AHI's ability to pay any amounts payable under this Plea Agreement.

a. Payments

Within 7 days of the entry of AHI's guilty plea, AHI will make the following disbursements:

(1) $125 (one hundred twenty-five dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the special assessment.

(2) $5,000,000 (five million dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the fine;

(3) $1,000,000 (one million dollars) to the Virginia Department of Health Professions. These funds must be remitted in the form of certified funds made payable to the "Treasurer of Virginia." The comment section of the check should note "DHP-Enforcement" in recognition of direct assistance provided to the United States during the investigation; and

(4) $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) made payable to the United States Marshals Service, as directed by the USAO as payment of a forfeiture money judgment.

b. Forfeiture

AHI agrees to the entry of a forfeiture money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency ("Forfeiture Money Judgment") pursuant to 21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c). AHI agrees that the value of the quantities of prescription drugs which were misbranded in violation of 21 U.S.C. § 331(a) totaled at least $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency.

AHI acknowledges and agrees the quantities of the drugs which were misbranded in violation of 21 U.S.C. § 331(a) cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, AHI agrees the government is entitled to forfeit as substitute assets any other assets of AHI up to the value of the now missing directly forfeitable assets, pursuant to

21 U.S.C. § 853(p). Payment in full of the Forfeiture Money Judgment shall satisfy any and all forfeiture obligations that AHI may have as a result of this guilty plea. AHI consents to the entry of an Order of Forfeiture pursuant to Rule 32.2 of the Federal Rules of Criminal Procedure forfeiting the above-referenced Forfeiture Money Judgment.

AHI agrees to sign any documentation necessary and to cooperate fully with the United States to accomplish the forfeiture. AHI agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of these funds to the United States.

AHI agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. AHI agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgement in any administrative or judicial proceeding.

AHI understands and agrees forfeiture of this property is proportionate to the degree and nature of the offense. AHI freely and knowingly waives any and all constitutional and statutory challenges to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including, but not limited to, that the forfeiture constitutes an excessive fine or punishment. AHI further understands and agrees this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty or other monetary judgment that may be imposed by the court.

c. Restitution

The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no restitution will be ordered.

4. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, AHI withdraws its plea, AHI agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny it committed the crime to which it has pled guilty; (4) comply with any reasonable request of the United States Attorney's Office and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement.

Neither AHI, nor its corporate parent (Patterson Companies, Inc. ["Patterson"]), will (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If Patterson or AHI makes a public statement that in whole or in part contradicts any such statement or provision, AHI may avoid being in violation of this Plea Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by Patterson's and AHI's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) Patterson or AHI websites. Notwithstanding the above, Patterson and AHI may avail themselves of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by

any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

5. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, AHI agrees AHI will not appeal the conviction or sentence imposed. AHI is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). AHI expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. AHI understands the United States expressly reserves all of its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, AHI may file a cross appeal of that same sentence. AHI agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this Plea Agreement.

6. INFORMATION ACCESS WAIVER

AHI agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a. However, if a third party obtains any records pertaining to the investigation or prosecution of this case under the Freedom of Information Act, AHI shall have the right to request copies of such disclosed records.

7. ADMISSIBILITY OF STATEMENTS

AHI understands any statements made on its behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against AHI by the United States in this or any other proceeding. AHI knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other proceeding. If, and only if, the Court rejects this Plea Agreement, and, as a result, AHI withdraws its plea, AHI will not be bound by the waivers set forth in this section of the Plea Agreement.

8. COMPLETION OF PROSECUTION

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), so long as AHI complies with all of its obligations under this Plea Agreement, the United States agrees, other than the charge in the attached Information, it shall not further criminally prosecute AHI for any additional federal criminal

charges or forfeiture action with respect to any offenses set forth in the Information or Non-Prosecution Agreement with Patterson (Attached as Attachment B).

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

9. LIMITATION OF PLEA AGREEMENT

This Plea Agreement is limited to the United States Department of Justice and does not bind any other federal, state, or local authority.

10. COMPLIANCE AND REMEDIAL MEASURES

AHI agrees to comply with the Corporate Compliance Program Agreement attached hereto as Attachment C.

11. COOPERATION

AHI acknowledges that its ongoing and future cooperation is important and a material fact underlying the United States' decision to enter into this Plea Agreement. AHI agrees to continue to cooperate fully and actively with the United States regarding any matter, including, but not limited to, matters involving (a) current and former AHI personnel, and (b) other entities who operate in the same commercial segment as AHI and/or Patterson during the Term of the Non-Prosecution Agreement with Patterson, provided however that any cooperation in an ongoing investigation or prosecution shall continue until such investigation or prosecution is concluded.

Nothing in this Plea Agreement shall be construed to require Patterson or AHI to waive any attorney-client privilege or work-product protection.

12. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THIS PLEA AGREEMENT

AHI understands if: (1) AHI attempts to withdraw its plea (in the absence of the Court refusing to accept this Plea Agreement); (2) AHI fails to comply with any provision of this Plea Agreement; (3) AHI's conviction is set aside, for any reason; and/or (4) AHI fails to execute all required paperwork prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement titled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, AHI will still be bound by its obligations under this Plea Agreement. AHI hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of this Plea Agreement. AHI hereby waives any statute of limitations argument as to any such charges.

13. EFFECTIVE REPRESENTATION

AHI has discussed the terms of this Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, AHI has no dissatisfaction or complaint with its attorneys' representation. AHI agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint AHI may have with its attorneys' representation.

14. EFFECT OF AHI'S SIGNATURE

AHI understands its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. AHI understands the United States has not accepted AHI's offer until the authorized representative of the United States has signed this Plea Agreement.

15. GENERAL UNDERSTANDINGS

AHI understands a presentence investigation will be conducted and sentencing recommendations independent of the USAO will be made by the presentence preparer.

AHI understands the United States and AHI retain the right, notwithstanding any provision in this Plea Agreement, to inform the probation office and the Court of all facts, to address the Court with respect to the nature and seriousness of the offense and the offender, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, and to respond to any statements made to the Court.

AHI willingly stipulates there is a sufficient factual basis for the Court to accept the plea.

AHI understands this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

AHI has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. AHI understands its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. AHI understands AHI will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing, the Non-Prosecution Agreement with Patterson (attached as Attachment B), the Corporate Compliance Program Agreement (attached as Attachment C), and the Agreed Order of Forfeiture (attached as Attachment D) are the complete and only agreements between the United States and AHI concerning resolution of this matter. In addition, AHI has no objection to the filing of the Information.

The agreements and documents listed in this section set forth the entire understanding between the parties and constitute the complete agreement between the United States Attorney for the Western District of Virginia and AHI and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and AHI. AHI consents to public disclosure of all of the agreements and other documents referenced in this section.

AHI has consulted with its attorneys and fully understands its rights. AHI has read this Plea Agreement and carefully reviewed every part of it with its attorneys. AHI understands this Plea Agreement and AHI voluntarily agrees to it. Being aware of all of the possible consequences of its plea, AHI has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer ("Officer") below.

The Officer, by signing below, hereby certifies to the following:

(1) The Officer is fully authorized to enter into this Plea Agreement on behalf of AHI;

(2) The Officer has read the entire Plea Agreement and documents referenced herein and discussed them with AHI's Board of Directors;

(3) AHI understands all the terms of this Plea Agreement and those terms correctly reflect the results of plea negotiations;

(4) AHI is fully satisfied with AHI's attorneys' representation during all phases of this case;

(5) AHI is freely and voluntarily pleading guilty in this case;

(6) AHI is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea; and

(7) AHI understands it is waiving its right to appeal the judgment and conviction in this case.

AHI acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Officer. A copy of a certification by AHI's Board of Directors authorizing the Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of AHI is attached as Attachment A.

Date: 2/13/2020 Keri M. Fahlman

Authorized Corporate Officer
AHI

Counsel has fully explained to the Board of Directors of AHI the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the Sentencing Guidelines; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and documents referenced herein with the client, through its Officer. AHI understands the terms and conditions of this Plea Agreement, and AHI's decision to enter into this Plea Agreement is knowing and voluntary. AHI's execution of and entry into the Plea Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED
2/11/2020
JULIA C. DUDLEY, CLERK
BY: LOTTIE LUNSFORD
DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20CR00007
v.	)	
	)	**Violations: 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)**
ANIMAL HEALTH INTERNATIONAL, INC.	)	

INFORMATION

INTRODUCTION

1. Defendant Animal Health International, Inc. ("AHI") is a Colorado corporation with its principal place of business in Colorado. AHI is comprised of two legacy organizations, Lextron, Inc. ("Lextron") and Walco International, Inc. ("Walco"). In June 2011, Lextron acquired all outstanding stock of the parent company of Walco and changed its name to AHI. Walco continued operations as a subsidiary of AHI until December 2011 when Animal Health Holdings, Inc. and each of its wholly-owned subsidiaries, including Walco, were merged with and into AHI and no longer had separate corporate existences. AHI, and its predecessor entities, dispense, distribute and sell, among other products, veterinary prescription drugs to customers in the production animal industry across the United States. Specifically, AHI obtains prescription drugs for production animals from manufacturers for further distribution to veterinarians, farms, feedlots, and other distribution facilities.

2. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulates the distribution and labeling of all drugs, including animal drugs, shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C § 301, *et seq.* ("FDCA"). Veterinary prescription drugs are drugs intended for use by animals that, because of their toxicity or other potentiality for harmful

effect, or the method of their use, or the collateral measures necessary for their use, are not safe for animal use except under the professional supervision of a licensed veterinarian. 21 U.S.C. § 353(f)(1)(A).

3. Under the FDCA, a drug is misbranded if, among other things, its labeling does not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). Adequate directions for use is defined as "directions under which the *layman* can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5 (emphasis added). Prescription veterinary drugs by definition can only safely be used under the professional supervision of a licensed veterinarian and therefore they must qualify for an exemption to this requirement in order to move in interstate commerce. These exemptions are set out in 21 C.F.R. Part 201, Subpart D ("Exemptions from Adequate Directions for Use").

4. Veterinary prescription drugs are exempt from the requirement that their labeling contain adequate directions for use if they meet all enumerated conditions, including that they be distributed through a closed supply chain in which every entity that possesses a prescription drug must have legal authorization to do so. *See* 21 C.F.R. § 201.105 (a)(1) (a veterinary prescription drug must be in the possession of: a person lawfully engaged in the manufacture, transportation, storage or wholesale distribution of drugs; a retail pharmacy or other person authorized under state law to dispense veterinary prescription drugs; or a licensed veterinarian for use in the course of his professional practice). Moreover, the veterinary prescription drug must be dispensed in accordance with 21 U.S.C. § 353(f), i.e., pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian's professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105 (a)(2).

5. The FDCA's restrictions on veterinary prescription drugs are not primarily to protect animals from the potential harms of prescription drugs, but are to protect the human food supply from unsafe drug residues in the edible tissues of animals sold for slaughter. Common causes of illegal residues include: (1) exceeding the drug's approved dose; (2) using a shorter withdrawal period than what is stated on the drug's label (if a higher than approved dose is given, the labeled withdrawal period may not be enough to allow the drug in the edible tissues to deplete to levels that are at or below the tolerance); (3) using a drug in an extra-label manner (for indications and dosages outside the approved labeling) without a veterinarian's involvement; (4) giving a drug not approved for that species; and (5) using an unapproved route of administration. Drug residues in the nation's drug supply are concerning because: (1) they may contribute to antibiotic resistance in the human population, rendering human drugs less effective to treat human disease and contributing to the mutations of "superbugs"; and (2) they may cause allergic reactions in individuals with certain drug allergies.

6. Certain legacy customers of AHI, namely Marlin Webb and Billy K. Groce, were not properly licensed to receive, transport, store, distribute, or dispense veterinary prescription drugs in the Commonwealth of Virginia from January 2012 through April 2015.

7. Webb was the store manager of a cooperative in Hillsville, Virginia. The cooperative was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Webb operated a side business from the cooperative's location in which he illegally circumvented the FDA's regulation of veterinary prescription drugs by illegally obtaining from Billy K. Groce and AHI and reselling veterinary prescription drugs using unlawful prescriptions written by a veterinarian who was licensed in Tennessee but who was not properly licensed to

practice veterinary medicine in Virginia and who did not have a veterinarian-patient relationship with the animals in question. That veterinarian died in 2015.

8. Groce was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Groce operated an unlicensed veterinary prescription drug distribution business. Groce worked with the same veterinarian as did Webb.

9. Webb and Groce obtained veterinary prescription drugs from AHI in interstate commerce without valid prescriptions, and, on many occasions, with no prescription at all.

10. On April 29, 2015, the government executed search warrants at locations in Virginia and Tennessee associated with Groce and Webb. In 2016 and 2017, respectively, Groce and Webb pled guilty to illegally conspiring to defraud the FDA by obtaining and distributing veterinary prescription drugs from July 2009 through April 29, 2015 in a manner that circumvented the FDA's regulation of veterinary prescription drugs.

11. Groce and Webb were legacy customers of, among others, Lextron and Walco, and continued to be customers after the companies merged to form AHI in 2012 until May 2015. Neither Lextron, Walco, nor AHI performed adequate customer diligence processes, nor adequately trained sales representatives to raise questions regarding Groce's, Webb's or the veterinarian's activities in Virginia and Tennessee. For example, Groce operated a business that stored and distributed veterinary prescription drugs out of a storefront called "Goin' Postal" and his personal residence. Neither of those locations resembled a veterinarian establishment and should have raised questions for sales representatives who personally visited them. After learning of search warrants executed on each of the customers' locations, AHI took some steps to block the sale of veterinary prescription drugs to these customers on May 4, 2015.

12. Furthermore, between January 2012 and May 2015, AHI did not maintain the proper licenses to ship from its Memphis, Tennessee, facility into Virginia or from its Wolcott, Indiana, facility into Virginia or Tennessee, but, despite this deficiency, shipped products from those locations to Virginia and Tennessee.

13. All veterinary prescription drugs distributed by AHI to Groce and Webb were misbranded because, neither recipient was licensed to possess or distribute veterinary prescription drugs, and the prescribing veterinarian was not properly licensed to practice veterinary medicine in Virginia and consequently none of the drugs he caused to be dispensed were prescribed pursuant to lawful orders.

14. From the illegal shipments to and on behalf of Groce and Webb, AHI received $7,427,928 (seven million four hundred twenty-seven thousand nine hundred twenty-eight dollars) and made a profit of $558,309 (five hundred fifty-eight thousand three hundred nine dollars) by unlawfully distributing veterinary prescription drugs to or on behalf of Groce and Webb.

15. From 2012 through on or about 2018, AHI caused additional misbranded veterinary prescription drug shipments to be made throughout the United States by distributing veterinary prescription drugs from its wholesale locations directly to end users in states where such shipments were illegal and, in some instances, by shipping veterinary prescription drugs to locations in states in which AHI did not have legal authority to make such shipments. AHI obtained not less than $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) from such shipments. Its profits from such shipments were a small percentage of the amount received.

COUNT ONE

Introduction of Misbranded Drugs into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)

The United States Attorney charges that:

16. The Information is realleged and incorporated by reference into this Count.

17. From about January 2012 to April 2015, in the Western District of Virginia, Animal Health Incorporated ("AHI") introduced and delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce, of veterinary prescription drugs that were misbranded in that the drugs' labeling did not bear adequate directions for the use of such drugs.

18. The offense conduct included, but was not limited to, the following:

a. AHI distributed veterinary prescription drugs directly to Billy K. Groce and Marlin Webb, notwithstanding that neither Groce nor Webb was legally authorized to possess or distribute the drugs; and

b. AHI distributed veterinary prescription drugs to customers of Billy K. Groce and Marlin Webb without a lawful prescription having been issued for those drugs.

19. Since these veterinary prescription drugs were not lawfully distributed or prescribed, they failed to qualify for the exemption from the requirement that they bear labeling containing adequate directions for lay use. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1).

NOTICE OF FORFEITURE

20. Upon conviction of the offense alleged in this Information, AHI shall forfeit to the United States veterinary prescription drugs that were misbranded or became misbranded as a result of AHI's conduct, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

21. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of $46,802,203 pursuant to 21 U.S.C. § 853(p).

DATED: February 11, 2020

Randy Ramseyer
for THOMAS T. CULLEN
United States Attorney

NON-PROSECUTION AGREEMENT

1. The United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") and Patterson Companies, Inc. ("Patterson"), and any and all current and former affiliated entities including, but not limited to, Animal Health International, Inc. ("AHI") (collectively referred to as the "Company") enter into this Non-Prosecution Agreement ("Agreement") to resolve the investigation by the USAO-WDVA of the Company related to possible violations of federal laws relating to the licensing, dispensing, distribution, or sale of veterinary prescription drugs.

2. This Agreement, in conjunction with the Plea Agreement with AHI ("Plea Agreement"), resolves all of the Company's potential federal criminal liability for the offenses covered herein and in the Plea Agreement.

3. The USAO-WDVA enters into this Agreement based on the individual circumstances presented by this case including:

a. Patterson's cooperation with the USAO-WDVA investigation since June 2018, and AHI's subsequent cooperation under the direction of Patterson, as well as the Company's continued cooperation under the direction of the Special Investigation Committee of the Board of Directors of Patterson ("SIC") which was formed in April 2019. Since 2018, the Company has conducted a thorough and robust internal investigation; proactively brought information to the USAO-WDVA's attention, remediated noncompliant activity and implemented control enhancements, including certain licensing, dispensing, distribution and related sales practices company-wide; made factual presentations to the USAO-WDVA; timely and fully produced all requested documents; entered into agreements tolling relevant statutes of limitations; and collected, analyzed, and organized voluminous data and information for the USAO-WDVA.

b. Patterson's voluntary disclosure to the USAO-WDVA of non-compliant licensing, dispensing, distribution, and sales at AHI and Patterson beyond AHI's conduct set forth in the Information and Plea Agreement, and its timely efforts to remediate non-compliant activity and enhance controls and processes to mitigate against future reoccurrence. The additional non-compliant activity involved wholesale distribution of veterinary prescription drugs: (i) without verifying the continued validity of all practitioners' licenses in the receiving state; (ii) without verifying that an alternate location requested by the customer was authorized by state law to receive veterinary prescription drugs; (iii) without verifying that veterinarians licensed in Virginia were also associated with a veterinary establishment registered with the Virginia Board of Veterinary Medicine, (iv) without valid licensure to ship to the state to which the drugs were shipped, and/or (v) to end users in states where drop shipments by wholesalers to end users is not allowed. The additional non-compliant activity was due to prior weaknesses and inconsistencies among AHI and Patterson regulatory functions and processes, as well as system challenges presented by the Company's enterprise resource planning implementation. The Company has since taken extensive

proactive steps to enhance its regulatory function, capabilities and support to guide the business and other control functions on regulatory compliance matters. It has also enhanced its regulatory system controls to address the issues disclosed in the investigation and to verify that veterinary prescription drugs are shipped from facilities with required state licenses and to customers and locations authorized by state law to receive veterinary prescription drugs. Consistent with its approach to the USAO-WDVA, Patterson also disclosed the pending federal investigation to state regulators in all 50 states and continues to engage with state regulators, as appropriate, on matters related to the USAO-WDVA investigation.

c. The Company's enhanced regulatory compliance processes and commitment to implement a compliance program that meets the minimum elements set forth in Attachment C to the Plea Agreement ("Corporate Compliance Program Agreement").

d. The Company's agreement to comply with the terms of the Agreement and Plea Agreement.

e. AHI's admission to and the Company's agreement with the facts and allegations set forth in the Plea Agreement.

f. Although the investigation did not involve controlled substances, the Company's recognition that diversion of controlled substances, including drugs of the type that are prescribed and dispensed by veterinarians, such as buprenorphine and hydrocodone, should be a concern of all distributors and dispensers of those drugs and the Company's ongoing commitment to be proactive in deterring diversion and identifying and notifying authorities of suspicious ordering.

4. The Company agrees it will not take any tax deduction or seek or accept directly or indirectly reimbursement or indemnification from any source for any payments made pursuant to the Plea Agreement.

5. No money paid by the Company will be returned, and the Company expressly agrees to release any and all claims it may have to the money. The Company will not file any claim or otherwise contest the payment of money set forth in this Plea Agreement, and it will not assist anyone in asserting a claim to the money.

6. Nothing in this Agreement or any related documents is an admission by the United States that the amounts paid by the Company are the maximum amounts that could be recovered from the Company in the absence of an accepted plea agreement. If the Company does not comply with all of its obligations under this Agreement, the United States is not precluded from arguing or presenting evidence that the total amount to be paid by the Company should be higher.

7. The Company's obligations under this Agreement shall have a term of 42 months from the date on which the Agreement is executed (the "Term").

8. During the Term, the Company will fully cooperate with the USAO-WDVA.

9. During the Term, the Company shall undertake and abide by the terms of the Corporate Compliance Program Agreement in Attachment C to the Plea Agreement.

10. If the Company complies with all of the terms of this Agreement and the Plea Agreement, the USAO-WDVA will not prosecute the Company for any criminal conduct occurring prior to the entering of this agreement concerning:

a. The subject matter of the Information to which AHI is pleading guilty; or

b. Facts disclosed by the Company to the USAO prior to entering this agreement related to the Company's licensing, dispensing, distribution, or sale of veterinary prescription drugs.

11. However, if the USAO-WDVA, in its sole discretion, determines the Company (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement or (b) violated any provision of this Agreement, then the USAO-WDVA will not be bound to their agreement not to prosecute the Company for the matters covered in paragraph 10. Should the USAO-WDVA determine that the Company has violated any provision of this Agreement, the USAO-WDVA shall provide prompt written notice to the Company addressed to its General Counsel, and to its outside counsel, Amy Conway-Hatcher, Baker Botts LLP, 1299 Pennsylvania Avenue NW, Washington, DC, or to any successor the Company may designate, of the alleged violation and provide the Company with a 45 (forty-five) day period from the date of receipt of notice in which to make a presentation to the USAO-WDVA to demonstrate that no violation occurred, or, to the extent applicable, that the violation should not result in adverse action, including because the violation has been cured by the Company. In the event of a violation, the Company will not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other rule or law, that any statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible in any proceeding brought by the Department of Justice. If, as a result of a violation, the United States charges the Company, the Company hereby waives any statute of limitations defense for any offense not time-barred by the applicable statute of limitations on the date this Agreement is signed, including time protected as the result of existing agreements to toll the applicable statute of limitations.

12. The Company will not, through its present or future directors, officers, employees, agents, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If the Company makes a public statement that in whole or in part contradicts any such statement or provision, the Company may avoid being in violation of this Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by the Company's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) the Company's

websites. Notwithstanding the above, the Company may avail itself of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

13. The terms of this Agreement bind the USAO-WDVA and other divisions of the Department of Justice (collectively referred to as the "United States"), except that they do not bind the Tax Division of the Department of Justice or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities. The USAO-WDVA will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

14. The Company and the United States may disclose this Agreement and any other documents used to effectuate the objectives of this Agreement to the public.

15. Nothing in this Agreement resolves, in any way, any liability of any individual.

16. This Agreement and the Plea Agreement set forth all the terms of the agreement between the Company and the USAO-WDVA. No amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the USAO-WDVA, the attorneys for the Company, and a duly authorized representative of the Company.

The Company acknowledges its acceptance of this Agreement by the signature of its counsel and Officer. A copy of a resolution by the Company's Board of Directors authorizing the Officer to execute this Agreement and all other documents to resolve this matter on behalf of the Company is attached as Addendum 1.

Date: February 12, 2020

Mark S. Walchirk
Authorized Corporate Officer
Patterson Companies, Inc.

Counsel has fully explained to the Board of Directors of the Company the facts and circumstances of the investigation and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein with the client, through its Officer. The Company understands the terms and conditions of this Agreement, and the Company's decision to enter into this Agreement is knowing and voluntary. The Company's execution of and entry into this Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI and Patterson Companies, Inc.

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

EXHIBIT A

RESOLUTION OF THE
BOARD OF DIRECTORS
OF
PATTERSON COMPANIES, INC.

NON-PROSECUTION AGREEMENT

WHEREAS, the Company, together with outside counsel reporting to the Special Investigation Committee of the Board ("SIC Counsel"), has been in discussions with the U.S. Attorney's Office for the Western District of Virginia ("USAO-WDVA") to resolve its investigation into Animal Health International, Inc. by, among other things, having the Company enter into a Non-Prosecution Agreement (the "Agreement");

WHEREAS, SIC Counsel has advised the Board of the terms of the Agreement and the consequences of entering into the Agreement; and

WHEREAS, the Board has determined that it is in the best interest of the Company to enter into the Agreement.

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby approves the Agreement and authorizes any executive officer of the Company (the "Authorized Officers") and SIC Counsel to execute and deliver the Agreement on behalf of the Company, with such changes thereto as the Authorized Officers may approve, such approval to be conclusively evidenced by the execution of the changed Agreement.

RESOLVED FURTHER, that the Authorized Officers and SIC Counsel are hereby authorized and directed to execute and deliver all other documents necessary to carry out the provisions of the Agreement.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to acknowledge on behalf of the Company that the Agreement and related documents fully set forth the agreement made between the Company and the USAO-WDVA, and that no additional promises or representations have been made to the Company by any officials of the USAO-WDVA in connection with the Agreement and related documents, other than those set forth in therein.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to make any payments required in connection with the Agreement.

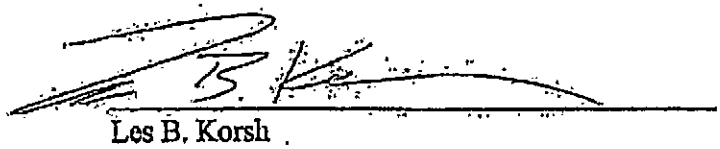
RESOLVED FURTHER, that each Authorized Officer is authorized and empowered, in the name and on behalf of the Company, to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such documents, certificates and instruments as they may deem appropriate in order to effectuate fully the purpose of the foregoing resolutions, and that any actions taken heretofore and hereafter to accomplish such purposes be, and they hereby are approved, ratified and confirmed.

CERTIFICATE OF SECRETARY

I, Les B. Korsh, herby certify that I am now, and at all times mentioned herein have been, the duly elected, qualified, and acting Secretary of **PATTERSON COMPANIES, INC.**, a Minnesota corporation (the "Corporation") and, as such officer, I have access to the records of the Company, which records of the Company reflect that:

1. RESOLUTIONS. Attached hereto as **Exhibit A** is a true and correct copy of resolutions that have been duly adopted by the Board of Directors of the Corporation on February 4, 2020, in compliance with, and not in contravention of, the articles of organization and bylaws of the Corporation; none of such resolutions have been repealed or modified in any respect, and all of such resolutions are in full force and effect on and as of the date hereof, and constitute the only action taken by the Board of Directors of the Corporation with respect to the subject matter hereof.

IN WITNESS WHEREOF, I duly executed this Certificate this 10th day of February, 2020.



Les B. Korsh
Secretary of Patterson Companies, Inc.

CORPORATE COMPLIANCE PROGRAM AGREEMENT

The following Patterson Companies, Inc. ("Patterson" or the "Company") Corporate Compliance Program Agreement ("Corporate Compliance Program Agreement") has been prepared pursuant to the Non-Prosecution Agreement dated this same date between Patterson and the United States Attorney's Office for the Western District of Virginia ("USAO-WDVA"). Compliance with all the terms and standards of the Corporate Compliance Program Agreement is a condition of the Non-Prosecution Agreement and shall continue for the Term of the Non-Prosecution Agreement ("Term").

Applicability and Purpose

1. This Corporate Compliance Program Agreement shall be incorporated into the Non-Prosecution Agreement by reference, and compliance with the terms of the Corporate Compliance Program Agreement will be a condition of the Non-Prosecution Agreement. The USAO-WDVA acknowledges that the Company has already implemented many of these terms as of the date of the resolution.

2. Any proposed modifications to this Corporate Compliance Program Agreement must be made in writing and signed by the Company and the designated signatory for the USAO-WDVA.

3. The Corporate Compliance Program Agreement does not in any way release the Company from complying with any applicable federal or state statutes and/or regulations, and does not limit the imposition of any sanctions, penalties or any other actions available under those state or federal statutes and regulations.

The Corporate Compliance Program Agreement

4. The Company and the USAO-WDVA agree that the Company shall undertake the following voluntary compliance measures. The Corporate Compliance Program Agreement does and will continue to contain policies and procedures designed to prevent, detect, and correct violations of federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* and FDA requirements. These policies and procedures shall be designed to ensure that the Company complies with, among other things, the FDCA's prohibitions against causing the introduction into interstate commerce of a drug that is misbranded or otherwise violates the FDCA.

5. *Compliance Officer.* Prior to the effective date of the Non-Prosecution Agreement, the Company established the position of Chief Compliance Officer ("Compliance Officer") and appointed an individual to serve in the role on an interim basis until such time as the Company can fill the role on a permanent basis. The Company shall maintain a Compliance Officer for the Term. During the Term, the Compliance Officer shall be authorized to oversee compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA, FDA requirements, and the requirements of the Corporate

Compliance Program Agreement. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures and practices designed to address compliance with the requirements set forth in this Corporate Compliance Program Agreement, with federal and state statutes and/or regulations concerning federal prescription drug distribution and FDA requirements. The Compliance Officer shall be a member of senior management of the Company, and shall report directly to the Chief Executive Officer of the Company. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Patterson Company's Board of Directors (hereinafter the "Board") or any authorized committee thereof, and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the Company as well as for any obligations created under the Corporate Compliance Program Agreement. Any non-compliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in the Corporate Compliance Program Agreement.

6. *Compliance Committee.* Prior to the effective date of the Non-Prosecution Agreement, the Company formed a Compliance Committee (hereafter "Compliance Committee") which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the compliance program. The Company shall maintain the Compliance Committee for the Term. The Compliance Committee shall include, at a minimum, the Compliance Officer and other members of senior management necessary to meet the requirements of the Corporate Compliance Program Agreement (e.g., senior executives of relevant departments, such as legal, regulatory, audit, human resources, and operations.) The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Company's risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

7. *Board of Directors Compliance Obligations.* Prior to the effective date of the Non-Prosecution Agreement, the Board formed a committee responsible for overseeing the Company's compliance program ("Board Committee"). The Company shall maintain the Board Committee for the Term. The Board Committee shall consist of no less than three (3) non-employee directors, including at least one (1) member of the Special Investigation Committee formed in response to the USAO-WDVA investigation for a minimum of twelve (12) months from the date of this Non-Prosecution Agreement. The Board Committee shall oversee the Company's compliance program, including at a minimum:

a. the Company's obligations under the Corporate Compliance Program Agreement

b. receiving updates about adoption and implementation of policies, procedures and practices designed to ensure compliance with the FDCA and FDA requirements, and

c. evaluating the effectiveness of the compliance program.

8. The Company shall continue to evaluate its current business to ensure that it is not currently receiving, distributing or handling misbranded or unapproved federal prescription drugs. Should the Company find it is receiving, distributing, or handling misbranded or unapproved federal prescription drugs, it shall take necessary steps to remediate any such conduct.

9. The Company shall continue to enhance its current training program to ensure that pertinent employees are familiar with the requirements of the FDCA and FDA requirements that could potentially apply to the Company's conduct.

10. The Company will put in place processes to (a) encourage employees to report suspected non-compliant activities by the Company, customers, or others and to (b) acknowledge or otherwise recognize employees for reporting confirmed non-compliant activity, as appropriate.

11. The Company will maintain, or as necessary establish, policies and procedures designed to ensure effective investigation of any complaints and/or potential deficiencies relating to compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA and FDA requirements. Such policies and procedures shall include, but are not limited to:

a. Training and providing guidance to all pertinent employees as to the requirement to report all information regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to the Compliance Officer, who in turn will review and determine whether corrective actions are required; and

b. Tracking allegations and remediation action plans regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to identify issues that may require corrective actions.

12. Within 60 days of the end of the Company's fiscal year, the Company's Chief Executive Officer will certify, under oath, to (a) the United States Attorney's Office during the Term and (b) the United States Probation Office for any period during which Animal Health International, Inc. is on probation, that (1) the Company fully complied with all federal laws and regulations pursuant to the Food, Drug, and Cosmetic Act ("FDCA") in the preceding year (or, in the instance of the first such certification, the period from execution of the Non-Prosecution Agreement through the end of the Company's fiscal year 2020), or in the alternative, (2) list all non-compliant activity and the steps taken by the company to remedy such non-compliant activity. Any listing of non-compliant activity shall not be considered by the government or the Probation Officer as a per se violation of the terms of probation or the Non-Prosecution Agreement. Instead, other factors will be taken into account, including whether the conduct violated policies the Company has adopted, whether the Company provided training addressing the subject matter of the reported conduct, whether it was an isolated or systemic occurrence, the Company's response, and any remedial actions taken after the Company learned of the conduct reported.

Non-Compliance

13. The Corporate Compliance Program Agreement is part of the Non-Prosecution Agreement and adherence to it will be an enforceable condition. Deliberate, intentional or knowing failure to comply with any part of the Corporate Compliance Program Agreement is a violation of the Non-Prosecution Agreement.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	Criminal No.
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before 7 days from the date of entry of a guilty plea, the defendant will voluntarily remit payment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant upon entry, and shall be made a part of the sentence and included in the judgment.

ENTERED THIS _____ DAY OF _____, 2020.

UNITED STATES DISTRICT JUDGE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Please see attached disclosure statement.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

Animal Health International

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Animal Health International, Inc. (AHI) Disclosure Statement

a. On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement and a fine, and AHI paid $41,250.

b. On April 18, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Visalia, California Veterinary Food- Animal Drug Retailer license for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

c. On June 18, 2013, the Missouri Division of Professional Regulation issued a drug distributor license to Animal Health International, Inc.'s (AHI) Salina, Kansas facility. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

d. On August 30, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failing to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

e. On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no misconduct allegations beyond the conduct in Arkansas, which led to the non-disciplinary order and fine.

f. In March 2017, the Colorado Board of Pharmacy issued a letter of admonishment to Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license following allegations that it failed to timely submit an application detailing a change in designated representative. AHI was required to pay the costs associated with the Board's order.

g. On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

h. On July 20, 2020, Animal Health International, Inc. (AHI) in Boaz, AL entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an

administrative fine of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The facility in Boaz, Alabama facility, subject to discipline was AHI's Boaz, Alabama, wholesale drug distributor license.

i. On July 20, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas, wholesale drugdistributor license.

j. On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license. This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

k. On December 31, 2024, Animal Health International's Sioux Center, Iowa Wholesale Distributor facility entered into a Consent Order with the Illinois Department of Financial and Professional Regulation in which the facility's Illinois Wholesale Distributor license was reprimanded and fined $10,000. This action was based entirely on the Department of Justice case against AHI related to distribution activities predating current ownership. The Federal case was reported to State Boards during the investigation in July 2019 and again in February 2020 once the case was resolved.

l. On January 9, 2025, Animal Health International's ("AHI") Ceres, California Wholesale Distributor Facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 6 days in 2016, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

m. On January 9, 2025, Animal Health International's ("AHI") Roanoke, Texas Wholesale Distributor facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 165 days in 2014, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil

penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

n. On January 9, 2025, Animal Health International's ("AHI") Twin Falls, Idaho pharmacy entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 3 days in 2016, the pharmacy dispensed prescriptions into Oregon without an active pharmacy license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $3,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. Please note that the activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice case was reported to the state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. A copy of the Oregon Consent Order is enclosed. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054

Name: Elanco US Inc
Address: 2500 Innovation Way N City: Greenfield, State: IN Zip: 46140

Name: Boehringer Ingelheim
Address: 900 Ridgebury Rd City: Ridgefield State: CT Zip: 06877

Name: Huvepharma, Inc.
Address: 525 Westpark Drive, Suite 230 City: Peachtree City State: GA Zip: 30269

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Colorado
Parent Company (if any): Patterson Companies, Inc.
Corporation/Organization Name: Animal Health International, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner **owning more than 10% of the business** stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Animal Health International, Inc.

Facility Name

Kevin M Barry

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/6/25

Date

Board Use Only	Date Received: 5/19/25	Amount: $1000.00

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515
State of Incorporation:	Minnesota

ANIMAL HEALTH INTERNATIONAL, INC. – Officer List

Corporate Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Phone Number:	970-353-2000
FEIN #:	84-0575063
State of Incorporation:	Colorado (5/16/1967)

Robert J. Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Steven M. Cunningham	**President**
Business Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Business Phone:	970-353-2000
Email:	Facilitylicensing@pattersoncompanies.com

Kevin M. Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Leslie B. Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Animal Health International, Inc.

is a

Corporation

formed or registered on 05/16/1967 under the law of Colorado, has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 19871193550 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 05/06/2025 that have been posted, and by documents delivered to this office electronically through 05/08/2025 @ 06:42:52 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 05/08/2025 @ 06:42:52 in accordance with applicable law. This certificate is assigned Confirmation Number 17280636 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/drug-manufacturers-distributors/applications-forms-drug-manufacturers-distributor**
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

ANIMAL HEALTH INTERNATIONAL INC ATTN REGULATORY
1031 MENDOTA HEIGHTS RD
SAINT PAUL MN 55120

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

ANIMAL HEALTH INTERNATIONAL INC

804 HENRIETTA CREEK RD
ROANOKE, TX 76262

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1001033
Expires: August 30, 2026

NON-TRANSFERABLE

Commissioner

518559

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0488038	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

ANIMAL HEALTH INTERNATIONAL, INC.
804 HENRIETTA CREEK RD
ROANOKE, TX 762626325

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0488038	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

ANIMAL HEALTH INTERNATIONAL, INC.
804 HENRIETTA CREEK RD
ROANOKE, TX 762626325

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0488038	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

ANIMAL HEALTH INTERNATIONAL, INC.
804 HENRIETTA CREEK RD
ROANOKE, TX 762626325

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/07/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400 CN102114303-Stnd-GAWU-24-25	**CONTACT NAME:** Marsh | U.S. Operations & Technology **PHONE (A/C, No, Ext):** 866-966-4664 **FAX (A/C, No):** **E-MAIL ADDRESS:** Minneapolis.CertRequest@marsh.com	
	INSURER(S) AFFORDING COVERAGE	**NAIC #**
	INSURER A : Starr Indemnity & Liability Company	38318
INSURED Animal Health International, Inc. and Subsidiaries 822 7th Street, Suite 740 Greeley, CO 80631	**INSURER B :** Starr Specialty Insurance Company	16109
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** CHI-010764188-03 **REVISION NUMBER:** 1

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	2,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	0
							PERSONAL & ADV INJURY	$	2,000,000
							GENERAL AGGREGATE	$	10,000,000
							PRODUCTS - COMP/OP AGG	$	4,000,000
								$	
A	**AUTOMOBILE LIABILITY**			1000198195241 (AOS)	11/01/2024	11/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	3,000,000
A	X ANY AUTO OWNED AUTOS ONLY [ ] SCHEDULED AUTOS HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY			1000198196241 (MA)	11/01/2024	11/01/2025	BODILY INJURY (Per person)	$	
							BODILY INJURY (Per accident)	$	
							PROPERTY DAMAGE (Per accident)	$	
								$	
A	X **UMBRELLA LIAB** [X] OCCUR **EXCESS LIAB** [ ] CLAIMS-MADE DED [X] RETENTION $ 25,000			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	5,000,000
							AGGREGATE	$	5,000,000
								$	
B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y / N			100 0005556 (AOS)	11/01/2024	11/01/2025	[X] PER STATUTE [ ] OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [N]	N / A		100 0005558 (FL,MA)	11/01/2024	11/01/2025	E.L. EACH ACCIDENT	$	1,000,000
B	**(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below			100 0005559 (WI)	11/01/2024	11/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance

CERTIFICATE HOLDER

Animal Health International, Inc.
and Subsidiaries
822 7th Street, Suite 740
Greeley, CO 80631

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K09623152

Application/License No. _____

Animal Health International, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
804 Henrietta Creek Road, Roanoke, TX 76262, as
(Address of Applicant/Principal)
PRINCIPAL, and Westchester Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Pennsylvania
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
436 Walnut Street, Philadelphia, PA 19106 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 11, 2018.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of April, 2018.

APPLICANT/PRINCIPAL
Animal Health International, Inc.

Authorized Representative

SURETY COMPANY
Westchester Fire Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

Witness

Witness

BONNIE K. RAMIREZ
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID 20054017910
MY COMMISSION EXPIRES MAY 4, 2021

Countersigned by:

N/A
Nevada Resident Agent

ACKNOWLEDGMENT BY SURETY

STATE OF Missouri }
City of St. Louis } ss.

On this 11th day of April, 2018, before me personally appeared Cynthia L. Choren, known to me to be the Attorney-in-Fact of Westchester Fire Insurance Company, the corporation that executed the within instrument, and acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

My Commission Expires: May 20, 2020

(Seal)

DEBRA C. SCHNEIDER
Notary Public, Notary Seal
State of Missouri
St. Charles County
Commission # 12419088
My Commission Expires May 20, 2020

Debra C. Schneider
Notary Public in the State of Missouri
County of St. Charles
Commission No. 12419088

S-0230/GEEF 2/98

Power of Attorney

WESTCHESTER FIRE INSURANCE COMPANY

Know all men by these presents: That **WESTCHESTER FIRE INSURANCE COMPANY**, a corporation of the Commonwealth of Pennsylvania pursuant to the following Resolution, adopted by the Board of Directors of the said Company on December 11, 2006, to wit:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such persons written appointment as such attorney-in-fact .

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested.

Does hereby nominate, constitute and appoint Brittany D Clavin, Cynthia L Choren, Debra C Schneider, Heidi A Notheisen, JoAnn R Frank, Karen L Roider, Pamela A Beelman, Sandra L Ham all of the City of SAINT LOUIS, Missouri, each individually if there be more than one named, its true and lawful attorney-in-fact, to make, execute, seal and deliver on its behalf, and as its act and deed any and all bonds, undertakings, recognizances, contracts and other writings in the nature thereof in penalties not exceeding SEVENTY MILLION DOLLARS & ZERO CENTS ($70,000,000.00) and the execution of such writings in pursuance of these presents shall be as binding upon said Company, as fully and amply as if they had been duly executed and acknowledged by the regularly elected officers of the Company at its principal office.

IN WITNESS WHEREOF, the said Stephen M. Haney, Vice-President, has hereunto subscribed his name and affixed the Corporate seal of the said **WESTCHESTER FIRE INSURANCE COMPANY** this 9 day of October 2017

WESTCHESTER FIRE INSURANCE COMPANY

Stephen M. Haney , Vice President

COMMONWEALTH OF PENNSYLVANIA
COUNTY OF PHILADELPHIA ss.

On this 9 day of October, 2017 before me, a Notary Public of the Commonwealth of Pennsylvania in and for the County of Philadelphia came Stephen M. Haney ,Vice-President of the **WESTCHESTER FIRE INSURANCE COMPANY** to me personally known to be the individual and officer who executed the preceding instrument, and he acknowledged that he executed the same, and that the seal affixed to the preceding instrument is the corporate seal of said Company; that the said corporate seal and his signature were duly affixed by the authority and direction of the said corporation, and that Resolution, adopted by the Board of Directors of said Company, referred to in the preceding instrument, is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at the Cityof Philadelphia the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
KAREN E. BRANDT, Notary Public
City of Philadelphia, Phila. County
My Commission Expires Sept. 26, 2018

Notary Public

I, the undersigned Assistant Secretary of the **WESTCHESTER FIRE INSURANCE COMPANY**, do hereby certify that the original POWER OF ATTORNEY, of which the foregoing is a substantially true and correct copy, is in full force and effect.

In witness whereof, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of the Corporation, this 11th day of April 2018

Dawn M. Chloros, Assistant Secretary

THIS POWER OF ATTORNEY MAY NOT BE USED TO EXECUTE ANY BOND WITH AN INCEPTION DATE AFTER OCTOBER 09, 2019.

DocuGard #04546 contains a security pantograph, blue background, heat-sensitive ink, coin-reactive watermark, and microtext printing on border.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler –
Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Animal Health International, Inc. MDEG License # (if applicable): _____

Physical Address: 804 Henrietta Creek Rd

City: Roanoke State: TX Zip: 76262

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 970-656-1957 Website: https://www.animalhealthinternational.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Sergio Middle: Alberto Last: Gutierrez

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Addre[redacted]

City: Rhome State: TX Zip: [redacted]

Telephone: [redacted] Email: Sergio.Gutierrez@animalhealthinternational.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Crooked Oak High School		08/94 - 05/98	
Address	**City**	**State**	**Zip**
2017 Emco Drive	Oklahoma City	OK	73129
Diploma/Degree obtained, if any			
HS Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY - MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2020-present	[redacted]	Rhome	TX	[redacted]
01/2019-08/2020		Fort Worth	TX	
01/2018-01/2019		Keller	TX	
From - To (MM/YY – MM/YY)		City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International, Inc.			02/2000 - Present	
Business Address		**City**	**State**	**Zip**
804 Henrietta Creek Road		Roanoke	TX	76262
Phone	**Title**		**Number of Employed Hours**	
970-584-5206	Department Manager		52,000	
Description of Duties				
The Dept Manager for Receiving and Inventory Control oversees the handling of incoming shipments, the receiving process, inspecting goods, monitoring stock levels, conducting audits, and coordinating inventory control activities.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/27/28
Date

I, Sergio Gutierrez, **certify that as the MDEG Administrator for**

Animal Health International, Inc.,

that I (initial that you have read and meet the following requirements):

1. SG Have a high school diploma or its equivalent;
2. SG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sergio Gutierrez

Print Name (First, Last)

SG

Original Signature (electronic, copies or stamps not accepted)

5/27/25

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Animal Health International, Inc.

Pharmacy/Wholesaler License # (if applicable): WLS 6863

Physical Address: 804 Henrietta Creek Rd

City: Roanoke State: TX Zip: 76262

Mailing Address (if different from physical address): 1031 Mendota Heights Road

City: Saint Paul State: MN Zip: 55120

Telephone: 970-656-1957 Website: www.animalhealthinternational.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Sergio Middle: Alberto Last: Gutierrez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addres[redacted]

City: Rhome State: TX Zip: [redacted]

Telephone[redacted] Email: Sergio.Gutierrez@animalhealthinternational.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Crooked Oak High School		08/94 - 05/98	
Address	**City**	**State**	**Zip**
2017 Emco Drive	Oklahoma City	OK	73129
Diploma/Degree obtained, if any			
HS Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2020-present	[redacted]	Rhome	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	
01/2019-08/2020		Fort Worth	TX	
From - To (MM/YY – MM/YY)		City	State	
01/2018-01/2019		Keller	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International, Inc.			02/2000 - Present	
Business Address		**City**	**State**	**Zip**
804 Henrietta Creek Road		Roanoke	TX	76262
Phone	**Title**		**Number of Employed Hours**	
970-584-5206	Department Manager		40/week - 52,000 +	
Description of Duties				
The Department Manager for Receiving and Inventory Control oversee the handling of incoming shipments, the receiving process, inspecting goods, monitoring stock levels, conducting audits, and coordinating inventory control activities				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Sergio Gutierrez, **certify that as the designated representative for**

ANIMAL HEALTH INTERNATIONAL,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SG I am at least 21 years of age;
3. SG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sergio Gutierrez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4 29 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sergio Gutierrez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/29/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Denton

I, Sergio Gutierrez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/29/2025

Date

Subscribed and Sworn to before me this 29th day of April 2025

Notary Public Signature

KELSEY CRUST
Notary Public, State of Texas
Comm. Expires 08-18-2027
Notary ID 134516335

(Seal)

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Employee List

804 Henrietta Creek Road
Roanoke, TX 76262
License Number: WH02465

Legal Name
Crossland, Christopher
Walker, Davina Lynn
Dempster, Jesse Mariah
Finnerty, Kristin
Lettsome, Arvan R
Foote, Lynn A
Slusher, Scott
Holman, Damie Wynne
Calderon Rivera, Celsa
Rangel, Yaquelin
Rodriguez Bravo, Abiud Y
Otero, Mariana
Norvell, Freda Lynn
Hogan, Domonique M
McLaughlin, Maggie
Bustamante, Yunuen
Speakes, Mireya Carmen
Harden-Jerry, Kwan D
Angarita, Joanna Cristina
Arreola, Maria Faith
Whitley, Bob Alan
Ovalle, Jacob
Labrew, James
Williams, Cindy Vongsavanh
Sanchez, Maricela
Mena, Richard L
Whited, Esther
Kowalski, Ann Louise
Bittle, Sara R
Satterlee, Misty R
Reid, Julie Turner
Andrews, Suzanne Berrian
Jones, Charles Westley
Cochran, Brandon William
Gutierrez, Sergio A
Krause, Glen P
Smith, Amber Nichole
Smith, Christopher Dale
Garza, Andrea Villareal
Frederick, Neoshia
Christian, Caitlyn
Rosales, Antonio
POST, John
Wilembrecht, Donald
Frost, Dana
Torchia, Tanja
Lopez, Michael D
Meza, Josseling
Hudson, Joshua
Hathorn, Justin
Saavedra, Erik Alberto
Stafford, Tashia
Caceres, Yorlene
Collins, Amari
Zeleke, Elsabet
Coronado Serrano, Norma Alicia
Caceres, Sochilt
Blair, Nicholas
Modeste, Edwin
Loos, Ronald
Prieto Sanchez, Angel
Chapman, Krista
Rodriguez Bravo, Eliud
Jensen, Robert
Meza Robelo, Leyding Dinora
Zavala, Martha
Johnson, Allen
Dawson, Laurie
Lesperance, Bertony
Caceres, Kenia Yarasset
Amador, Genesis
Canada, Alicia
Bojorge Jimenez, Cesar Antonio
Guajardo, Jason
Torres, Yoselyn
Arreola, Daniel
Cano, Leocadia
Ramirez, Alexis
Hildreth, Dwayne
Twendele, Devin
Meraz, Sonia E
Lindquist, Josh
Njome, Darnell

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH 02464	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Animal Health International, Inc.

Physical Address: 640 South Main Street

City: Spanish Fork State: UT Zip: 84660

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 801-798-7347 Website: https://www.animalhealthinternational.com/home

Name of Designated Representative (DR): Swade Bartlett

Licensing Company Email: facilitylicensing@pattersoncompa DR Email: Swade.Bartlett@animalhealthinternational.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class I & Class II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Universities/Research		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/14/2020		VA	Abingdon	Washington

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DVAW120CR00007-001	United States District Court, Wetern District of Virginia Abingdon

Reason/Charge
Violation of Title 21, US Code, Sections 221(1), 333(a)(1), and (352)(f)(l)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

FEB 14 2020

JULIA C. DUDLEY, CLERK
BY: DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20-cr-00007
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

PLEA AGREEMENT

ANIMAL HEALTH INTERNATIONAL, INC. (EIN: 84-0575063) ("AHI") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this Plea Agreement are as follows:

1. CHARGE TO WHICH AHI IS PLEADING GUILTY AND WAIVER OF RIGHTS

AHI will enter a plea of guilty to Count One of the Information charging it with violating Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) in the Western District of Virginia by introducing and delivering for introduction, and causing the introduction and delivery for introduction, into interstate commerce of veterinary prescription drugs that were misbranded.

AHI understands, and the parties agree and stipulate, the maximum statutory penalty is a fine of $14,855,856 (fourteen million eight hundred fifty-five thousand eight hundred fifty-six dollars), pursuant to Title 18, United States Code, Section 3571(d), and a period of probation of five (5) years, pursuant to Title 18, United States Code, Section 3561(c)(2). In addition, AHI's assets are subject to forfeiture. AHI understands fees may be imposed to pay for probation and there will be a $125 (one hundred twenty-five dollars) special assessment for Count One, pursuant to Title 18, United States Code, Section 3013(a)(1)(B)(iii). AHI's attorneys have informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before AHI could be found guilty as charged.

AHI admits and agrees that all of the statements and allegations in the Information are true and correct.

AHI acknowledges AHI has had all of its rights explained to it. AHI expressly recognizes that, as a corporation, AHI may have the following constitutional rights and by voluntarily pleading guilty AHI knowingly waives and gives up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses.

The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

AHI is pleading guilty as described above because AHI is in fact guilty and because AHI believes it is in its best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for its plea of guilty. AHI agrees all of the matters set forth in the Information are true and correct.

AHI understands the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree the 2018 version of the United States Sentencing Commission Guidelines Manual ("U.S.S.G.") is the appropriate Guidelines Manual to utilize. According to U.S.S.G. § 8C2.1, the organizational fine provisions do not apply to the count of conviction in this case, which is a misdemeanor under 21 U.S.C. § 333(a)(1).

The parties agree and stipulate:

a. the fine shall be $5,000,000 (five million dollars);
b. AHI shall pay $1,000,000 (one million dollars) to the Virginia Department of Health Professions ("DHP") in recognition of direct assistance provided by DHP to the United States during the investigation;
c. AHI shall forfeit $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars); and
d. AHI shall serve a term of probation of one to three years, as determined by the Court.

The Court will determine what terms and length of probation are appropriate and the parties will be free to argue for which terms and length of probation they believe are appropriate. AHI understands and agrees if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum may be imposed.

The parties agree if the Court refuses to accept this Plea Agreement with the agreed-upon sentence, AHI will be free to withdraw its guilty plea. In the event the Court refuses to accept this Plea Agreement and AHI withdraws its guilty plea within ten days of being notified of the Court's refusal, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410. Under these circumstances, the United States will move to dismiss the Information without prejudice and the United States may file any charges it could have filed in the absence of the plea agreement. AHI agrees to toll the statute of limitations between the date of the plea and the filing of any such charges.

3. FINANCIAL OBLIGATIONS

AHI agrees and understands any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept this Plea Agreement with the agreed-upon sentence and, as a result, AHI withdraws its guilty plea. If the Court rejects this Plea Agreement and AHI withdraws its guilty plea, the United States will return all money paid by AHI, without

interest, not more than thirty (30) days after AHI withdraws its guilty plea and notifies the United States Attorney's Office for the Western District of Virginia ("USAO"), in writing, it wishes to have the money returned.

In addition, in accordance with 18 U.S.C. § 3572(d)(3), AHI will notify the Court of any material change in AHI's economic circumstances that might affect AHI's ability to pay any amounts payable under this Plea Agreement.

a. Payments

Within 7 days of the entry of AHI's guilty plea, AHI will make the following disbursements:

(1) $125 (one hundred twenty-five dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the special assessment.

(2) $5,000,000 (five million dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the fine;

(3) $1,000,000 (one million dollars) to the Virginia Department of Health Professions. These funds must be remitted in the form of certified funds made payable to the "Treasurer of Virginia." The comment section of the check should note "DHP-Enforcement" in recognition of direct assistance provided to the United States during the investigation; and

(4) $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) made payable to the United States Marshals Service, as directed by the USAO as payment of a forfeiture money judgment.

b. Forfeiture

AHI agrees to the entry of a forfeiture money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency ("Forfeiture Money Judgment") pursuant to 21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c). AHI agrees that the value of the quantities of prescription drugs which were misbranded in violation of 21 U.S.C. § 331(a) totaled at least $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency.

AHI acknowledges and agrees the quantities of the drugs which were misbranded in violation of 21 U.S.C. § 331(a) cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, AHI agrees the government is entitled to forfeit as substitute assets any other assets of AHI up to the value of the now missing directly forfeitable assets, pursuant to

21 U.S.C. § 853(p). Payment in full of the Forfeiture Money Judgment shall satisfy any and all forfeiture obligations that AHI may have as a result of this guilty plea. AHI consents to the entry of an Order of Forfeiture pursuant to Rule 32.2 of the Federal Rules of Criminal Procedure forfeiting the above-referenced Forfeiture Money Judgment.

AHI agrees to sign any documentation necessary and to cooperate fully with the United States to accomplish the forfeiture. AHI agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of these funds to the United States.

AHI agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. AHI agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgement in any administrative or judicial proceeding.

AHI understands and agrees forfeiture of this property is proportionate to the degree and nature of the offense. AHI freely and knowingly waives any and all constitutional and statutory challenges to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including, but not limited to, that the forfeiture constitutes an excessive fine or punishment. AHI further understands and agrees this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty or other monetary judgment that may be imposed by the court.

c. Restitution

The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no restitution will be ordered.

4. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, AHI withdraws its plea, AHI agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny it committed the crime to which it has pled guilty; (4) comply with any reasonable request of the United States Attorney's Office and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement.

Neither AHI, nor its corporate parent (Patterson Companies, Inc. ["Patterson"]), will (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If Patterson or AHI makes a public statement that in whole or in part contradicts any such statement or provision, AHI may avoid being in violation of this Plea Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by Patterson's and AHI's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) Patterson or AHI websites. Notwithstanding the above, Patterson and AHI may avail themselves of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by

any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

5. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, AHI agrees AHI will not appeal the conviction or sentence imposed. AHI is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). AHI expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. AHI understands the United States expressly reserves all of its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, AHI may file a cross appeal of that same sentence. AHI agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this Plea Agreement.

6. INFORMATION ACCESS WAIVER

AHI agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a. However, if a third party obtains any records pertaining to the investigation or prosecution of this case under the Freedom of Information Act, AHI shall have the right to request copies of such disclosed records.

7. ADMISSIBILITY OF STATEMENTS

AHI understands any statements made on its behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against AHI by the United States in this or any other proceeding. AHI knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other proceeding. If, and only if, the Court rejects this Plea Agreement, and, as a result, AHI withdraws its plea, AHI will not be bound by the waivers set forth in this section of the Plea Agreement.

8. COMPLETION OF PROSECUTION

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), so long as AHI complies with all of its obligations under this Plea Agreement, the United States agrees, other than the charge in the attached Information, it shall not further criminally prosecute AHI for any additional federal criminal

charges or forfeiture action with respect to any offenses set forth in the Information or Non-Prosecution Agreement with Patterson (Attached as Attachment B).

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

9. LIMITATION OF PLEA AGREEMENT

This Plea Agreement is limited to the United States Department of Justice and does not bind any other federal, state, or local authority.

10. COMPLIANCE AND REMEDIAL MEASURES

AHI agrees to comply with the Corporate Compliance Program Agreement attached hereto as Attachment C.

11. COOPERATION

AHI acknowledges that its ongoing and future cooperation is important and a material fact underlying the United States' decision to enter into this Plea Agreement. AHI agrees to continue to cooperate fully and actively with the United States regarding any matter, including, but not limited to, matters involving (a) current and former AHI personnel, and (b) other entities who operate in the same commercial segment as AHI and/or Patterson during the Term of the Non-Prosecution Agreement with Patterson, provided however that any cooperation in an ongoing investigation or prosecution shall continue until such investigation or prosecution is concluded.

Nothing in this Plea Agreement shall be construed to require Patterson or AHI to waive any attorney-client privilege or work-product protection.

12. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THIS PLEA AGREEMENT

AHI understands if: (1) AHI attempts to withdraw its plea (in the absence of the Court refusing to accept this Plea Agreement); (2) AHI fails to comply with any provision of this Plea Agreement; (3) AHI's conviction is set aside, for any reason; and/or (4) AHI fails to execute all required paperwork prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement titled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, AHI will still be bound by its obligations under this Plea Agreement. AHI hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of this Plea Agreement. AHI hereby waives any statute of limitations argument as to any such charges.

13. EFFECTIVE REPRESENTATION

AHI has discussed the terms of this Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, AHI has no dissatisfaction or complaint with its attorneys' representation. AHI agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint AHI may have with its attorneys' representation.

14. EFFECT OF AHI'S SIGNATURE

AHI understands its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. AHI understands the United States has not accepted AHI's offer until the authorized representative of the United States has signed this Plea Agreement.

15. GENERAL UNDERSTANDINGS

AHI understands a presentence investigation will be conducted and sentencing recommendations independent of the USAO will be made by the presentence preparer.

AHI understands the United States and AHI retain the right, notwithstanding any provision in this Plea Agreement, to inform the probation office and the Court of all facts, to address the Court with respect to the nature and seriousness of the offense and the offender, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, and to respond to any statements made to the Court.

AHI willingly stipulates there is a sufficient factual basis for the Court to accept the plea.

AHI understands this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

AHI has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. AHI understands its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. AHI understands AHI will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing, the Non-Prosecution Agreement with Patterson (attached as Attachment B), the Corporate Compliance Program Agreement (attached as Attachment C), and the Agreed Order of Forfeiture (attached as Attachment D) are the complete and only agreements between the United States and AHI concerning resolution of this matter. In addition, AHI has no objection to the filing of the Information.

The agreements and documents listed in this section set forth the entire understanding between the parties and constitute the complete agreement between the United States Attorney for the Western District of Virginia and AHI and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and AHI. AHI consents to public disclosure of all of the agreements and other documents referenced in this section.

AHI has consulted with its attorneys and fully understands its rights. AHI has read this Plea Agreement and carefully reviewed every part of it with its attorneys. AHI understands this Plea Agreement and AHI voluntarily agrees to it. Being aware of all of the possible consequences of its plea, AHI has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer ("Officer") below.

The Officer, by signing below, hereby certifies to the following:

(1) The Officer is fully authorized to enter into this Plea Agreement on behalf of AHI;

(2) The Officer has read the entire Plea Agreement and documents referenced herein and discussed them with AHI's Board of Directors;

(3) AHI understands all the terms of this Plea Agreement and those terms correctly reflect the results of plea negotiations;

(4) AHI is fully satisfied with AHI's attorneys' representation during all phases of this case;

(5) AHI is freely and voluntarily pleading guilty in this case;

(6) AHI is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea; and

(7) AHI understands it is waiving its right to appeal the judgment and conviction in this case.

AHI acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Officer. A copy of a certification by AHI's Board of Directors authorizing the Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of AHI is attached as Attachment A.

Date: 2/13/2020 Keri M. Fahlman

Authorized Corporate Officer
AHI

Counsel has fully explained to the Board of Directors of AHI the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the Sentencing Guidelines; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and documents referenced herein with the client, through its Officer. AHI understands the terms and conditions of this Plea Agreement, and AHI's decision to enter into this Plea Agreement is knowing and voluntary. AHI's execution of and entry into the Plea Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED
2/11/2020
JULIA C. DUDLEY, CLERK
BY: LOTTIE LUNSFORD
DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No. 1:20CR00007**
v.	)	
	)	**Violations: 21 U.S.C. §§ 331(a),**
ANIMAL HEALTH INTERNATIONAL, INC.	)	**333(a)(1), and 352(f)(1)**

INFORMATION

INTRODUCTION

1. Defendant Animal Health International, Inc. ("AHI") is a Colorado corporation with its principal place of business in Colorado. AHI is comprised of two legacy organizations, Lextron, Inc. ("Lextron") and Walco International, Inc. ("Walco"). In June 2011, Lextron acquired all outstanding stock of the parent company of Walco and changed its name to AHI. Walco continued operations as a subsidiary of AHI until December 2011 when Animal Health Holdings, Inc. and each of its wholly-owned subsidiaries, including Walco, were merged with and into AHI and no longer had separate corporate existences. AHI, and its predecessor entities, dispense, distribute and sell, among other products, veterinary prescription drugs to customers in the production animal industry across the United States. Specifically, AHI obtains prescription drugs for production animals from manufacturers for further distribution to veterinarians, farms, feedlots, and other distribution facilities.

2. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulates the distribution and labeling of all drugs, including animal drugs, shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C § 301, *et seq.* ("FDCA"). Veterinary prescription drugs are drugs intended for use by animals that, because of their toxicity or other potentiality for harmful

effect, or the method of their use, or the collateral measures necessary for their use, are not safe for animal use except under the professional supervision of a licensed veterinarian. 21 U.S.C. § 353(f)(1)(A).

3. Under the FDCA, a drug is misbranded if, among other things, its labeling does not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). Adequate directions for use is defined as "directions under which the *layman* can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5 (emphasis added). Prescription veterinary drugs by definition can only safely be used under the professional supervision of a licensed veterinarian and therefore they must qualify for an exemption to this requirement in order to move in interstate commerce. These exemptions are set out in 21 C.F.R. Part 201, Subpart D ("Exemptions from Adequate Directions for Use").

4. Veterinary prescription drugs are exempt from the requirement that their labeling contain adequate directions for use if they meet all enumerated conditions, including that they be distributed through a closed supply chain in which every entity that possesses a prescription drug must have legal authorization to do so. *See* 21 C.F.R. § 201.105 (a)(1) (a veterinary prescription drug must be in the possession of: a person lawfully engaged in the manufacture, transportation, storage or wholesale distribution of drugs; a retail pharmacy or other person authorized under state law to dispense veterinary prescription drugs; or a licensed veterinarian for use in the course of his professional practice). Moreover, the veterinary prescription drug must be dispensed in accordance with 21 U.S.C. § 353(f), i.e., pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian's professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105 (a)(2).

5. The FDCA's restrictions on veterinary prescription drugs are not primarily to protect animals from the potential harms of prescription drugs, but are to protect the human food supply from unsafe drug residues in the edible tissues of animals sold for slaughter. Common causes of illegal residues include: (1) exceeding the drug's approved dose; (2) using a shorter withdrawal period than what is stated on the drug's label (if a higher than approved dose is given, the labeled withdrawal period may not be enough to allow the drug in the edible tissues to deplete to levels that are at or below the tolerance); (3) using a drug in an extra-label manner (for indications and dosages outside the approved labeling) without a veterinarian's involvement; (4) giving a drug not approved for that species; and (5) using an unapproved route of administration. Drug residues in the nation's drug supply are concerning because: (1) they may contribute to antibiotic resistance in the human population, rendering human drugs less effective to treat human disease and contributing to the mutations of "superbugs"; and (2) they may cause allergic reactions in individuals with certain drug allergies.

6. Certain legacy customers of AHI, namely Marlin Webb and Billy K. Groce, were not properly licensed to receive, transport, store, distribute, or dispense veterinary prescription drugs in the Commonwealth of Virginia from January 2012 through April 2015.

7. Webb was the store manager of a cooperative in Hillsville, Virginia. The cooperative was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Webb operated a side business from the cooperative's location in which he illegally circumvented the FDA's regulation of veterinary prescription drugs by illegally obtaining from Billy K. Groce and AHI and reselling veterinary prescription drugs using unlawful prescriptions written by a veterinarian who was licensed in Tennessee but who was not properly licensed to

practice veterinary medicine in Virginia and who did not have a veterinarian-patient relationship with the animals in question. That veterinarian died in 2015.

8. Groce was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Groce operated an unlicensed veterinary prescription drug distribution business. Groce worked with the same veterinarian as did Webb.

9. Webb and Groce obtained veterinary prescription drugs from AHI in interstate commerce without valid prescriptions, and, on many occasions, with no prescription at all.

10. On April 29, 2015, the government executed search warrants at locations in Virginia and Tennessee associated with Groce and Webb. In 2016 and 2017, respectively, Groce and Webb pled guilty to illegally conspiring to defraud the FDA by obtaining and distributing veterinary prescription drugs from July 2009 through April 29, 2015 in a manner that circumvented the FDA's regulation of veterinary prescription drugs.

11. Groce and Webb were legacy customers of, among others, Lextron and Walco, and continued to be customers after the companies merged to form AHI in 2012 until May 2015. Neither Lextron, Walco, nor AHI performed adequate customer diligence processes, nor adequately trained sales representatives to raise questions regarding Groce's, Webb's or the veterinarian's activities in Virginia and Tennessee. For example, Groce operated a business that stored and distributed veterinary prescription drugs out of a storefront called "Goin' Postal" and his personal residence. Neither of those locations resembled a veterinarian establishment and should have raised questions for sales representatives who personally visited them. After learning of search warrants executed on each of the customers' locations, AHI took some steps to block the sale of veterinary prescription drugs to these customers on May 4, 2015.

12. Furthermore, between January 2012 and May 2015, AHI did not maintain the proper licenses to ship from its Memphis, Tennessee, facility into Virginia or from its Wolcott, Indiana, facility into Virginia or Tennessee, but, despite this deficiency, shipped products from those locations to Virginia and Tennessee.

13. All veterinary prescription drugs distributed by AHI to Groce and Webb were misbranded because, neither recipient was licensed to possess or distribute veterinary prescription drugs, and the prescribing veterinarian was not properly licensed to practice veterinary medicine in Virginia and consequently none of the drugs he caused to be dispensed were prescribed pursuant to lawful orders.

14. From the illegal shipments to and on behalf of Groce and Webb, AHI received $7,427,928 (seven million four hundred twenty-seven thousand nine hundred twenty-eight dollars) and made a profit of $558,309 (five hundred fifty-eight thousand three hundred nine dollars) by unlawfully distributing veterinary prescription drugs to or on behalf of Groce and Webb.

15. From 2012 through on or about 2018, AHI caused additional misbranded veterinary prescription drug shipments to be made throughout the United States by distributing veterinary prescription drugs from its wholesale locations directly to end users in states where such shipments were illegal and, in some instances, by shipping veterinary prescription drugs to locations in states in which AHI did not have legal authority to make such shipments. AHI obtained not less than $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) from such shipments. Its profits from such shipments were a small percentage of the amount received.

COUNT ONE

Introduction of Misbranded Drugs into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)

The United States Attorney charges that:

16. The Information is realleged and incorporated by reference into this Count.

17. From about January 2012 to April 2015, in the Western District of Virginia, Animal Health Incorporated ("AHI") introduced and delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce, of veterinary prescription drugs that were misbranded in that the drugs' labeling did not bear adequate directions for the use of such drugs.

18. The offense conduct included, but was not limited to, the following:

a. AHI distributed veterinary prescription drugs directly to Billy K. Groce and Marlin Webb, notwithstanding that neither Groce nor Webb was legally authorized to possess or distribute the drugs; and

b. AHI distributed veterinary prescription drugs to customers of Billy K. Groce and Marlin Webb without a lawful prescription having been issued for those drugs.

19. Since these veterinary prescription drugs were not lawfully distributed or prescribed, they failed to qualify for the exemption from the requirement that they bear labeling containing adequate directions for lay use. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1).

NOTICE OF FORFEITURE

20. Upon conviction of the offense alleged in this Information, AHI shall forfeit to the United States veterinary prescription drugs that were misbranded or became misbranded as a result of AHI's conduct, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

21. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of $46,802,203 pursuant to 21 U.S.C. § 853(p).

DATED: February 11, 2020

Randy Ramseyer
for THOMAS T. CULLEN
United States Attorney

NON-PROSECUTION AGREEMENT

1. The United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") and Patterson Companies, Inc. ("Patterson"), and any and all current and former affiliated entities including, but not limited to, Animal Health International, Inc. ("AHI") (collectively referred to as the "Company") enter into this Non-Prosecution Agreement ("Agreement") to resolve the investigation by the USAO-WDVA of the Company related to possible violations of federal laws relating to the licensing, dispensing, distribution, or sale of veterinary prescription drugs.

2. This Agreement, in conjunction with the Plea Agreement with AHI ("Plea Agreement"), resolves all of the Company's potential federal criminal liability for the offenses covered herein and in the Plea Agreement.

3. The USAO-WDVA enters into this Agreement based on the individual circumstances presented by this case including:

a. Patterson's cooperation with the USAO-WDVA investigation since June 2018, and AHI's subsequent cooperation under the direction of Patterson, as well as the Company's continued cooperation under the direction of the Special Investigation Committee of the Board of Directors of Patterson ("SIC") which was formed in April 2019. Since 2018, the Company has conducted a thorough and robust internal investigation; proactively brought information to the USAO-WDVA's attention, remediated noncompliant activity and implemented control enhancements, including certain licensing, dispensing, distribution and related sales practices company-wide; made factual presentations to the USAO-WDVA; timely and fully produced all requested documents; entered into agreements tolling relevant statutes of limitations; and collected, analyzed, and organized voluminous data and information for the USAO-WDVA.

b. Patterson's voluntary disclosure to the USAO-WDVA of non-compliant licensing, dispensing, distribution, and sales at AHI and Patterson beyond AHI's conduct set forth in the Information and Plea Agreement, and its timely efforts to remediate non-compliant activity and enhance controls and processes to mitigate against future reoccurrence. The additional non-compliant activity involved wholesale distribution of veterinary prescription drugs: (i) without verifying the continued validity of all practitioners' licenses in the receiving state; (ii) without verifying that an alternate location requested by the customer was authorized by state law to receive veterinary prescription drugs; (iii) without verifying that veterinarians licensed in Virginia were also associated with a veterinary establishment registered with the Virginia Board of Veterinary Medicine, (iv) without valid licensure to ship to the state to which the drugs were shipped, and/or (v) to end users in states where drop shipments by wholesalers to end users is not allowed. The additional non-compliant activity was due to prior weaknesses and inconsistencies among AHI and Patterson regulatory functions and processes, as well as system challenges presented by the Company's enterprise resource planning implementation. The Company has since taken extensive

proactive steps to enhance its regulatory function, capabilities and support to guide the business and other control functions on regulatory compliance matters. It has also enhanced its regulatory system controls to address the issues disclosed in the investigation and to verify that veterinary prescription drugs are shipped from facilities with required state licenses and to customers and locations authorized by state law to receive veterinary prescription drugs. Consistent with its approach to the USAO-WDVA, Patterson also disclosed the pending federal investigation to state regulators in all 50 states and continues to engage with state regulators, as appropriate, on matters related to the USAO-WDVA investigation.

c. The Company's enhanced regulatory compliance processes and commitment to implement a compliance program that meets the minimum elements set forth in Attachment C to the Plea Agreement ("Corporate Compliance Program Agreement").

d. The Company's agreement to comply with the terms of the Agreement and Plea Agreement.

e. AHI's admission to and the Company's agreement with the facts and allegations set forth in the Plea Agreement.

f. Although the investigation did not involve controlled substances, the Company's recognition that diversion of controlled substances, including drugs of the type that are prescribed and dispensed by veterinarians, such as buprenorphine and hydrocodone, should be a concern of all distributors and dispensers of those drugs and the Company's ongoing commitment to be proactive in deterring diversion and identifying and notifying authorities of suspicious ordering.

4. The Company agrees it will not take any tax deduction or seek or accept directly or indirectly reimbursement or indemnification from any source for any payments made pursuant to the Plea Agreement.

5. No money paid by the Company will be returned, and the Company expressly agrees to release any and all claims it may have to the money. The Company will not file any claim or otherwise contest the payment of money set forth in this Plea Agreement, and it will not assist anyone in asserting a claim to the money.

6. Nothing in this Agreement or any related documents is an admission by the United States that the amounts paid by the Company are the maximum amounts that could be recovered from the Company in the absence of an accepted plea agreement. If the Company does not comply with all of its obligations under this Agreement, the United States is not precluded from arguing or presenting evidence that the total amount to be paid by the Company should be higher.

7. The Company's obligations under this Agreement shall have a term of 42 months from the date on which the Agreement is executed (the "Term").

8. During the Term, the Company will fully cooperate with the USAO-WDVA.

9. During the Term, the Company shall undertake and abide by the terms of the Corporate Compliance Program Agreement in Attachment C to the Plea Agreement.

10. If the Company complies with all of the terms of this Agreement and the Plea Agreement, the USAO-WDVA will not prosecute the Company for any criminal conduct occurring prior to the entering of this agreement concerning:

a. The subject matter of the Information to which AHI is pleading guilty; or

b. Facts disclosed by the Company to the USAO prior to entering this agreement related to the Company's licensing, dispensing, distribution, or sale of veterinary prescription drugs.

11. However, if the USAO-WDVA, in its sole discretion, determines the Company (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement or (b) violated any provision of this Agreement, then the USAO-WDVA will not be bound to their agreement not to prosecute the Company for the matters covered in paragraph 10. Should the USAO-WDVA determine that the Company has violated any provision of this Agreement, the USAO-WDVA shall provide prompt written notice to the Company addressed to its General Counsel, and to its outside counsel, Amy Conway-Hatcher, Baker Botts LLP, 1299 Pennsylvania Avenue NW, Washington, DC, or to any successor the Company may designate, of the alleged violation and provide the Company with a 45 (forty-five) day period from the date of receipt of notice in which to make a presentation to the USAO-WDVA to demonstrate that no violation occurred, or, to the extent applicable, that the violation should not result in adverse action, including because the violation has been cured by the Company. In the event of a violation, the Company will not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other rule or law, that any statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible in any proceeding brought by the Department of Justice. If, as a result of a violation, the United States charges the Company, the Company hereby waives any statute of limitations defense for any offense not time-barred by the applicable statute of limitations on the date this Agreement is signed, including time protected as the result of existing agreements to toll the applicable statute of limitations.

12. The Company will not, through its present or future directors, officers, employees, agents, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If the Company makes a public statement that in whole or in part contradicts any such statement or provision, the Company may avoid being in violation of this Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by the Company's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) the Company's

websites. Notwithstanding the above, the Company may avail itself of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

13. The terms of this Agreement bind the USAO-WDVA and other divisions of the Department of Justice (collectively referred to as the "United States"), except that they do not bind the Tax Division of the Department of Justice or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities. The USAO-WDVA will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

14. The Company and the United States may disclose this Agreement and any other documents used to effectuate the objectives of this Agreement to the public.

15. Nothing in this Agreement resolves, in any way, any liability of any individual.

16. This Agreement and the Plea Agreement set forth all the terms of the agreement between the Company and the USAO-WDVA. No amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the USAO-WDVA, the attorneys for the Company, and a duly authorized representative of the Company.

The Company acknowledges its acceptance of this Agreement by the signature of its counsel and Officer. A copy of a resolution by the Company's Board of Directors authorizing the Officer to execute this Agreement and all other documents to resolve this matter on behalf of the Company is attached as Addendum 1.

Date: February 12, 2020

Mark S. Walchirk
Authorized Corporate Officer
Patterson Companies, Inc.

Counsel has fully explained to the Board of Directors of the Company the facts and circumstances of the investigation and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein with the client, through its Officer. The Company understands the terms and conditions of this Agreement, and the Company's decision to enter into this Agreement is knowing and voluntary. The Company's execution of and entry into this Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI and Patterson Companies, Inc.

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

EXHIBIT A

RESOLUTION OF THE
BOARD OF DIRECTORS
OF
PATTERSON COMPANIES, INC.

NON-PROSECUTION AGREEMENT

WHEREAS, the Company, together with outside counsel reporting to the Special Investigation Committee of the Board ("SIC Counsel"), has been in discussions with the U.S. Attorney's Office for the Western District of Virginia ("USAO-WDVA") to resolve its investigation into Animal Health International, Inc. by, among other things, having the Company enter into a Non-Prosecution Agreement (the "Agreement");

WHEREAS, SIC Counsel has advised the Board of the terms of the Agreement and the consequences of entering into the Agreement; and

WHEREAS, the Board has determined that it is in the best interest of the Company to enter into the Agreement.

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby approves the Agreement and authorizes any executive officer of the Company (the "Authorized Officers") and SIC Counsel to execute and deliver the Agreement on behalf of the Company, with such changes thereto as the Authorized Officers may approve, such approval to be conclusively evidenced by the execution of the changed Agreement.

RESOLVED FURTHER, that the Authorized Officers and SIC Counsel are hereby authorized and directed to execute and deliver all other documents necessary to carry out the provisions of the Agreement.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to acknowledge on behalf of the Company that the Agreement and related documents fully set forth the agreement made between the Company and the USAO-WDVA, and that no additional promises or representations have been made to the Company by any officials of the USAO-WDVA in connection with the Agreement and related documents, other than those set forth in therein.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to make any payments required in connection with the Agreement.

RESOLVED FURTHER, that each Authorized Officer is authorized and empowered, in the name and on behalf of the Company, to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such documents, certificates and instruments as they may deem appropriate in order to effectuate fully the purpose of the foregoing resolutions, and that any actions taken heretofore and hereafter to accomplish such purposes be, and they hereby are approved, ratified and confirmed.

CERTIFICATE OF SECRETARY

I, Les B. Korsh, herby certify that I am now, and at all times mentioned herein have been, the duly elected, qualified, and acting Secretary of **PATTERSON COMPANIES, INC.**, a Minnesota corporation (the "Corporation") and, as such officer, I have access to the records of the Company, which records of the Company reflect that:

1. RESOLUTIONS. Attached hereto as **Exhibit A** is a true and correct copy of resolutions that have been duly adopted by the Board of Directors of the Corporation on February 4, 2020, in compliance with, and not in contravention of, the articles of organization and bylaws of the Corporation; none of such resolutions have been repealed or modified in any respect, and all of such resolutions are in full force and effect on and as of the date hereof, and constitute the only action taken by the Board of Directors of the Corporation with respect to the subject matter hereof.

IN WITNESS WHEREOF, I duly executed this Certificate this 10th day of February, 2020.

Les B. Korsh
Secretary of Patterson Companies, Inc.

CORPORATE COMPLIANCE PROGRAM AGREEMENT

The following Patterson Companies, Inc. ("Patterson" or the "Company") Corporate Compliance Program Agreement ("Corporate Compliance Program Agreement") has been prepared pursuant to the Non-Prosecution Agreement dated this same date between Patterson and the United States Attorney's Office for the Western District of Virginia ("USAO-WDVA"). Compliance with all the terms and standards of the Corporate Compliance Program Agreement is a condition of the Non-Prosecution Agreement and shall continue for the Term of the Non-Prosecution Agreement ("Term").

Applicability and Purpose

1. This Corporate Compliance Program Agreement shall be incorporated into the Non-Prosecution Agreement by reference, and compliance with the terms of the Corporate Compliance Program Agreement will be a condition of the Non-Prosecution Agreement. The USAO-WDVA acknowledges that the Company has already implemented many of these terms as of the date of the resolution.

2. Any proposed modifications to this Corporate Compliance Program Agreement must be made in writing and signed by the Company and the designated signatory for the USAO-WDVA.

3. The Corporate Compliance Program Agreement does not in any way release the Company from complying with any applicable federal or state statutes and/or regulations, and does not limit the imposition of any sanctions, penalties or any other actions available under those state or federal statutes and regulations.

The Corporate Compliance Program Agreement

4. The Company and the USAO-WDVA agree that the Company shall undertake the following voluntary compliance measures. The Corporate Compliance Program Agreement does and will continue to contain policies and procedures designed to prevent, detect, and correct violations of federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* and FDA requirements. These policies and procedures shall be designed to ensure that the Company complies with, among other things, the FDCA's prohibitions against causing the introduction into interstate commerce of a drug that is misbranded or otherwise violates the FDCA.

5. *Compliance Officer.* Prior to the effective date of the Non-Prosecution Agreement, the Company established the position of Chief Compliance Officer ("Compliance Officer") and appointed an individual to serve in the role on an interim basis until such time as the Company can fill the role on a permanent basis. The Company shall maintain a Compliance Officer for the Term. During the Term, the Compliance Officer shall be authorized to oversee compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA, FDA requirements, and the requirements of the Corporate

Compliance Program Agreement. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures and practices designed to address compliance with the requirements set forth in this Corporate Compliance Program Agreement, with federal and state statutes and/or regulations concerning federal prescription drug distribution and FDA requirements. The Compliance Officer shall be a member of senior management of the Company, and shall report directly to the Chief Executive Officer of the Company. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Patterson Company's Board of Directors (hereinafter the "Board") or any authorized committee thereof, and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the Company as well as for any obligations created under the Corporate Compliance Program Agreement. Any non-compliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in the Corporate Compliance Program Agreement.

6. *Compliance Committee.* Prior to the effective date of the Non-Prosecution Agreement, the Company formed a Compliance Committee (hereafter "Compliance Committee") which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the compliance program. The Company shall maintain the Compliance Committee for the Term. The Compliance Committee shall include, at a minimum, the Compliance Officer and other members of senior management necessary to meet the requirements of the Corporate Compliance Program Agreement (e.g., senior executives of relevant departments, such as legal, regulatory, audit, human resources, and operations.) The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Company's risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

7. *Board of Directors Compliance Obligations.* Prior to the effective date of the Non-Prosecution Agreement, the Board formed a committee responsible for overseeing the Company's compliance program ("Board Committee"). The Company shall maintain the Board Committee for the Term. The Board Committee shall consist of no less than three (3) non-employee directors, including at least one (1) member of the Special Investigation Committee formed in response to the USAO-WDVA investigation for a minimum of twelve (12) months from the date of this Non-Prosecution Agreement. The Board Committee shall oversee the Company's compliance program, including at a minimum:

a. the Company's obligations under the Corporate Compliance Program Agreement

b. receiving updates about adoption and implementation of policies, procedures and practices designed to ensure compliance with the FDCA and FDA requirements, and

c. evaluating the effectiveness of the compliance program.

8. The Company shall continue to evaluate its current business to ensure that it is not currently receiving, distributing or handling misbranded or unapproved federal prescription drugs. Should the Company find it is receiving, distributing, or handling misbranded or unapproved federal prescription drugs, it shall take necessary steps to remediate any such conduct.

9. The Company shall continue to enhance its current training program to ensure that pertinent employees are familiar with the requirements of the FDCA and FDA requirements that could potentially apply to the Company's conduct.

10. The Company will put in place processes to (a) encourage employees to report suspected non-compliant activities by the Company, customers, or others and to (b) acknowledge or otherwise recognize employees for reporting confirmed non-compliant activity, as appropriate.

11. The Company will maintain, or as necessary establish, policies and procedures designed to ensure effective investigation of any complaints and/or potential deficiencies relating to compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA and FDA requirements. Such policies and procedures shall include, but are not limited to:

a. Training and providing guidance to all pertinent employees as to the requirement to report all information regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to the Compliance Officer, who in turn will review and determine whether corrective actions are required; and

b. Tracking allegations and remediation action plans regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to identify issues that may require corrective actions.

12. Within 60 days of the end of the Company's fiscal year, the Company's Chief Executive Officer will certify, under oath, to (a) the United States Attorney's Office during the Term and (b) the United States Probation Office for any period during which Animal Health International, Inc. is on probation, that (1) the Company fully complied with all federal laws and regulations pursuant to the Food, Drug, and Cosmetic Act ("FDCA") in the preceding year (or, in the instance of the first such certification, the period from execution of the Non-Prosecution Agreement through the end of the Company's fiscal year 2020), or in the alternative, (2) list all non-compliant activity and the steps taken by the company to remedy such non-compliant activity. Any listing of non-compliant activity shall not be considered by the government or the Probation Officer as a per se violation of the terms of probation or the Non-Prosecution Agreement. Instead, other factors will be taken into account, including whether the conduct violated policies the Company has adopted, whether the Company provided training addressing the subject matter of the reported conduct, whether it was an isolated or systemic occurrence, the Company's response, and any remedial actions taken after the Company learned of the conduct reported.

Non-Compliance

13. The Corporate Compliance Program Agreement is part of the Non-Prosecution Agreement and adherence to it will be an enforceable condition. Deliberate, intentional or knowing failure to comply with any part of the Corporate Compliance Program Agreement is a violation of the Non-Prosecution Agreement.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	Criminal No.
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before 7 days from the date of entry of a guilty plea, the defendant will voluntarily remit payment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(c).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant upon entry, and shall be made a part of the sentence and included in the judgment.

ENTERED THIS _____ DAY OF _____, 2020.

_____
UNITED STATES DISTRICT JUDGE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Please see attached disclosure statement.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Animal Health International, Inc. (AHI) Disclosure Statement

a. On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement and a fine, and AHI paid $41,250.

b. On April 18, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Visalia, California Veterinary Food- Animal Drug Retailer license for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

c. On June 18, 2013, the Missouri Division of Professional Regulation issued a drug distributor license to Animal Health International, Inc.'s (AHI) Salina, Kansas facility. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

d. On August 30, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failing to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

e. On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no misconduct allegations beyond the conduct in Arkansas, which led to the non-disciplinary order and fine.

f. In March 2017, the Colorado Board of Pharmacy issued a letter of admonishment to Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license following allegations that it failed to timely submit an application detailing a change in designated representative. AHI was required to pay the costs associated with the Board's order.

g. On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

h. On July 20, 2020, Animal Health International, Inc. (AHI) in Boaz, AL entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an

administrative fine of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The facility in Boaz, Alabama facility, subject to discipline was AHI's Boaz, Alabama, wholesale drug distributor license.

i. On July 20, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas, wholesale drugdistributor license.

j. On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license. This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

k. On December 31, 2024, Animal Health International's Sioux Center, Iowa Wholesale Distributor facility entered into a Consent Order with the Illinois Department of Financial and Professional Regulation in which the facility's Illinois Wholesale Distributor license was reprimanded and fined $10,000. This action was based entirely on the Department of Justice case against AHI related to distribution activities predating current ownership. The Federal case was reported to State Boards during the investigation in July 2019 and again in February 2020 once the case was resolved.

l. On January 9, 2025, Animal Health International's ("AHI") Ceres, California Wholesale Distributor Facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 6 days in 2016, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

m. On January 9, 2025, Animal Health International's ("AHI") Roanoke, Texas Wholesale Distributor facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 165 days in 2014, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil

penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

n. On January 9, 2025, Animal Health International's ("AHI") Twin Falls, Idaho pharmacy entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 3 days in 2016, the pharmacy dispensed prescriptions into Oregon without an active pharmacy license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $3,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. Please note that the activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice case was reported to the state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. A copy of the Oregon Consent Order is enclosed. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054

Name: Elanco US Inc
Address: 2500 Innovation Way N City: Greenfield, State: IN Zip: 46140

Name: Boehringer Ingelheim
Address: 900 Ridgebury Rd City: Ridgefield State: CT Zip: 06877

Name: Huvepharma, Inc.
Address: 525 Westpark Drive, Suite 230 City: Peachtree City State: GA Zip: 30269

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Colorado
Parent Company (if any): Patterson Companies, Inc.
Corporation/Organization Name: Animal Health International, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Animal Health International, Inc.

Facility Name

Kevin M Barry

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/6/25

Date

Board Use Only	Date Received: 5/19/25	Amount: $1000

Animal Health INTERNATIONAL
2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515
State of Incorporation:	Minnesota

ANIMAL HEALTH INTERNATIONAL, INC. – Officer List

Corporate Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Phone Number:	970-353-2000
FEIN #:	84-0575063
State of Incorporation:	Colorado (5/16/1967)

Robert J. Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com
Steven M. Cunningham	**President**
Business Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Business Phone:	970-353-2000
Email:	Facilitylicensing@pattersoncompanies.com
Kevin M. Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com
Leslie B. Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Animal Health International, Inc.

is a

Corporation

formed or registered on 05/16/1967 under the law of Colorado, has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 19871193550 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 05/06/2025 that have been posted, and by documents delivered to this office electronically through 05/08/2025 @ 06:42:52 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 05/08/2025 @ 06:42:52 in accordance with applicable law. This certificate is assigned Confirmation Number 17280636 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LIMITED LICENSE

Animal Health International, Inc.

EFFECTIVE **12/09/2016**

EXPIRATION **09/30/2025**

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

10147875-1714 Pharmacy - Class E Business

Veterinarian Pharmaceutical Facility

DBA: None Associated

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

ANIMAL HEALTH INTERNATIONAL, INC.
640 S MAIN ST
SPANISH FORK UT 84660

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

ACTIVE LIMITED LICENSE

EFFECTIVE DATE: **12/09/2016**

EXPIRATION DATE: **09/30/2025**

ISSUED TO: **Animal Health International, Inc.**
640 S MAIN ST
SPANISH FORK UT 84660

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

10147875-1714 **Pharmacy - Class E Business**

Veterinarian Pharmaceutical Facility

DBA: **None Associated**

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/07/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400 CN102114303-Stnd-GAWU-24-25	**CONTACT NAME:** Marsh | U.S. Operations & Technology **PHONE (A/C, No, Ext):** 866-966-4664 **FAX (A/C, No):** **E-MAIL ADDRESS:** Minneapolis.CertRequest@marsh.com
INSURED Animal Health International, Inc. and Subsidiaries 822 7th Street, Suite 740 Greeley, CO 80631	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Starr Indemnity & Liability Company — 38318 **INSURER B :** Starr Specialty Insurance Company — 16109 **INSURER C :** **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CHI-010764188-03 **REVISION NUMBER:** 1

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	2,000,000 1,000,000 0 2,000,000 10,000,000 4,000,000
A A	**AUTOMOBILE LIABILITY** X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			1000198195241 (AOS) 1000198196241 (MA)	11/01/2024 11/01/2024	11/01/2025 11/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	3,000,000
A	X **UMBRELLA LIAB** [X] OCCUR **EXCESS LIAB** [ ] CLAIMS-MADE DED [X] RETENTION $ 25,000			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE AGGREGATE	$ $	5,000,000 5,000,000
B B B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [N] If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		100 0005556 (AOS) 100 0005558 (FL,MA) 100 0005559 (WI)	11/01/2024 11/01/2024 11/01/2024	11/01/2025 11/01/2025 11/01/2025	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance

CERTIFICATE HOLDER

Animal Health International, Inc.
and Subsidiaries
822 7th Street, Suite 740
Greeley, CO 80631

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K09623140

Application/License No. _____

Animal Health International, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
640 South Main Street, Spanish Fork, UT 84660, as
(Address of Applicant/Principal)
PRINCIPAL, and Westchester Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Pennsylvania
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
436 Walnut Street, Philadelphia, PA 19106 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 2, 2018.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 2nd day of April, 2018.

APPLICANT/PRINCIPAL

Animal Health International, Inc.

Authorized Representative

SURETY COMPANY

Westchester Fire Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact

print name

Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

BONNIE K. RAMIREZ
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID 20054017910
MY COMMISSION EXPIRES MAY 4, 2021

Countersigned by:

N/A

Nevada Resident Agent

ACKNOWLEDGMENT BY SURETY

STATE OF Missouri }
City of St. Louis } ss.

On this 2nd day of April, 2018, before me personally appeared Cynthia L. Choren, known to me to be the Attorney-in-Fact of Westchester Fire Insurance Company, the corporation that executed the within instrument, and acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

My Commission Expires: May 20, 2020

(Seal)

Debra C. Schneider
Notary Public in the State of Missouri
County of St. Charles
Commission No. 12419088

DEBRA C. SCHNEIDER
Notary Public, Notary Seal
State of Missouri
St. Charles County
Commission # 12419088
My Commission Expires May 20, 2020

S-0230/GEEF 2/98

Power of Attorney

WESTCHESTER FIRE INSURANCE COMPANY

Know all men by these presents: That **WESTCHESTER FIRE INSURANCE COMPANY**, a corporation of the Commonwealth of Pennsylvania pursuant to the following Resolution, adopted by the Board of Directors of the said Company on December 11, 2006, to wit:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such persons written appointment as such attorney-in-fact .

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested.

Does hereby nominate, constitute and appoint Brittany D Clavin, Cynthia L Choren, Debra C Schneider, Heidi A Notheisen, JoAnn R Frank, Karen L Roider, Pamela A Beelman, Sandra L Ham all of the City of SAINT LOUIS, Missouri, each individually if there be more than one named, its true and lawful attorney-in-fact, to make, execute, seal and deliver on its behalf, and as its act and deed any and all bonds, undertakings, recognizances, contracts and other writings in the nature thereof in penalties not exceeding SEVENTY MILLION DOLLARS & ZERO CENTS ($70,000,000.00) and the execution of such writings in pursuance of these presents shall be as binding upon said Company, as fully and amply as if they had been duly executed and acknowledged by the regularly elected officers of the Company at its principal office.

IN WITNESS WHEREOF, the said Stephen M. Haney, Vice-President, has hereunto subscribed his name and affixed the Corporate seal of the said **WESTCHESTER FIRE INSURANCE COMPANY** this 9 day of October 2017

WESTCHESTER FIRE INSURANCE COMPANY

Stephen M. Haney

Stephen M. Haney , Vice President

COMMONWEALTH OF PENNSYLVANIA
COUNTY OF PHILADELPHIA ss.

On this 9 day of October, 2017 before me, a Notary Public of the Commonwealth of Pennsylvania in and for the County of Philadelphia came Stephen M. Haney ,Vice-President of the **WESTCHESTER FIRE INSURANCE COMPANY** to me personally known to be the individual and officer who executed the preceding instrument, and he acknowledged that he executed the same, and that the seal affixed to the preceding instrument is the corporate seal of said Company; that the said corporate seal and his signature were duly affixed by the authority and direction of the said corporation, and that Resolution, adopted by the Board of Directors of said Company, referred to in the preceding instrument, is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at the Cityof Philadelphia the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
KAREN E. BRANDT, Notary Public
City of Philadelphia, Phila. County
My Commission Expires Sept. 26, 2018

Karen E Brandt

Notary Public

I, the undersigned Assistant Secretary of the **WESTCHESTER FIRE INSURANCE COMPANY**, do hereby certify that the original POWER OF ATTORNEY, of which the foregoing is a substantially true and correct copy, is in full force and effect.

In witness whereof, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of the Corporation, this 2nd day of April 2018.

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

THIS POWER OF ATTORNEY MAY NOT BE USED TO EXECUTE ANY BOND WITH AN INCEPTION DATE AFTER OCTOBER 09, 2019.

DocuGard #04546 contains a security pantograph, blue background, heat-sensitive ink, coin-reactive watermark, and microtext printing on border.

HEAT SENSITIVE SHIELD • FADES WITH HEAT OR TOUCH •

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Animal Health International, Inc. MDEG License # (if applicable): _____

Physical Address: 640 South Main Street

City: Spanish Fork State: UT Zip: 84660

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 970-656-1957 Website: https://www.animalhealthinternational.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Swade Middle: Brent Last: Bartlett

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Addres: [redacted]

City: Nephi State: UT Zip: [redacted]

Telephon: [redacted] Email: swade.bartlett@animalhealthinternational.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Yes	No

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Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Springville High School		08/2007 - 05/2010	
Address	**City**	**State**	**Zip**
1205 E 900 S	Springville	UT	84663
Diploma/Degree obtained, if any			
Graduation Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2019 - Current	[redacted]	Nephi	UT	[redacted]
01/2015 - 06/2019		Payson	UT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International, Inc.			08/2012 - Present	
Business Address		**City**	**State**	**Zip**
640 South Main Street		Spanish Fork	UT	84660
Phone	**Title**		**Number of Employed Hours**	
801-822-1657	Facility		6000 +++	
Description of Duties				
Oversee all inbound and outbound shipments. Responsible for all facility employees and their duties.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

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Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

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Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5-23-25
Date

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I, Swade Brent Bartlett, certify that as the MDEG Administrator for

Animal Health International, Inc.

that I (initial that you have read and meet the following requirements):

1. SB Have a high school diploma or its equivalent;
2. SB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Swade Bartlett
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-23-25
Date

Board Use Only	Date Received:

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Animal Health International, Inc.

Pharmacy/Wholesaler License # (if applicable): WH02464

Physical Address: 640 South Main Street

City: Spanish Fork State: UT Zip: 84660

Mailing Address (If different from physical address): 1031 Mendota Heights Road

City: Saint Paul State: MN Zip: 55120

Telephone: 970-656-1957 Website: www.animalhealthinternational.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Swade Middle: Brent Last: Bartlett

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Addres: [redacted]

City: Nephi State: UT Zip: [redacted]

Telephon: [redacted] Email: swade.bartlett@animalhealthinternational.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Springville High School		08/2007 - 05/2010	
Address	**City**	**State**	**Zip**
1205 E 900 S	Springville	UT	84663
Diploma/Degree obtained, if any			
Graduation Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2019 - Current	[redacted]	Nephi	UT	[redacted]
01/2015 - 06/2019	[redacted]	Payson	UT	[redacted]

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)
Animal Health International, Inc.		08/2012 - Present
Business Address	**City**	**State / Zip**
640 South Main Street	Spanish Fork	UT / 84660
Phone	**Title**	**Number of Employed Hours**
801-822-1657	Facility Manager	

Description of Duties

Oversee all inbound and outbound shipments. Responsible for all facility employees and their duties.

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	Yes	✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

3/17/25

Date

I, Swade Brent Bartlett, certify that as the designated representative for

Animal Health International, Inc.

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SB I am at least 21 years of age;
3. SB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Swade Brent Bartlett

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/17/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Swade Brent Bartlett

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/17/25

Date

Please have this section completed in the presence of a Notary Public.

State of UTAH, ss. County of UTAH

I, Swade Bartlett, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3-18-25

Date

Subscribed and Sworn to before me this 18th day of MARCH 2025

Notary Public Signature

LANDON SWENSON
NOTARY PUBLIC • STATE OF UTAH
My Commission Expires July 20, 2027
COMMISSION NUMBER 732200

(Seal)

Animal Health INTERNATIONAL
A Patterson Company

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Employee List

640 South Main Street
Spanish Fork, UT 84660
License Number: WH02464

Legal Name

Wentz, Jacob David
Olsen, Amanda Lee
Bartlett, Swade
Roach, Kenneth
Lamb, Kale
Lamb, Shad

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03586	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Animal Health International, Inc.

Physical Address: 203 Fourth Avenue West

City: Twin Falls State: ID Zip: 83301

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 970-347-3322 Website: https://www.animalhealthinternational.com/home

Name of Designated Representative (DR): Luke Theberge

Licensing Company Email: facilitylicensing@pattersoncompai DR Email: Luke.Theberge@animalhealthinternational.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class II & Class II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Universities/Research		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/14/2020		VA	Abingdon	Washington
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
DVAW120CR00007-001		United States District Court, Wetern District of Virginia Abingdon		
Reason/Charge				
Violation of Title 21, US Code, Sections 221(1), 333(a)(1), and (352)(f)(l)				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Animal Health International, Inc.		N/A		
Name of Business/Industry/Entity				
Animal Health International, Inc.				

Provide explanation below:

On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

FEB 14 2020

JULIA C. DUDLEY, CLERK
BY: DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20-cr-00007
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

PLEA AGREEMENT

ANIMAL HEALTH INTERNATIONAL, INC. (EIN: 84-0575063) ("AHI") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this Plea Agreement are as follows:

1. CHARGE TO WHICH AHI IS PLEADING GUILTY AND WAIVER OF RIGHTS

AHI will enter a plea of guilty to Count One of the Information charging it with violating Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) in the Western District of Virginia by introducing and delivering for introduction, and causing the introduction and delivery for introduction, into interstate commerce of veterinary prescription drugs that were misbranded.

AHI understands, and the parties agree and stipulate, the maximum statutory penalty is a fine of $14,855,856 (fourteen million eight hundred fifty-five thousand eight hundred fifty-six dollars), pursuant to Title 18, United States Code, Section 3571(d), and a period of probation of five (5) years, pursuant to Title 18, United States Code, Section 3561(c)(2). In addition, AHI's assets are subject to forfeiture. AHI understands fees may be imposed to pay for probation and there will be a $125 (one hundred twenty-five dollars) special assessment for Count One, pursuant to Title 18, United States Code, Section 3013(a)(1)(B)(iii). AHI's attorneys have informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before AHI could be found guilty as charged.

AHI admits and agrees that all of the statements and allegations in the Information are true and correct.

AHI acknowledges AHI has had all of its rights explained to it. AHI expressly recognizes that, as a corporation, AHI may have the following constitutional rights and by voluntarily pleading guilty AHI knowingly waives and gives up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses.

The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

AHI is pleading guilty as described above because AHI is in fact guilty and because AHI believes it is in its best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for its plea of guilty. AHI agrees all of the matters set forth in the Information are true and correct.

AHI understands the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree the 2018 version of the United States Sentencing Commission Guidelines Manual ("U.S.S.G.") is the appropriate Guidelines Manual to utilize. According to U.S.S.G. § 8C2.1, the organizational fine provisions do not apply to the count of conviction in this case, which is a misdemeanor under 21 U.S.C. § 333(a)(1).

The parties agree and stipulate:

a. the fine shall be $5,000,000 (five million dollars);
b. AHI shall pay $1,000,000 (one million dollars) to the Virginia Department of Health Professions ("DHP") in recognition of direct assistance provided by DHP to the United States during the investigation;
c. AHI shall forfeit $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars); and
d. AHI shall serve a term of probation of one to three years, as determined by the Court.

The Court will determine what terms and length of probation are appropriate and the parties will be free to argue for which terms and length of probation they believe are appropriate. AHI understands and agrees if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum may be imposed.

The parties agree if the Court refuses to accept this Plea Agreement with the agreed-upon sentence, AHI will be free to withdraw its guilty plea. In the event the Court refuses to accept this Plea Agreement and AHI withdraws its guilty plea within ten days of being notified of the Court's refusal, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410. Under these circumstances, the United States will move to dismiss the Information without prejudice and the United States may file any charges it could have filed in the absence of the plea agreement. AHI agrees to toll the statute of limitations between the date of the plea and the filing of any such charges.

3. FINANCIAL OBLIGATIONS

AHI agrees and understands any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept this Plea Agreement with the agreed-upon sentence and, as a result, AHI withdraws its guilty plea. If the Court rejects this Plea Agreement and AHI withdraws its guilty plea, the United States will return all money paid by AHI, without

interest, not more than thirty (30) days after AHI withdraws its guilty plea and notifies the United States Attorney's Office for the Western District of Virginia ("USAO"), in writing, it wishes to have the money returned.

In addition, in accordance with 18 U.S.C. § 3572(d)(3), AHI will notify the Court of any material change in AHI's economic circumstances that might affect AHI's ability to pay any amounts payable under this Plea Agreement.

a. Payments

Within 7 days of the entry of AHI's guilty plea, AHI will make the following disbursements:

(1) $125 (one hundred twenty-five dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the special assessment.

(2) $5,000,000 (five million dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the fine;

(3) $1,000,000 (one million dollars) to the Virginia Department of Health Professions. These funds must be remitted in the form of certified funds made payable to the "Treasurer of Virginia." The comment section of the check should note "DHP-Enforcement" in recognition of direct assistance provided to the United States during the investigation; and

(4) $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) made payable to the United States Marshals Service, as directed by the USAO as payment of a forfeiture money judgment.

b. Forfeiture

AHI agrees to the entry of a forfeiture money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency ("Forfeiture Money Judgment") pursuant to 21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c). AHI agrees that the value of the quantities of prescription drugs which were misbranded in violation of 21 U.S.C. § 331(a) totaled at least $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency.

AHI acknowledges and agrees the quantities of the drugs which were misbranded in violation of 21 U.S.C. § 331(a) cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, AHI agrees the government is entitled to forfeit as substitute assets any other assets of AHI up to the value of the now missing directly forfeitable assets, pursuant to

21 U.S.C. § 853(p). Payment in full of the Forfeiture Money Judgment shall satisfy any and all forfeiture obligations that AHI may have as a result of this guilty plea. AHI consents to the entry of an Order of Forfeiture pursuant to Rule 32.2 of the Federal Rules of Criminal Procedure forfeiting the above-referenced Forfeiture Money Judgment.

AHI agrees to sign any documentation necessary and to cooperate fully with the United States to accomplish the forfeiture. AHI agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of these funds to the United States.

AHI agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. AHI agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgement in any administrative or judicial proceeding.

AHI understands and agrees forfeiture of this property is proportionate to the degree and nature of the offense. AHI freely and knowingly waives any and all constitutional and statutory challenges to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including, but not limited to, that the forfeiture constitutes an excessive fine or punishment. AHI further understands and agrees this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty or other monetary judgment that may be imposed by the court.

c. Restitution

The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no restitution will be ordered.

4. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, AHI withdraws its plea, AHI agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny it committed the crime to which it has pled guilty; (4) comply with any reasonable request of the United States Attorney's Office and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement.

Neither AHI, nor its corporate parent (Patterson Companies, Inc. ["Patterson"]), will (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If Patterson or AHI makes a public statement that in whole or in part contradicts any such statement or provision, AHI may avoid being in violation of this Plea Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by Patterson's and AHI's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) Patterson or AHI websites. Notwithstanding the above, Patterson and AHI may avail themselves of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by

any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

5. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, AHI agrees AHI will not appeal the conviction or sentence imposed. AHI is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). AHI expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. AHI understands the United States expressly reserves all of its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, AHI may file a cross appeal of that same sentence. AHI agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this Plea Agreement.

6. INFORMATION ACCESS WAIVER

AHI agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a. However, if a third party obtains any records pertaining to the investigation or prosecution of this case under the Freedom of Information Act, AHI shall have the right to request copies of such disclosed records.

7. ADMISSIBILITY OF STATEMENTS

AHI understands any statements made on its behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against AHI by the United States in this or any other proceeding. AHI knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other proceeding. If, and only if, the Court rejects this Plea Agreement, and, as a result, AHI withdraws its plea, AHI will not be bound by the waivers set forth in this section of the Plea Agreement.

8. COMPLETION OF PROSECUTION

Pursuant to Fed. R. Crim. P. 11(c)(l)(A), so long as AHI complies with all of its obligations under this Plea Agreement, the United States agrees, other than the charge in the attached Information, it shall not further criminally prosecute AHI for any additional federal criminal

charges or forfeiture action with respect to any offenses set forth in the Information or Non-Prosecution Agreement with Patterson (Attached as Attachment B).

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

9. LIMITATION OF PLEA AGREEMENT

This Plea Agreement is limited to the United States Department of Justice and does not bind any other federal, state, or local authority.

10. COMPLIANCE AND REMEDIAL MEASURES

AHI agrees to comply with the Corporate Compliance Program Agreement attached hereto as Attachment C.

11. COOPERATION

AHI acknowledges that its ongoing and future cooperation is important and a material fact underlying the United States' decision to enter into this Plea Agreement. AHI agrees to continue to cooperate fully and actively with the United States regarding any matter, including, but not limited to, matters involving (a) current and former AHI personnel, and (b) other entities who operate in the same commercial segment as AHI and/or Patterson during the Term of the Non-Prosecution Agreement with Patterson, provided however that any cooperation in an ongoing investigation or prosecution shall continue until such investigation or prosecution is concluded.

Nothing in this Plea Agreement shall be construed to require Patterson or AHI to waive any attorney-client privilege or work-product protection.

12. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THIS PLEA AGREEMENT

AHI understands if: (1) AHI attempts to withdraw its plea (in the absence of the Court refusing to accept this Plea Agreement); (2) AHI fails to comply with any provision of this Plea Agreement; (3) AHI's conviction is set aside, for any reason; and/or (4) AHI fails to execute all required paperwork prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement titled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, AHI will still be bound by its obligations under this Plea Agreement. AHI hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of this Plea Agreement. AHI hereby waives any statute of limitations argument as to any such charges.

13. EFFECTIVE REPRESENTATION

AHI has discussed the terms of this Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, AHI has no dissatisfaction or complaint with its attorneys' representation. AHI agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint AHI may have with its attorneys' representation.

14. EFFECT OF AHI'S SIGNATURE

AHI understands its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. AHI understands the United States has not accepted AHI's offer until the authorized representative of the United States has signed this Plea Agreement.

15. GENERAL UNDERSTANDINGS

AHI understands a presentence investigation will be conducted and sentencing recommendations independent of the USAO will be made by the presentence preparer.

AHI understands the United States and AHI retain the right, notwithstanding any provision in this Plea Agreement, to inform the probation office and the Court of all facts, to address the Court with respect to the nature and seriousness of the offense and the offender, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, and to respond to any statements made to the Court.

AHI willingly stipulates there is a sufficient factual basis for the Court to accept the plea.

AHI understands this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

AHI has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. AHI understands its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. AHI understands AHI will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing, the Non-Prosecution Agreement with Patterson (attached as Attachment B), the Corporate Compliance Program Agreement (attached as Attachment C), and the Agreed Order of Forfeiture (attached as Attachment D) are the complete and only agreements between the United States and AHI concerning resolution of this matter. In addition, AHI has no objection to the filing of the Information.

The agreements and documents listed in this section set forth the entire understanding between the parties and constitute the complete agreement between the United States Attorney for the Western District of Virginia and AHI and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and AHI. AHI consents to public disclosure of all of the agreements and other documents referenced in this section.

AHI has consulted with its attorneys and fully understands its rights. AHI has read this Plea Agreement and carefully reviewed every part of it with its attorneys. AHI understands this Plea Agreement and AHI voluntarily agrees to it. Being aware of all of the possible consequences of its plea, AHI has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer ("Officer") below.

The Officer, by signing below, hereby certifies to the following:

(1) The Officer is fully authorized to enter into this Plea Agreement on behalf of AHI;

(2) The Officer has read the entire Plea Agreement and documents referenced herein and discussed them with AHI's Board of Directors;

(3) AHI understands all the terms of this Plea Agreement and those terms correctly reflect the results of plea negotiations;

(4) AHI is fully satisfied with AHI's attorneys' representation during all phases of this case;

(5) AHI is freely and voluntarily pleading guilty in this case;

(6) AHI is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea; and

(7) AHI understands it is waiving its right to appeal the judgment and conviction in this case.

AHI acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Officer. A copy of a certification by AHI's Board of Directors authorizing the Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of AHI is attached as Attachment A.

Date: 2/13/2020

Authorized Corporate Officer
AHI

Counsel has fully explained to the Board of Directors of AHI the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the Sentencing Guidelines; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and documents referenced herein with the client, through its Officer. AHI understands the terms and conditions of this Plea Agreement, and AHI's decision to enter into this Plea Agreement is knowing and voluntary. AHI's execution of and entry into the Plea Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED
2/11/2020
JULIA C. DUDLEY, CLERK
BY: LOTTIE LUNSFORD
DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20CR00007
v.	)	
	)	**Violations: 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)**
ANIMAL HEALTH INTERNATIONAL, INC.	)	

INFORMATION

INTRODUCTION

1. Defendant Animal Health International, Inc. ("AHI") is a Colorado corporation with its principal place of business in Colorado. AHI is comprised of two legacy organizations, Lextron, Inc. ("Lextron") and Walco International, Inc. ("Walco"). In June 2011, Lextron acquired all outstanding stock of the parent company of Walco and changed its name to AHI. Walco continued operations as a subsidiary of AHI until December 2011 when Animal Health Holdings, Inc. and each of its wholly-owned subsidiaries, including Walco, were merged with and into AHI and no longer had separate corporate existences. AHI, and its predecessor entities, dispense, distribute and sell, among other products, veterinary prescription drugs to customers in the production animal industry across the United States. Specifically, AHI obtains prescription drugs for production animals from manufacturers for further distribution to veterinarians, farms, feedlots, and other distribution facilities.

2. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulates the distribution and labeling of all drugs, including animal drugs, shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C § 301, *et seq.* ("FDCA"). Veterinary prescription drugs are drugs intended for use by animals that, because of their toxicity or other potentiality for harmful

effect, or the method of their use, or the collateral measures necessary for their use, are not safe for animal use except under the professional supervision of a licensed veterinarian. 21 U.S.C. § 353(f)(1)(A).

3. Under the FDCA, a drug is misbranded if, among other things, its labeling does not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). Adequate directions for use is defined as "directions under which the *layman* can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5 (emphasis added). Prescription veterinary drugs by definition can only safely be used under the professional supervision of a licensed veterinarian and therefore they must qualify for an exemption to this requirement in order to move in interstate commerce. These exemptions are set out in 21 C.F.R. Part 201, Subpart D ("Exemptions from Adequate Directions for Use").

4. Veterinary prescription drugs are exempt from the requirement that their labeling contain adequate directions for use if they meet all enumerated conditions, including that they be distributed through a closed supply chain in which every entity that possesses a prescription drug must have legal authorization to do so. *See* 21 C.F.R. § 201.105 (a)(1) (a veterinary prescription drug must be in the possession of: a person lawfully engaged in the manufacture, transportation, storage or wholesale distribution of drugs; a retail pharmacy or other person authorized under state law to dispense veterinary prescription drugs; or a licensed veterinarian for use in the course of his professional practice). Moreover, the veterinary prescription drug must be dispensed in accordance with 21 U.S.C. § 353(f), i.e., pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian's professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105 (a)(2).

5. The FDCA's restrictions on veterinary prescription drugs are not primarily to protect animals from the potential harms of prescription drugs, but are to protect the human food supply from unsafe drug residues in the edible tissues of animals sold for slaughter. Common causes of illegal residues include: (1) exceeding the drug's approved dose; (2) using a shorter withdrawal period than what is stated on the drug's label (if a higher than approved dose is given, the labeled withdrawal period may not be enough to allow the drug in the edible tissues to deplete to levels that are at or below the tolerance); (3) using a drug in an extra-label manner (for indications and dosages outside the approved labeling) without a veterinarian's involvement; (4) giving a drug not approved for that species; and (5) using an unapproved route of administration. Drug residues in the nation's drug supply are concerning because: (1) they may contribute to antibiotic resistance in the human population, rendering human drugs less effective to treat human disease and contributing to the mutations of "superbugs"; and (2) they may cause allergic reactions in individuals with certain drug allergies.

6. Certain legacy customers of AHI, namely Marlin Webb and Billy K. Groce, were not properly licensed to receive, transport, store, distribute, or dispense veterinary prescription drugs in the Commonwealth of Virginia from January 2012 through April 2015.

7. Webb was the store manager of a cooperative in Hillsville, Virginia. The cooperative was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Webb operated a side business from the cooperative's location in which he illegally circumvented the FDA's regulation of veterinary prescription drugs by illegally obtaining from Billy K. Groce and AHI and reselling veterinary prescription drugs using unlawful prescriptions written by a veterinarian who was licensed in Tennessee but who was not properly licensed to

practice veterinary medicine in Virginia and who did not have a veterinarian-patient relationship with the animals in question. That veterinarian died in 2015.

8. Groce was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Groce operated an unlicensed veterinary prescription drug distribution business. Groce worked with the same veterinarian as did Webb.

9. Webb and Groce obtained veterinary prescription drugs from AHI in interstate commerce without valid prescriptions, and, on many occasions, with no prescription at all.

10. On April 29, 2015, the government executed search warrants at locations in Virginia and Tennessee associated with Groce and Webb. In 2016 and 2017, respectively, Groce and Webb pled guilty to illegally conspiring to defraud the FDA by obtaining and distributing veterinary prescription drugs from July 2009 through April 29, 2015 in a manner that circumvented the FDA's regulation of veterinary prescription drugs.

11. Groce and Webb were legacy customers of, among others, Lextron and Walco, and continued to be customers after the companies merged to form AHI in 2012 until May 2015. Neither Lextron, Walco, nor AHI performed adequate customer diligence processes, nor adequately trained sales representatives to raise questions regarding Groce's, Webb's or the veterinarian's activities in Virginia and Tennessee. For example, Groce operated a business that stored and distributed veterinary prescription drugs out of a storefront called "Goin' Postal" and his personal residence. Neither of those locations resembled a veterinarian establishment and should have raised questions for sales representatives who personally visited them. After learning of search warrants executed on each of the customers' locations, AHI took some steps to block the sale of veterinary prescription drugs to these customers on May 4, 2015.

12. Furthermore, between January 2012 and May 2015, AHI did not maintain the proper licenses to ship from its Memphis, Tennessee, facility into Virginia or from its Wolcott, Indiana, facility into Virginia or Tennessee, but, despite this deficiency, shipped products from those locations to Virginia and Tennessee.

13. All veterinary prescription drugs distributed by AHI to Groce and Webb were misbranded because, neither recipient was licensed to possess or distribute veterinary prescription drugs, and the prescribing veterinarian was not properly licensed to practice veterinary medicine in Virginia and consequently none of the drugs he caused to be dispensed were prescribed pursuant to lawful orders.

14. From the illegal shipments to and on behalf of Groce and Webb, AHI received $7,427,928 (seven million four hundred twenty-seven thousand nine hundred twenty-eight dollars) and made a profit of $558,309 (five hundred fifty-eight thousand three hundred nine dollars) by unlawfully distributing veterinary prescription drugs to or on behalf of Groce and Webb.

15. From 2012 through on or about 2018, AHI caused additional misbranded veterinary prescription drug shipments to be made throughout the United States by distributing veterinary prescription drugs from its wholesale locations directly to end users in states where such shipments were illegal and, in some instances, by shipping veterinary prescription drugs to locations in states in which AHI did not have legal authority to make such shipments. AHI obtained not less than $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) from such shipments. Its profits from such shipments were a small percentage of the amount received.

COUNT ONE

Introduction of Misbranded Drugs into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)

The United States Attorney charges that:

16. The Information is realleged and incorporated by reference into this Count.

17. From about January 2012 to April 2015, in the Western District of Virginia, Animal Health Incorporated ("AHI") introduced and delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce, of veterinary prescription drugs that were misbranded in that the drugs' labeling did not bear adequate directions for the use of such drugs.

18. The offense conduct included, but was not limited to, the following:

a. AHI distributed veterinary prescription drugs directly to Billy K. Groce and Marlin Webb, notwithstanding that neither Groce nor Webb was legally authorized to possess or distribute the drugs; and

b. AHI distributed veterinary prescription drugs to customers of Billy K. Groce and Marlin Webb without a lawful prescription having been issued for those drugs.

19. Since these veterinary prescription drugs were not lawfully distributed or prescribed, they failed to qualify for the exemption from the requirement that they bear labeling containing adequate directions for lay use. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1).

NOTICE OF FORFEITURE

20. Upon conviction of the offense alleged in this Information, AHI shall forfeit to the United States veterinary prescription drugs that were misbranded or became misbranded as a result of AHI's conduct, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

21. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of $46,802,203 pursuant to 21 U.S.C. § 853(p).

DATED: February 11, 2020

Randy Ramseyer
for THOMAS T. CULLEN
United States Attorney

NON-PROSECUTION AGREEMENT

1. The United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") and Patterson Companies, Inc. ("Patterson"), and any and all current and former affiliated entities including, but not limited to, Animal Health International, Inc. ("AHI") (collectively referred to as the "Company") enter into this Non-Prosecution Agreement ("Agreement") to resolve the investigation by the USAO-WDVA of the Company related to possible violations of federal laws relating to the licensing, dispensing, distribution, or sale of veterinary prescription drugs.

2. This Agreement, in conjunction with the Plea Agreement with AHI ("Plea Agreement"), resolves all of the Company's potential federal criminal liability for the offenses covered herein and in the Plea Agreement.

3. The USAO-WDVA enters into this Agreement based on the individual circumstances presented by this case including:

a. Patterson's cooperation with the USAO-WDVA investigation since June 2018, and AHI's subsequent cooperation under the direction of Patterson, as well as the Company's continued cooperation under the direction of the Special Investigation Committee of the Board of Directors of Patterson ("SIC") which was formed in April 2019. Since 2018, the Company has conducted a thorough and robust internal investigation; proactively brought information to the USAO-WDVA's attention, remediated noncompliant activity and implemented control enhancements, including certain licensing, dispensing, distribution and related sales practices company-wide; made factual presentations to the USAO-WDVA; timely and fully produced all requested documents; entered into agreements tolling relevant statutes of limitations; and collected, analyzed, and organized voluminous data and information for the USAO-WDVA.

b. Patterson's voluntary disclosure to the USAO-WDVA of non-compliant licensing, dispensing, distribution, and sales at AHI and Patterson beyond AHI's conduct set forth in the Information and Plea Agreement, and its timely efforts to remediate non-compliant activity and enhance controls and processes to mitigate against future reoccurrence. The additional non-compliant activity involved wholesale distribution of veterinary prescription drugs: (i) without verifying the continued validity of all practitioners' licenses in the receiving state; (ii) without verifying that an alternate location requested by the customer was authorized by state law to receive veterinary prescription drugs; (iii) without verifying that veterinarians licensed in Virginia were also associated with a veterinary establishment registered with the Virginia Board of Veterinary Medicine, (iv) without valid licensure to ship to the state to which the drugs were shipped, and/or (v) to end users in states where drop shipments by wholesalers to end users is not allowed. The additional non-compliant activity was due to prior weaknesses and inconsistencies among AHI and Patterson regulatory functions and processes, as well as system challenges presented by the Company's enterprise resource planning implementation. The Company has since taken extensive

proactive steps to enhance its regulatory function, capabilities and support to guide the business and other control functions on regulatory compliance matters. It has also enhanced its regulatory system controls to address the issues disclosed in the investigation and to verify that veterinary prescription drugs are shipped from facilities with required state licenses and to customers and locations authorized by state law to receive veterinary prescription drugs. Consistent with its approach to the USAO-WDVA, Patterson also disclosed the pending federal investigation to state regulators in all 50 states and continues to engage with state regulators, as appropriate, on matters related to the USAO-WDVA investigation.

c. The Company's enhanced regulatory compliance processes and commitment to implement a compliance program that meets the minimum elements set forth in Attachment C to the Plea Agreement ("Corporate Compliance Program Agreement").

d. The Company's agreement to comply with the terms of the Agreement and Plea Agreement.

e. AHI's admission to and the Company's agreement with the facts and allegations set forth in the Plea Agreement.

f. Although the investigation did not involve controlled substances, the Company's recognition that diversion of controlled substances, including drugs of the type that are prescribed and dispensed by veterinarians, such as buprenorphine and hydrocodone, should be a concern of all distributors and dispensers of those drugs and the Company's ongoing commitment to be proactive in deterring diversion and identifying and notifying authorities of suspicious ordering.

4. The Company agrees it will not take any tax deduction or seek or accept directly or indirectly reimbursement or indemnification from any source for any payments made pursuant to the Plea Agreement.

5. No money paid by the Company will be returned, and the Company expressly agrees to release any and all claims it may have to the money. The Company will not file any claim or otherwise contest the payment of money set forth in this Plea Agreement, and it will not assist anyone in asserting a claim to the money.

6. Nothing in this Agreement or any related documents is an admission by the United States that the amounts paid by the Company are the maximum amounts that could be recovered from the Company in the absence of an accepted plea agreement. If the Company does not comply with all of its obligations under this Agreement, the United States is not precluded from arguing or presenting evidence that the total amount to be paid by the Company should be higher.

7. The Company's obligations under this Agreement shall have a term of 42 months from the date on which the Agreement is executed (the "Term").

8. During the Term, the Company will fully cooperate with the USAO-WDVA.

9. During the Term, the Company shall undertake and abide by the terms of the Corporate Compliance Program Agreement in Attachment C to the Plea Agreement.

10. If the Company complies with all of the terms of this Agreement and the Plea Agreement, the USAO-WDVA will not prosecute the Company for any criminal conduct occurring prior to the entering of this agreement concerning:

a. The subject matter of the Information to which AHI is pleading guilty; or

b. Facts disclosed by the Company to the USAO prior to entering this agreement related to the Company's licensing, dispensing, distribution, or sale of veterinary prescription drugs.

11. However, if the USAO-WDVA, in its sole discretion, determines the Company (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement or (b) violated any provision of this Agreement, then the USAO-WDVA will not be bound to their agreement not to prosecute the Company for the matters covered in paragraph 10. Should the USAO-WDVA determine that the Company has violated any provision of this Agreement, the USAO-WDVA shall provide prompt written notice to the Company addressed to its General Counsel, and to its outside counsel, Amy Conway-Hatcher, Baker Botts LLP, 1299 Pennsylvania Avenue NW, Washington, DC, or to any successor the Company may designate, of the alleged violation and provide the Company with a 45 (forty-five) day period from the date of receipt of notice in which to make a presentation to the USAO-WDVA to demonstrate that no violation occurred, or, to the extent applicable, that the violation should not result in adverse action, including because the violation has been cured by the Company. In the event of a violation, the Company will not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other rule or law, that any statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible in any proceeding brought by the Department of Justice. If, as a result of a violation, the United States charges the Company, the Company hereby waives any statute of limitations defense for any offense not time-barred by the applicable statute of limitations on the date this Agreement is signed, including time protected as the result of existing agreements to toll the applicable statute of limitations.

12. The Company will not, through its present or future directors, officers, employees, agents, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If the Company makes a public statement that in whole or in part contradicts any such statement or provision, the Company may avoid being in violation of this Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by the Company's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) the Company's

websites. Notwithstanding the above, the Company may avail itself of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

13. The terms of this Agreement bind the USAO-WDVA and other divisions of the Department of Justice (collectively referred to as the "United States"), except that they do not bind the Tax Division of the Department of Justice or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities. The USAO-WDVA will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

14. The Company and the United States may disclose this Agreement and any other documents used to effectuate the objectives of this Agreement to the public.

15. Nothing in this Agreement resolves, in any way, any liability of any individual.

16. This Agreement and the Plea Agreement set forth all the terms of the agreement between the Company and the USAO-WDVA. No amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the USAO-WDVA, the attorneys for the Company, and a duly authorized representative of the Company.

The Company acknowledges its acceptance of this Agreement by the signature of its counsel and Officer. A copy of a resolution by the Company's Board of Directors authorizing the Officer to execute this Agreement and all other documents to resolve this matter on behalf of the Company is attached as Addendum 1.

Date: February 12, 2020

Mark S. Walchirk
Authorized Corporate Officer
Patterson Companies, Inc.

Counsel has fully explained to the Board of Directors of the Company the facts and circumstances of the investigation and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein with the client, through its Officer. The Company understands the terms and conditions of this Agreement, and the Company's decision to enter into this Agreement is knowing and voluntary. The Company's execution of and entry into this Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI and Patterson Companies, Inc.

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

EXHIBIT A

RESOLUTION OF THE
BOARD OF DIRECTORS
OF
PATTERSON COMPANIES, INC.

NON-PROSECUTION AGREEMENT

WHEREAS, the Company, together with outside counsel reporting to the Special Investigation Committee of the Board ("SIC Counsel"), has been in discussions with the U.S. Attorney's Office for the Western District of Virginia ("USAO-WDVA") to resolve its investigation into Animal Health International, Inc. by, among other things, having the Company enter into a Non-Prosecution Agreement (the "Agreement");

WHEREAS, SIC Counsel has advised the Board of the terms of the Agreement and the consequences of entering into the Agreement; and

WHEREAS, the Board has determined that it is in the best interest of the Company to enter into the Agreement.

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby approves the Agreement and authorizes any executive officer of the Company (the "Authorized Officers") and SIC Counsel to execute and deliver the Agreement on behalf of the Company, with such changes thereto as the Authorized Officers may approve, such approval to be conclusively evidenced by the execution of the changed Agreement.

RESOLVED FURTHER, that the Authorized Officers and SIC Counsel are hereby authorized and directed to execute and deliver all other documents necessary to carry out the provisions of the Agreement.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to acknowledge on behalf of the Company that the Agreement and related documents fully set forth the agreement made between the Company and the USAO-WDVA, and that no additional promises or representations have been made to the Company by any officials of the USAO-WDVA in connection with the Agreement and related documents, other than those set forth in therein.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to make any payments required in connection with the Agreement.

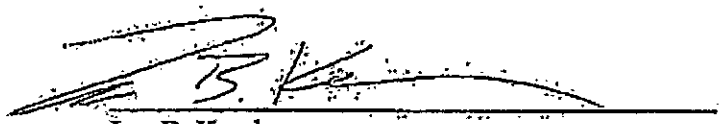
RESOLVED FURTHER, that each Authorized Officer is authorized and empowered, in the name and on behalf of the Company, to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such documents, certificates and instruments as they may deem appropriate in order to effectuate fully the purpose of the foregoing resolutions, and that any actions taken heretofore and hereafter to accomplish such purposes be, and they hereby are approved, ratified and confirmed.

CERTIFICATE OF SECRETARY

I, Les B. Korsh, herby certify that I am now, and at all times mentioned herein have been, the duly elected, qualified, and acting Secretary of **PATTERSON COMPANIES, INC.**, a Minnesota corporation (the "Corporation") and, as such officer, I have access to the records of the Company, which records of the Company reflect that:

1. RESOLUTIONS. Attached hereto as **Exhibit A** is a true and correct copy of resolutions that have been duly adopted by the Board of Directors of the Corporation on February 4, 2020, in compliance with, and not in contravention of, the articles of organization and bylaws of the Corporation; none of such resolutions have been repealed or modified in any respect, and all of such resolutions are in full force and effect on and as of the date hereof, and constitute the only action taken by the Board of Directors of the Corporation with respect to the subject matter hereof.

IN WITNESS WHEREOF, I duly executed this Certificate this 10th day of February, 2020.



Les B. Korsh
Secretary of Patterson Companies, Inc.

CORPORATE COMPLIANCE PROGRAM AGREEMENT

The following Patterson Companies, Inc. ("Patterson" or the "Company") Corporate Compliance Program Agreement ("Corporate Compliance Program Agreement") has been prepared pursuant to the Non-Prosecution Agreement dated this same date between Patterson and the United States Attorney's Office for the Western District of Virginia ("USAO-WDVA"). Compliance with all the terms and standards of the Corporate Compliance Program Agreement is a condition of the Non-Prosecution Agreement and shall continue for the Term of the Non-Prosecution Agreement ("Term").

Applicability and Purpose

1. This Corporate Compliance Program Agreement shall be incorporated into the Non-Prosecution Agreement by reference, and compliance with the terms of the Corporate Compliance Program Agreement will be a condition of the Non-Prosecution Agreement. The USAO-WDVA acknowledges that the Company has already implemented many of these terms as of the date of the resolution.

2. Any proposed modifications to this Corporate Compliance Program Agreement must be made in writing and signed by the Company and the designated signatory for the USAO-WDVA.

3. The Corporate Compliance Program Agreement does not in any way release the Company from complying with any applicable federal or state statutes and/or regulations, and does not limit the imposition of any sanctions, penalties or any other actions available under those state or federal statutes and regulations.

The Corporate Compliance Program Agreement

4. The Company and the USAO-WDVA agree that the Company shall undertake the following voluntary compliance measures. The Corporate Compliance Program Agreement does and will continue to contain policies and procedures designed to prevent, detect, and correct violations of federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* and FDA requirements. These policies and procedures shall be designed to ensure that the Company complies with, among other things, the FDCA's prohibitions against causing the introduction into interstate commerce of a drug that is misbranded or otherwise violates the FDCA.

5. *Compliance Officer.* Prior to the effective date of the Non-Prosecution Agreement, the Company established the position of Chief Compliance Officer ("Compliance Officer") and appointed an individual to serve in the role on an interim basis until such time as the Company can fill the role on a permanent basis. The Company shall maintain a Compliance Officer for the Term. During the Term, the Compliance Officer shall be authorized to oversee compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA, FDA requirements, and the requirements of the Corporate

Compliance Program Agreement. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures and practices designed to address compliance with the requirements set forth in this Corporate Compliance Program Agreement, with federal and state statutes and/or regulations concerning federal prescription drug distribution and FDA requirements. The Compliance Officer shall be a member of senior management of the Company, and shall report directly to the Chief Executive Officer of the Company. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Patterson Company's Board of Directors (hereinafter the "Board") or any authorized committee thereof, and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the Company as well as for any obligations created under the Corporate Compliance Program Agreement. Any non-compliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in the Corporate Compliance Program Agreement.

6. *Compliance Committee.* Prior to the effective date of the Non-Prosecution Agreement, the Company formed a Compliance Committee (hereafter "Compliance Committee") which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the compliance program. The Company shall maintain the Compliance Committee for the Term. The Compliance Committee shall include, at a minimum, the Compliance Officer and other members of senior management necessary to meet the requirements of the Corporate Compliance Program Agreement (e.g., senior executives of relevant departments, such as legal, regulatory, audit, human resources, and operations.) The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Company's risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

7. *Board of Directors Compliance Obligations.* Prior to the effective date of the Non-Prosecution Agreement, the Board formed a committee responsible for overseeing the Company's compliance program ("Board Committee"). The Company shall maintain the Board Committee for the Term. The Board Committee shall consist of no less than three (3) non-employee directors, including at least one (1) member of the Special Investigation Committee formed in response to the USAO-WDVA investigation for a minimum of twelve (12) months from the date of this Non-Prosecution Agreement. The Board Committee shall oversee the Company's compliance program, including at a minimum:

a. the Company's obligations under the Corporate Compliance Program Agreement

b. receiving updates about adoption and implementation of policies, procedures and practices designed to ensure compliance with the FDCA and FDA requirements, and

c. evaluating the effectiveness of the compliance program.

8. The Company shall continue to evaluate its current business to ensure that it is not currently receiving, distributing or handling misbranded or unapproved federal prescription drugs. Should the Company find it is receiving, distributing, or handling misbranded or unapproved federal prescription drugs, it shall take necessary steps to remediate any such conduct.

9. The Company shall continue to enhance its current training program to ensure that pertinent employees are familiar with the requirements of the FDCA and FDA requirements that could potentially apply to the Company's conduct.

10. The Company will put in place processes to (a) encourage employees to report suspected non-compliant activities by the Company, customers, or others and to (b) acknowledge or otherwise recognize employees for reporting confirmed non-compliant activity, as appropriate.

11. The Company will maintain, or as necessary establish, policies and procedures designed to ensure effective investigation of any complaints and/or potential deficiencies relating to compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA and FDA requirements. Such policies and procedures shall include, but are not limited to:

a. Training and providing guidance to all pertinent employees as to the requirement to report all information regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to the Compliance Officer, who in turn will review and determine whether corrective actions are required; and

b. Tracking allegations and remediation action plans regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to identify issues that may require corrective actions.

12. Within 60 days of the end of the Company's fiscal year, the Company's Chief Executive Officer will certify, under oath, to (a) the United States Attorney's Office during the Term and (b) the United States Probation Office for any period during which Animal Health International, Inc. is on probation, that (1) the Company fully complied with all federal laws and regulations pursuant to the Food, Drug, and Cosmetic Act ("FDCA") in the preceding year (or, in the instance of the first such certification, the period from execution of the Non-Prosecution Agreement through the end of the Company's fiscal year 2020), or in the alternative, (2) list all non-compliant activity and the steps taken by the company to remedy such non-compliant activity. Any listing of non-compliant activity shall not be considered by the government or the Probation Officer as a per se violation of the terms of probation or the Non-Prosecution Agreement. Instead, other factors will be taken into account, including whether the conduct violated policies the Company has adopted, whether the Company provided training addressing the subject matter of the reported conduct, whether it was an isolated or systemic occurrence, the Company's response, and any remedial actions taken after the Company learned of the conduct reported.

Non-Compliance

13. The Corporate Compliance Program Agreement is part of the Non-Prosecution Agreement and adherence to it will be an enforceable condition. Deliberate, intentional or knowing failure to comply with any part of the Corporate Compliance Program Agreement is a violation of the Non-Prosecution Agreement.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	Criminal No.
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before 7 days from the date of entry of a guilty plea, the defendant will voluntarily remit payment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant upon entry, and shall be made a part of the sentence and included in the judgment.

ENTERED THIS _____ DAY OF _____, 2020.

UNITED STATES DISTRICT JUDGE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached disclosure statement.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Animal Health International, Inc. (AHI) Disclosure Statement

a. On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement and a fine, and AHI paid $41,250.

b. On April 18, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Visalia, California Veterinary Food- Animal Drug Retailer license for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

c. On June 18, 2013, the Missouri Division of Professional Regulation issued a drug distributor license to Animal Health International, Inc.'s (AHI) Salina, Kansas facility. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

d. On August 30, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failing to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

e. On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no misconduct allegations beyond the conduct in Arkansas, which led to the non-disciplinary order and fine.

f. In March 2017, the Colorado Board of Pharmacy issued a letter of admonishment to Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license following allegations that it failed to timely submit an application detailing a change in designated representative. AHI was required to pay the costs associated with the Board's order.

g. On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

h. On July 20, 2020, Animal Health International, Inc. (AHI) in Boaz, AL entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an

administrative fine of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The facility in Boaz, Alabama facility, subject to discipline was AHI's Boaz, Alabama, wholesale drug distributor license.

i. On July 20, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas, wholesale drugdistributor license.

j. On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license. This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

k. On December 31, 2024, Animal Health International's Sioux Center, Iowa Wholesale Distributor facility entered into a Consent Order with the Illinois Department of Financial and Professional Regulation in which the facility's Illinois Wholesale Distributor license was reprimanded and fined $10,000. This action was based entirely on the Department of Justice case against AHI related to distribution activities predating current ownership. The Federal case was reported to State Boards during the investigation in July 2019 and again in February 2020 once the case was resolved.

l. On January 9, 2025, Animal Health International's ("AHI") Ceres, California Wholesale Distributor Facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 6 days in 2016, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

m. On January 9, 2025, Animal Health International's ("AHI") Roanoke, Texas Wholesale Distributor facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 165 days in 2014, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil

penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

n. On January 9, 2025, Animal Health International's ("AHI") Twin Falls, Idaho pharmacy entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 3 days in 2016, the pharmacy dispensed prescriptions into Oregon without an active pharmacy license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $3,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. Please note that the activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice case was reported to the state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. A copy of the Oregon Consent Order is enclosed. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054

Name: Elanco US Inc
Address: 2500 Innovation Way N City: Greenfield, State: IN Zip: 46140

Name: Boehringer Ingelheim
Address: 900 Ridgebury Rd City: Ridgefield State: CT Zip: 06877

Name: Huvepharma, Inc.
Address: 525 Westpark Drive, Suite 230 City: Peachtree City State: GA Zip: 30269

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Colorado
Parent Company (if any): Patterson Companies, Inc.
Corporation/Organization Name: Animal Health International, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner **owning more than 10% of the business** stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Animal Health International, Inc.

Facility Name

Kevin M Barry

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/6/25

Date

Board Use Only	Date Received: 5/19/25	Amount: $1000.00

Animal Health INTERNATIONAL
A Patterson Company

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515
State of Incorporation:	Minnesota

ANIMAL HEALTH INTERNATIONAL, INC. – Officer List

Corporate Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Phone Number:	970-353-2000
FEIN #:	84-0575063
State of Incorporation:	Colorado (5/16/1967)

Robert J. Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Steven M. Cunningham	**President**
Business Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Business Phone:	970-353-2000
Email:	Facilitylicensing@pattersoncompanies.com

Kevin M. Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Leslie B. Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Animal Health International, Inc.

is a

Corporation

formed or registered on 05/16/1967 under the law of Colorado, has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 19871193550 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 05/06/2025 that have been posted, and by documents delivered to this office electronically through 05/08/2025 @ 06:42:52 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 05/08/2025 @ 06:42:52 in accordance with applicable law. This certificate is assigned Confirmation Number 17280636 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

Division of Occupational and Professional Licenses
11341 W Chinden Blvd. Boise, ID 83720-0063
dopl.idaho.gov

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Idaho statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below.

ANIMAL HEALTH INTERNATIONAL

Wholesale Distributor License
W41110

Issued: 05-Nov-2024 Expires: 31-Dec-2025

Renewal Required

Russell Barron
Administrator

Printed: 05-Nov-2024

ANIMAL HEALTH INTERNATIONAL
Wholesale Distributor License
W41110

Expires: 31-Dec-2025

Russell Barron
Administrator

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/07/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400 CN102114303-Stnd-GAWU-24-25	**CONTACT NAME:** Marsh | U.S. Operations & Technology **PHONE (A/C, No, Ext):** 866-966-4664 **FAX (A/C, No):** **E-MAIL ADDRESS:** Minneapolis.CertRequest@marsh.com
INSURED Animal Health International, Inc. and Subsidiaries 822 7th Street, Suite 740 Greeley, CO 80631	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Starr Indemnity & Liability Company — 38318 **INSURER B :** Starr Specialty Insurance Company — 16109 **INSURER C :** **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CHI-010764188-03 **REVISION NUMBER:** 1

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	2,000,000 1,000,000 0 2,000,000 10,000,000 4,000,000
A A	**AUTOMOBILE LIABILITY** X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			1000198195241 (AOS) 1000198196241 (MA)	11/01/2024 11/01/2024	11/01/2025 11/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	3,000,000
A	X **UMBRELLA LIAB** X OCCUR **EXCESS LIAB** CLAIMS-MADE DED X RETENTION $ 25,000			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE AGGREGATE	$ $	5,000,000 5,000,000
B B B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y/N ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		100 0005556 (AOS) 100 0005558 (FL,MA) 100 0005559 (WI)	11/01/2024 11/01/2024 11/01/2024	11/01/2025 11/01/2025 11/01/2025	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance

CERTIFICATE HOLDER

Animal Health International, Inc.
and Subsidiaries
822 7th Street, Suite 740
Greeley, CO 80631

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K41888453

Application/License No. _____

Animal Health International, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 203 Fourth Avenue West, Twin Falls, ID 83301 (Address of Applicant/Principal), as PRINCIPAL, and Federal Insurance Company (Surety Company), a corporation organized under the laws of the state of Indiana (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 202B Halls Mill Road, Whitehouse Station, NJ 08889-3454 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 25, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25 day of February, 2025.

APPLICANT/PRINCIPAL
Animal Health International, Inc.

Authorized Representative

SURETY COMPANY
Federal Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness JoAnn R. Frank

Witness Brittany D. Stuckel

Countersigned by:

N/A
Nevada Resident Agent

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Cynthia L. Choren

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024.**

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22, 2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this February 25, 2025

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Animal Health International, Inc. MDEG License # (if applicable): _____

Physical Address: 203 4th Avenue West

City: Twin Falls State: ID Zip: 83301

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 970-656-1957 Website: https://www.animalhealthinternational.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Luke Middle: James Last: Theberge

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Twin Falls State: ID Zip: 83301

Telephone: [redacted] Email: luke.theberge@animalhealthinternational.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wendell High School		09/97-05/00	
Address	**City**	**State**	**Zip**
850 E Main Street	Wendell	ID	83355
Diploma/Degree obtained, if any			
Graduation Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
College of Southern Idaho		09/09-05/11	
Address	**City**	**State**	**Zip**
315 Falls Avenue	Twin Falls	ID	83301
Diploma/Degree obtained, if any			
Technical Certificate			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Technical Certificate	[redacted]	Twin Falls	ID	[redacted]
From - To (MM/YY – MM/YY)		City	State	
07/16 - 06/21		Jerome	ID	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Animal Health International, Inc.			From - To (MM/YY – MM/YY): 10/24 - Present
Business Address: 203 4th Avenue West	City: Twin Falls	State: ID	Zip: 83301
Phone: (970) 347-3273	Title: Operations Manager		Number of Employed Hours: 3040
Description of Duties: Plan and direct activities within the facility, staffing functions, inventory control, ensures regulatory compliance.			

Business Name: Animal Health International, Inc.			From - To (MM/YY – MM/YY): 10/24 - Present
Business Address: 203 4th Avenue West	City: Twin Falls	State: ID	Zip: 83301
Phone: (970) 347-3273	Title: Material Handler		Number of Employed Hours: 29,760
Description of Duties: Order filling, receiving, deliveries, customer service, training.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # N/A. **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

05/23/2025
Date

I, Luke Theberge, **certify that as the MDEG Administrator for**

Animal Health International, Inc.,

that I (initial that you have read and meet the following requirements):

1. LT Have a high school diploma or its equivalent;
2. LT Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. LT Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. LT Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Luke Theberge

Print Name (First, Last)

Luke Theberge

Original Signature (electronic, copies or stamps not accepted)

05/23/2025

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Animal Health International, Inc.

Pharmacy/Wholesaler License # (if applicable): WLS 6863

Physical Address: 203 4th Avenue West

City: Twin Falls State: ID Zip: 83301

Mailing Address (if different from physical address): 1031 Mendota Heights Road

City: Saint Paul State: MN Zip: 55120

Telephone: 970-656-1957 Website: www.animalhealthinternational.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Luke Middle: James Last: Theberge

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Twin Falls State: ID Zip: [redacted]

Telephone: [redacted] Email: luke.theberge@animalhealthinternational.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Wendell High School			09/97-05/00	
Address		City	State	Zip
850 E Main Street		Wendell	ID	83355
Diploma/Degree obtained, if any				
Graduation Diploma				
School Name			From - To (MM/YY – MM/YY)	
College of Southern Idaho			09/09-05/11	
Address		City	State	Zip
315 Falls Avenue		Twin Falls	ID	83301
Diploma/Degree obtained, if any				
Technical Certificate				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/21 - Present	[redacted]	Twin Falls	ID	[redacted]
07/16 - 06/21	[redacted]	Jerome	ID	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International, Inc.			10/24 - Present	
Business Address		**City**	**State**	**Zip**
203 4th Avenue West		Twin Falls	ID	83301
Phone	**Title**		**Number of Employed Hours**	
(970) 347-3273	Operations Manager		3040	
Description of Duties				
Plan and direct activities within the facility, staffing functions, inventory control, ensures regulatory compliance.				

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International, Inc.			06/10 - 10/24	
Business Address		**City**	**State**	**Zip**
203 4th Avenue West		Twin Falls	ID	83301
Phone	**Title**		**Number of Employed Hours**	
(970) 347-3273	Material Handler		29,760	
Description of Duties				
Order filling, receiving, deliveries, customer service, training.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Luke Theberge, **certify that as the designated representative for**

Animal Health International, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LT I am at least 21 years of age;
3. LT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Luke Theberge

Print Name (First, Last)

Luke Theberge

Original Signature (electronic, copies or stamps not accepted)

05/02/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Luke Theberge

Print Name (First, Last)

Luke Theberge

Original Signature (electronic, copies or stamps not accepted)

05/02/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Idaho, ss. County of Twin Falls

I, Luke Theberge, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Luke Theberge

Original Signature

05/02/2025

Date

Subscribed and Sworn to before me this 2 day of May 2025

Karolee Sorenson

Notary Public Signature

KAROLEE SORENSON NOTARY PUBLIC Comm. No. 47344 STATE OF IDAHO

(Seal)

Animal Health INTERNATIONAL
(A Patterson Company)

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Employee List

203 Fourth Avenue West
Twin Falls, ID 83301
License Number: WH03586

Legal Name
Adams, Cory M
Alarcon, Aldin
Alarcon, Douglas Daniel
Chandler, Dean Scott
Durfee, Michael D
Gray, Stepheni Raeann
Guard, Abram
Heinzman, Paul
Hutsell, Kane
Llamas, James Gregory
Morrison, Lance
Mourton, Russell Edward
Ortiz Vega, Silvia
Southern, Ethan
Stewart, Cheyenne Marie
Streithorst, Nathan Allen
Stroud, Brock
Theberge, Luke J
Vasquez, Mary Virginia
Westover, Troy Lynn
Whelan, Sean Pierce

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH 01639	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Animal Health International, Inc.

Physical Address: 8711 West Doe Avenue

City: Visalia State: CA Zip: 93291

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 559-635-3800 Website: https://www.animalhealthinternational.com/home

Name of Designated Representative (DR): ~~Carrie Eanes~~ Jaime Gonzalez

Licensing Company Email: facilitylicensing@pattersoncompa DR Email: Carrie.Eanes@animalhealthinternational.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class I & Class II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Universities/Research		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/14/2020		VA	Abingdon	Washington

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DVAW120CR00007-001	United States District Court, Wetern District of Virginia Abingdon

Reason/Charge
Violation of Title 21, US Code, Sections 221(1), 333(a)(1), and (352)(f)(l)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

FEB 14 2020

JULIA C. DUDLEY, CLERK
BY: DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20-cr-00007
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

PLEA AGREEMENT

ANIMAL HEALTH INTERNATIONAL, INC. (EIN: 84-0575063) ("AHI") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this Plea Agreement are as follows:

1. CHARGE TO WHICH AHI IS PLEADING GUILTY AND WAIVER OF RIGHTS

AHI will enter a plea of guilty to Count One of the Information charging it with violating Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) in the Western District of Virginia by introducing and delivering for introduction, and causing the introduction and delivery for introduction, into interstate commerce of veterinary prescription drugs that were misbranded.

AHI understands, and the parties agree and stipulate, the maximum statutory penalty is a fine of $14,855,856 (fourteen million eight hundred fifty-five thousand eight hundred fifty-six dollars), pursuant to Title 18, United States Code, Section 3571(d), and a period of probation of five (5) years, pursuant to Title 18, United States Code, Section 3561(c)(2). In addition, AHI's assets are subject to forfeiture. AHI understands fees may be imposed to pay for probation and there will be a $125 (one hundred twenty-five dollars) special assessment for Count One, pursuant to Title 18, United States Code, Section 3013(a)(1)(B)(iii). AHI's attorneys have informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before AHI could be found guilty as charged.

AHI admits and agrees that all of the statements and allegations in the Information are true and correct.

AHI acknowledges AHI has had all of its rights explained to it. AHI expressly recognizes that, as a corporation, AHI may have the following constitutional rights and by voluntarily pleading guilty AHI knowingly waives and gives up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses.

The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

AHI is pleading guilty as described above because AHI is in fact guilty and because AHI believes it is in its best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for its plea of guilty. AHI agrees all of the matters set forth in the Information are true and correct.

AHI understands the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree the 2018 version of the United States Sentencing Commission Guidelines Manual ("U.S.S.G.") is the appropriate Guidelines Manual to utilize. According to U.S.S.G. § 8C2.1, the organizational fine provisions do not apply to the count of conviction in this case, which is a misdemeanor under 21 U.S.C. § 333(a)(1).

The parties agree and stipulate:

a. the fine shall be $5,000,000 (five million dollars);
b. AHI shall pay $1,000,000 (one million dollars) to the Virginia Department of Health Professions ("DHP") in recognition of direct assistance provided by DHP to the United States during the investigation;
c. AHI shall forfeit $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars); and
d. AHI shall serve a term of probation of one to three years, as determined by the Court.

The Court will determine what terms and length of probation are appropriate and the parties will be free to argue for which terms and length of probation they believe are appropriate. AHI understands and agrees if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum may be imposed.

The parties agree if the Court refuses to accept this Plea Agreement with the agreed-upon sentence, AHI will be free to withdraw its guilty plea. In the event the Court refuses to accept this Plea Agreement and AHI withdraws its guilty plea within ten days of being notified of the Court's refusal, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410. Under these circumstances, the United States will move to dismiss the Information without prejudice and the United States may file any charges it could have filed in the absence of the plea agreement. AHI agrees to toll the statute of limitations between the date of the plea and the filing of any such charges.

3. FINANCIAL OBLIGATIONS

AHI agrees and understands any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept this Plea Agreement with the agreed-upon sentence and, as a result, AHI withdraws its guilty plea. If the Court rejects this Plea Agreement and AHI withdraws its guilty plea, the United States will return all money paid by AHI, without

interest, not more than thirty (30) days after AHI withdraws its guilty plea and notifies the United States Attorney's Office for the Western District of Virginia ("USAO"), in writing, it wishes to have the money returned.

In addition, in accordance with 18 U.S.C. § 3572(d)(3), AHI will notify the Court of any material change in AHI's economic circumstances that might affect AHI's ability to pay any amounts payable under this Plea Agreement.

a. Payments

Within 7 days of the entry of AHI's guilty plea, AHI will make the following disbursements:

(1) $125 (one hundred twenty-five dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the special assessment.

(2) $5,000,000 (five million dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the fine;

(3) $1,000,000 (one million dollars) to the Virginia Department of Health Professions. These funds must be remitted in the form of certified funds made payable to the "Treasurer of Virginia." The comment section of the check should note "DHP-Enforcement" in recognition of direct assistance provided to the United States during the investigation; and

(4) $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) made payable to the United States Marshals Service, as directed by the USAO as payment of a forfeiture money judgment.

b. Forfeiture

AHI agrees to the entry of a forfeiture money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency ("Forfeiture Money Judgment") pursuant to 21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c). AHI agrees that the value of the quantities of prescription drugs which were misbranded in violation of 21 U.S.C. § 331(a) totaled at least $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in United States currency.

AHI acknowledges and agrees the quantities of the drugs which were misbranded in violation of 21 U.S.C. § 331(a) cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, AHI agrees the government is entitled to forfeit as substitute assets any other assets of AHI up to the value of the now missing directly forfeitable assets, pursuant to

21 U.S.C. § 853(p). Payment in full of the Forfeiture Money Judgment shall satisfy any and all forfeiture obligations that AHI may have as a result of this guilty plea. AHI consents to the entry of an Order of Forfeiture pursuant to Rule 32.2 of the Federal Rules of Criminal Procedure forfeiting the above-referenced Forfeiture Money Judgment.

AHI agrees to sign any documentation necessary and to cooperate fully with the United States to accomplish the forfeiture. AHI agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of these funds to the United States.

AHI agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. AHI agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgement in any administrative or judicial proceeding.

AHI understands and agrees forfeiture of this property is proportionate to the degree and nature of the offense. AHI freely and knowingly waives any and all constitutional and statutory challenges to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including, but not limited to, that the forfeiture constitutes an excessive fine or punishment. AHI further understands and agrees this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty or other monetary judgment that may be imposed by the court.

c. Restitution

The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no restitution will be ordered.

4. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, AHI withdraws its plea, AHI agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny it committed the crime to which it has pled guilty; (4) comply with any reasonable request of the United States Attorney's Office and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement.

Neither AHI, nor its corporate parent (Patterson Companies, Inc. ["Patterson"]), will (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If Patterson or AHI makes a public statement that in whole or in part contradicts any such statement or provision, AHI may avoid being in violation of this Plea Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by Patterson's and AHI's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) Patterson or AHI websites. Notwithstanding the above, Patterson and AHI may avail themselves of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by

any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

5. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, AHI agrees AHI will not appeal the conviction or sentence imposed. AHI is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). AHI expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. AHI understands the United States expressly reserves all of its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, AHI may file a cross appeal of that same sentence. AHI agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this Plea Agreement.

6. INFORMATION ACCESS WAIVER

AHI agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a. However, if a third party obtains any records pertaining to the investigation or prosecution of this case under the Freedom of Information Act, AHI shall have the right to request copies of such disclosed records.

7. ADMISSIBILITY OF STATEMENTS

AHI understands any statements made on its behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against AHI by the United States in this or any other proceeding. AHI knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other proceeding. If, and only if, the Court rejects this Plea Agreement, and, as a result, AHI withdraws its plea, AHI will not be bound by the waivers set forth in this section of the Plea Agreement.

8. COMPLETION OF PROSECUTION

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), so long as AHI complies with all of its obligations under this Plea Agreement, the United States agrees, other than the charge in the attached Information, it shall not further criminally prosecute AHI for any additional federal criminal

charges or forfeiture action with respect to any offenses set forth in the Information or Non-Prosecution Agreement with Patterson (Attached as Attachment B).

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

9. LIMITATION OF PLEA AGREEMENT

This Plea Agreement is limited to the United States Department of Justice and does not bind any other federal, state, or local authority.

10. COMPLIANCE AND REMEDIAL MEASURES

AHI agrees to comply with the Corporate Compliance Program Agreement attached hereto as Attachment C.

11. COOPERATION

AHI acknowledges that its ongoing and future cooperation is important and a material fact underlying the United States' decision to enter into this Plea Agreement. AHI agrees to continue to cooperate fully and actively with the United States regarding any matter, including, but not limited to, matters involving (a) current and former AHI personnel, and (b) other entities who operate in the same commercial segment as AHI and/or Patterson during the Term of the Non-Prosecution Agreement with Patterson, provided however that any cooperation in an ongoing investigation or prosecution shall continue until such investigation or prosecution is concluded.

Nothing in this Plea Agreement shall be construed to require Patterson or AHI to waive any attorney-client privilege or work-product protection.

12. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THIS PLEA AGREEMENT

AHI understands if: (1) AHI attempts to withdraw its plea (in the absence of the Court refusing to accept this Plea Agreement); (2) AHI fails to comply with any provision of this Plea Agreement; (3) AHI's conviction is set aside, for any reason; and/or (4) AHI fails to execute all required paperwork prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement titled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, AHI will still be bound by its obligations under this Plea Agreement. AHI hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of this Plea Agreement. AHI hereby waives any statute of limitations argument as to any such charges.

13. EFFECTIVE REPRESENTATION

AHI has discussed the terms of this Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, AHI has no dissatisfaction or complaint with its attorneys' representation. AHI agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint AHI may have with its attorneys' representation.

14. EFFECT OF AHI'S SIGNATURE

AHI understands its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. AHI understands the United States has not accepted AHI's offer until the authorized representative of the United States has signed this Plea Agreement.

15. GENERAL UNDERSTANDINGS

AHI understands a presentence investigation will be conducted and sentencing recommendations independent of the USAO will be made by the presentence preparer.

AHI understands the United States and AHI retain the right, notwithstanding any provision in this Plea Agreement, to inform the probation office and the Court of all facts, to address the Court with respect to the nature and seriousness of the offense and the offender, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, and to respond to any statements made to the Court.

AHI willingly stipulates there is a sufficient factual basis for the Court to accept the plea.

AHI understands this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

AHI has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. AHI understands its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. AHI understands AHI will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing, the Non-Prosecution Agreement with Patterson (attached as Attachment B), the Corporate Compliance Program Agreement (attached as Attachment C), and the Agreed Order of Forfeiture (attached as Attachment D) are the complete and only agreements between the United States and AHI concerning resolution of this matter. In addition, AHI has no objection to the filing of the Information.

The agreements and documents listed in this section set forth the entire understanding between the parties and constitute the complete agreement between the United States Attorney for the Western District of Virginia and AHI and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and AHI. AHI consents to public disclosure of all of the agreements and other documents referenced in this section.

AHI has consulted with its attorneys and fully understands its rights. AHI has read this Plea Agreement and carefully reviewed every part of it with its attorneys. AHI understands this Plea Agreement and AHI voluntarily agrees to it. Being aware of all of the possible consequences of its plea, AHI has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer ("Officer") below.

The Officer, by signing below, hereby certifies to the following:

(1) The Officer is fully authorized to enter into this Plea Agreement on behalf of AHI;

(2) The Officer has read the entire Plea Agreement and documents referenced herein and discussed them with AHI's Board of Directors;

(3) AHI understands all the terms of this Plea Agreement and those terms correctly reflect the results of plea negotiations;

(4) AHI is fully satisfied with AHI's attorneys' representation during all phases of this case;

(5) AHI is freely and voluntarily pleading guilty in this case;

(6) AHI is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea; and

(7) AHI understands it is waiving its right to appeal the judgment and conviction in this case.

AHI acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Officer. A copy of a certification by AHI's Board of Directors authorizing the Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of AHI is attached as Attachment A.

Date: 2/13/2020

Authorized Corporate Officer
AHI

Counsel has fully explained to the Board of Directors of AHI the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the Sentencing Guidelines; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and documents referenced herein with the client, through its Officer. AHI understands the terms and conditions of this Plea Agreement, and AHI's decision to enter into this Plea Agreement is knowing and voluntary. AHI's execution of and entry into the Plea Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

CLERKS OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED
2/11/2020
JULIA C. DUDLEY, CLERK
BY: LOTTIE LUNSFORD
DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No. 1:20CR00007**
v.	)	
	)	**Violations: 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)**
ANIMAL HEALTH INTERNATIONAL, INC.	)	

INFORMATION

INTRODUCTION

1. Defendant Animal Health International, Inc. ("AHI") is a Colorado corporation with its principal place of business in Colorado. AHI is comprised of two legacy organizations, Lextron, Inc. ("Lextron") and Walco International, Inc. ("Walco"). In June 2011, Lextron acquired all outstanding stock of the parent company of Walco and changed its name to AHI. Walco continued operations as a subsidiary of AHI until December 2011 when Animal Health Holdings, Inc. and each of its wholly-owned subsidiaries, including Walco, were merged with and into AHI and no longer had separate corporate existences. AHI, and its predecessor entities, dispense, distribute and sell, among other products, veterinary prescription drugs to customers in the production animal industry across the United States. Specifically, AHI obtains prescription drugs for production animals from manufacturers for further distribution to veterinarians, farms, feedlots, and other distribution facilities.

2. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulates the distribution and labeling of all drugs, including animal drugs, shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C § 301, *et seq.* ("FDCA"). Veterinary prescription drugs are drugs intended for use by animals that, because of their toxicity or other potentiality for harmful

effect, or the method of their use, or the collateral measures necessary for their use, are not safe for animal use except under the professional supervision of a licensed veterinarian. 21 U.S.C. § 353(f)(1)(A).

3. Under the FDCA, a drug is misbranded if, among other things, its labeling does not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). Adequate directions for use is defined as "directions under which the *layman* can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5 (emphasis added). Prescription veterinary drugs by definition can only safely be used under the professional supervision of a licensed veterinarian and therefore they must qualify for an exemption to this requirement in order to move in interstate commerce. These exemptions are set out in 21 C.F.R. Part 201, Subpart D ("Exemptions from Adequate Directions for Use").

4. Veterinary prescription drugs are exempt from the requirement that their labeling contain adequate directions for use if they meet all enumerated conditions, including that they be distributed through a closed supply chain in which every entity that possesses a prescription drug must have legal authorization to do so. *See* 21 C.F.R. § 201.105 (a)(1) (a veterinary prescription drug must be in the possession of: a person lawfully engaged in the manufacture, transportation, storage or wholesale distribution of drugs; a retail pharmacy or other person authorized under state law to dispense veterinary prescription drugs; or a licensed veterinarian for use in the course of his professional practice). Moreover, the veterinary prescription drug must be dispensed in accordance with 21 U.S.C. § 353(f), i.e., pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian's professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105 (a)(2).

5. The FDCA's restrictions on veterinary prescription drugs are not primarily to protect animals from the potential harms of prescription drugs, but are to protect the human food supply from unsafe drug residues in the edible tissues of animals sold for slaughter. Common causes of illegal residues include: (1) exceeding the drug's approved dose; (2) using a shorter withdrawal period than what is stated on the drug's label (if a higher than approved dose is given, the labeled withdrawal period may not be enough to allow the drug in the edible tissues to deplete to levels that are at or below the tolerance); (3) using a drug in an extra-label manner (for indications and dosages outside the approved labeling) without a veterinarian's involvement; (4) giving a drug not approved for that species; and (5) using an unapproved route of administration. Drug residues in the nation's drug supply are concerning because: (1) they may contribute to antibiotic resistance in the human population, rendering human drugs less effective to treat human disease and contributing to the mutations of "superbugs"; and (2) they may cause allergic reactions in individuals with certain drug allergies.

6. Certain legacy customers of AHI, namely Marlin Webb and Billy K. Groce, were not properly licensed to receive, transport, store, distribute, or dispense veterinary prescription drugs in the Commonwealth of Virginia from January 2012 through April 2015.

7. Webb was the store manager of a cooperative in Hillsville, Virginia. The cooperative was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Webb operated a side business from the cooperative's location in which he illegally circumvented the FDA's regulation of veterinary prescription drugs by illegally obtaining from Billy K. Groce and AHI and reselling veterinary prescription drugs using unlawful prescriptions written by a veterinarian who was licensed in Tennessee but who was not properly licensed to

practice veterinary medicine in Virginia and who did not have a veterinarian-patient relationship with the animals in question. That veterinarian died in 2015.

8. Groce was neither a licensed wholesaler, a licensed pharmacy, nor a licensed veterinary clinic. Groce operated an unlicensed veterinary prescription drug distribution business. Groce worked with the same veterinarian as did Webb.

9. Webb and Groce obtained veterinary prescription drugs from AHI in interstate commerce without valid prescriptions, and, on many occasions, with no prescription at all.

10. On April 29, 2015, the government executed search warrants at locations in Virginia and Tennessee associated with Groce and Webb. In 2016 and 2017, respectively, Groce and Webb pled guilty to illegally conspiring to defraud the FDA by obtaining and distributing veterinary prescription drugs from July 2009 through April 29, 2015 in a manner that circumvented the FDA's regulation of veterinary prescription drugs.

11. Groce and Webb were legacy customers of, among others, Lextron and Walco, and continued to be customers after the companies merged to form AHI in 2012 until May 2015. Neither Lextron, Walco, nor AHI performed adequate customer diligence processes, nor adequately trained sales representatives to raise questions regarding Groce's, Webb's or the veterinarian's activities in Virginia and Tennessee. For example, Groce operated a business that stored and distributed veterinary prescription drugs out of a storefront called "Goin' Postal" and his personal residence. Neither of those locations resembled a veterinarian establishment and should have raised questions for sales representatives who personally visited them. After learning of search warrants executed on each of the customers' locations, AHI took some steps to block the sale of veterinary prescription drugs to these customers on May 4, 2015.

12. Furthermore, between January 2012 and May 2015, AHI did not maintain the proper licenses to ship from its Memphis, Tennessee, facility into Virginia or from its Wolcott, Indiana, facility into Virginia or Tennessee, but, despite this deficiency, shipped products from those locations to Virginia and Tennessee.

13. All veterinary prescription drugs distributed by AHI to Groce and Webb were misbranded because, neither recipient was licensed to possess or distribute veterinary prescription drugs, and the prescribing veterinarian was not properly licensed to practice veterinary medicine in Virginia and consequently none of the drugs he caused to be dispensed were prescribed pursuant to lawful orders.

14. From the illegal shipments to and on behalf of Groce and Webb, AHI received $7,427,928 (seven million four hundred twenty-seven thousand nine hundred twenty-eight dollars) and made a profit of $558,309 (five hundred fifty-eight thousand three hundred nine dollars) by unlawfully distributing veterinary prescription drugs to or on behalf of Groce and Webb.

15. From 2012 through on or about 2018, AHI caused additional misbranded veterinary prescription drug shipments to be made throughout the United States by distributing veterinary prescription drugs from its wholesale locations directly to end users in states where such shipments were illegal and, in some instances, by shipping veterinary prescription drugs to locations in states in which AHI did not have legal authority to make such shipments. AHI obtained not less than $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) from such shipments. Its profits from such shipments were a small percentage of the amount received.

COUNT ONE

Introduction of Misbranded Drugs into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)

The United States Attorney charges that:

16. The Information is realleged and incorporated by reference into this Count.

17. From about January 2012 to April 2015, in the Western District of Virginia, Animal Health Incorporated ("AHI") introduced and delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce, of veterinary prescription drugs that were misbranded in that the drugs' labeling did not bear adequate directions for the use of such drugs.

18. The offense conduct included, but was not limited to, the following:

a. AHI distributed veterinary prescription drugs directly to Billy K. Groce and Marlin Webb, notwithstanding that neither Groce nor Webb was legally authorized to possess or distribute the drugs; and

b. AHI distributed veterinary prescription drugs to customers of Billy K. Groce and Marlin Webb without a lawful prescription having been issued for those drugs.

19. Since these veterinary prescription drugs were not lawfully distributed or prescribed, they failed to qualify for the exemption from the requirement that they bear labeling containing adequate directions for lay use. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1).

NOTICE OF FORFEITURE

20. Upon conviction of the offense alleged in this Information, AHI shall forfeit to the United States veterinary prescription drugs that were misbranded or became misbranded as a result of AHI's conduct, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

21. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of $46,802,203 pursuant to 21 U.S.C. § 853(p).

DATED: February 11, 2020

Randy Ramseyer
for THOMAS T. CULLEN
United States Attorney

NON-PROSECUTION AGREEMENT

1. The United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") and Patterson Companies, Inc. ("Patterson"), and any and all current and former affiliated entities including, but not limited to, Animal Health International, Inc. ("AHI") (collectively referred to as the "Company") enter into this Non-Prosecution Agreement ("Agreement") to resolve the investigation by the USAO-WDVA of the Company related to possible violations of federal laws relating to the licensing, dispensing, distribution, or sale of veterinary prescription drugs.

2. This Agreement, in conjunction with the Plea Agreement with AHI ("Plea Agreement"), resolves all of the Company's potential federal criminal liability for the offenses covered herein and in the Plea Agreement.

3. The USAO-WDVA enters into this Agreement based on the individual circumstances presented by this case including:

a. Patterson's cooperation with the USAO-WDVA investigation since June 2018, and AHI's subsequent cooperation under the direction of Patterson, as well as the Company's continued cooperation under the direction of the Special Investigation Committee of the Board of Directors of Patterson ("SIC") which was formed in April 2019. Since 2018, the Company has conducted a thorough and robust internal investigation; proactively brought information to the USAO-WDVA's attention, remediated noncompliant activity and implemented control enhancements, including certain licensing, dispensing, distribution and related sales practices company-wide; made factual presentations to the USAO-WDVA; timely and fully produced all requested documents; entered into agreements tolling relevant statutes of limitations; and collected, analyzed, and organized voluminous data and information for the USAO-WDVA.

b. Patterson's voluntary disclosure to the USAO-WDVA of non-compliant licensing, dispensing, distribution, and sales at AHI and Patterson beyond AHI's conduct set forth in the Information and Plea Agreement, and its timely efforts to remediate non-compliant activity and enhance controls and processes to mitigate against future reoccurrence. The additional non-compliant activity involved wholesale distribution of veterinary prescription drugs: (i) without verifying the continued validity of all practitioners' licenses in the receiving state; (ii) without verifying that an alternate location requested by the customer was authorized by state law to receive veterinary prescription drugs; (iii) without verifying that veterinarians licensed in Virginia were also associated with a veterinary establishment registered with the Virginia Board of Veterinary Medicine, (iv) without valid licensure to ship to the state to which the drugs were shipped, and/or (v) to end users in states where drop shipments by wholesalers to end users is not allowed. The additional non-compliant activity was due to prior weaknesses and inconsistencies among AHI and Patterson regulatory functions and processes, as well as system challenges presented by the Company's enterprise resource planning implementation. The Company has since taken extensive

proactive steps to enhance its regulatory function, capabilities and support to guide the business and other control functions on regulatory compliance matters. It has also enhanced its regulatory system controls to address the issues disclosed in the investigation and to verify that veterinary prescription drugs are shipped from facilities with required state licenses and to customers and locations authorized by state law to receive veterinary prescription drugs. Consistent with its approach to the USAO-WDVA, Patterson also disclosed the pending federal investigation to state regulators in all 50 states and continues to engage with state regulators, as appropriate, on matters related to the USAO-WDVA investigation.

c. The Company's enhanced regulatory compliance processes and commitment to implement a compliance program that meets the minimum elements set forth in Attachment C to the Plea Agreement ("Corporate Compliance Program Agreement").

d. The Company's agreement to comply with the terms of the Agreement and Plea Agreement.

e. AHI's admission to and the Company's agreement with the facts and allegations set forth in the Plea Agreement.

f. Although the investigation did not involve controlled substances, the Company's recognition that diversion of controlled substances, including drugs of the type that are prescribed and dispensed by veterinarians, such as buprenorphine and hydrocodone, should be a concern of all distributors and dispensers of those drugs and the Company's ongoing commitment to be proactive in deterring diversion and identifying and notifying authorities of suspicious ordering.

4. The Company agrees it will not take any tax deduction or seek or accept directly or indirectly reimbursement or indemnification from any source for any payments made pursuant to the Plea Agreement.

5. No money paid by the Company will be returned, and the Company expressly agrees to release any and all claims it may have to the money. The Company will not file any claim or otherwise contest the payment of money set forth in this Plea Agreement, and it will not assist anyone in asserting a claim to the money.

6. Nothing in this Agreement or any related documents is an admission by the United States that the amounts paid by the Company are the maximum amounts that could be recovered from the Company in the absence of an accepted plea agreement. If the Company does not comply with all of its obligations under this Agreement, the United States is not precluded from arguing or presenting evidence that the total amount to be paid by the Company should be higher.

7. The Company's obligations under this Agreement shall have a term of 42 months from the date on which the Agreement is executed (the "Term").

8. During the Term, the Company will fully cooperate with the USAO-WDVA.

9. During the Term, the Company shall undertake and abide by the terms of the Corporate Compliance Program Agreement in Attachment C to the Plea Agreement.

10. If the Company complies with all of the terms of this Agreement and the Plea Agreement, the USAO-WDVA will not prosecute the Company for any criminal conduct occurring prior to the entering of this agreement concerning:

a. The subject matter of the Information to which AHI is pleading guilty; or

b. Facts disclosed by the Company to the USAO prior to entering this agreement related to the Company's licensing, dispensing, distribution, or sale of veterinary prescription drugs.

11. However, if the USAO-WDVA, in its sole discretion, determines the Company (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement or (b) violated any provision of this Agreement, then the USAO-WDVA will not be bound to their agreement not to prosecute the Company for the matters covered in paragraph 10. Should the USAO-WDVA determine that the Company has violated any provision of this Agreement, the USAO-WDVA shall provide prompt written notice to the Company addressed to its General Counsel, and to its outside counsel, Amy Conway-Hatcher, Baker Botts LLP, 1299 Pennsylvania Avenue NW, Washington, DC, or to any successor the Company may designate, of the alleged violation and provide the Company with a 45 (forty-five) day period from the date of receipt of notice in which to make a presentation to the USAO-WDVA to demonstrate that no violation occurred, or, to the extent applicable, that the violation should not result in adverse action, including because the violation has been cured by the Company. In the event of a violation, the Company will not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other rule or law, that any statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible in any proceeding brought by the Department of Justice. If, as a result of a violation, the United States charges the Company, the Company hereby waives any statute of limitations defense for any offense not time-barred by the applicable statute of limitations on the date this Agreement is signed, including time protected as the result of existing agreements to toll the applicable statute of limitations.

12. The Company will not, through its present or future directors, officers, employees, agents, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If the Company makes a public statement that in whole or in part contradicts any such statement or provision, the Company may avoid being in violation of this Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by the Company's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) the Company's

websites. Notwithstanding the above, the Company may avail itself of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

13. The terms of this Agreement bind the USAO-WDVA and other divisions of the Department of Justice (collectively referred to as the "United States"), except that they do not bind the Tax Division of the Department of Justice or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities. The USAO-WDVA will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

14. The Company and the United States may disclose this Agreement and any other documents used to effectuate the objectives of this Agreement to the public.

15. Nothing in this Agreement resolves, in any way, any liability of any individual.

16. This Agreement and the Plea Agreement set forth all the terms of the agreement between the Company and the USAO-WDVA. No amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the USAO-WDVA, the attorneys for the Company, and a duly authorized representative of the Company.

The Company acknowledges its acceptance of this Agreement by the signature of its counsel and Officer. A copy of a resolution by the Company's Board of Directors authorizing the Officer to execute this Agreement and all other documents to resolve this matter on behalf of the Company is attached as Addendum 1.

Date: February 12, 2020

Mark S. Walchirk
Authorized Corporate Officer
Patterson Companies, Inc.

Counsel has fully explained to the Board of Directors of the Company the facts and circumstances of the investigation and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein with the client, through its Officer. The Company understands the terms and conditions of this Agreement, and the Company's decision to enter into this Agreement is knowing and voluntary. The Company's execution of and entry into this Agreement is done with Counsel's consent.

Date: 2/13/2020

Amy Conway-Hatcher, Esquire
Kyle Clark, Esquire
Baker Botts L.L.P.
Counsel for AHI and Patterson Companies, Inc.

Date: 2-13-2020

Randy Ramseyer
Assistant United States Attorney

EXHIBIT A

RESOLUTION OF THE
BOARD OF DIRECTORS
OF
PATTERSON COMPANIES, INC.

NON-PROSECUTION AGREEMENT

WHEREAS, the Company, together with outside counsel reporting to the Special Investigation Committee of the Board ("SIC Counsel"), has been in discussions with the U.S. Attorney's Office for the Western District of Virginia ("USAO-WDVA") to resolve its investigation into Animal Health International, Inc. by, among other things, having the Company enter into a Non-Prosecution Agreement (the "Agreement");

WHEREAS, SIC Counsel has advised the Board of the terms of the Agreement and the consequences of entering into the Agreement; and

WHEREAS, the Board has determined that it is in the best interest of the Company to enter into the Agreement.

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby approves the Agreement and authorizes any executive officer of the Company (the "Authorized Officers") and SIC Counsel to execute and deliver the Agreement on behalf of the Company, with such changes thereto as the Authorized Officers may approve, such approval to be conclusively evidenced by the execution of the changed Agreement.

RESOLVED FURTHER, that the Authorized Officers and SIC Counsel are hereby authorized and directed to execute and deliver all other documents necessary to carry out the provisions of the Agreement.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to acknowledge on behalf of the Company that the Agreement and related documents fully set forth the agreement made between the Company and the USAO-WDVA, and that no additional promises or representations have been made to the Company by any officials of the USAO-WDVA in connection with the Agreement and related documents, other than those set forth in therein.

RESOLVED FURTHER, that each Authorized Officer is hereby authorized and directed to make any payments required in connection with the Agreement.

RESOLVED FURTHER, that each Authorized Officer is authorized and empowered, in the name and on behalf of the Company, to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such documents, certificates and instruments as they may deem appropriate in order to effectuate fully the purpose of the foregoing resolutions, and that any actions taken heretofore and hereafter to accomplish such purposes be, and they hereby are approved, ratified and confirmed.

CERTIFICATE OF SECRETARY

I, Les B. Korsh, herby certify that I am now, and at all times mentioned herein have been, the duly elected, qualified, and acting Secretary of **PATTERSON COMPANIES, INC.**, a Minnesota corporation (the "Corporation") and, as such officer, I have access to the records of the Company, which records of the Company reflect that:

1. RESOLUTIONS. Attached hereto as **Exhibit A** is a true and correct copy of resolutions that have been duly adopted by the Board of Directors of the Corporation on February 4, 2020, in compliance with, and not in contravention of, the articles of organization and bylaws of the Corporation; none of such resolutions have been repealed or modified in any respect, and all of such resolutions are in full force and effect on and as of the date hereof, and constitute the only action taken by the Board of Directors of the Corporation with respect to the subject matter hereof.

IN WITNESS WHEREOF, I duly executed this Certificate this 10th day of February, 2020.

Les B. Korsh
Secretary of Patterson Companies, Inc.

CORPORATE COMPLIANCE PROGRAM AGREEMENT

The following Patterson Companies, Inc. ("Patterson" or the "Company") Corporate Compliance Program Agreement ("Corporate Compliance Program Agreement") has been prepared pursuant to the Non-Prosecution Agreement dated this same date between Patterson and the United States Attorney's Office for the Western District of Virginia ("USAO-WDVA"). Compliance with all the terms and standards of the Corporate Compliance Program Agreement is a condition of the Non-Prosecution Agreement and shall continue for the Term of the Non-Prosecution Agreement ("Term").

Applicability and Purpose

1. This Corporate Compliance Program Agreement shall be incorporated into the Non-Prosecution Agreement by reference, and compliance with the terms of the Corporate Compliance Program Agreement will be a condition of the Non-Prosecution Agreement. The USAO-WDVA acknowledges that the Company has already implemented many of these terms as of the date of the resolution.

2. Any proposed modifications to this Corporate Compliance Program Agreement must be made in writing and signed by the Company and the designated signatory for the USAO-WDVA.

3. The Corporate Compliance Program Agreement does not in any way release the Company from complying with any applicable federal or state statutes and/or regulations, and does not limit the imposition of any sanctions, penalties or any other actions available under those state or federal statutes and regulations.

The Corporate Compliance Program Agreement

4. The Company and the USAO-WDVA agree that the Company shall undertake the following voluntary compliance measures. The Corporate Compliance Program Agreement does and will continue to contain policies and procedures designed to prevent, detect, and correct violations of federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* and FDA requirements. These policies and procedures shall be designed to ensure that the Company complies with, among other things, the FDCA's prohibitions against causing the introduction into interstate commerce of a drug that is misbranded or otherwise violates the FDCA.

5. *Compliance Officer.* Prior to the effective date of the Non-Prosecution Agreement, the Company established the position of Chief Compliance Officer ("Compliance Officer") and appointed an individual to serve in the role on an interim basis until such time as the Company can fill the role on a permanent basis. The Company shall maintain a Compliance Officer for the Term. During the Term, the Compliance Officer shall be authorized to oversee compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA, FDA requirements, and the requirements of the Corporate

Compliance Program Agreement. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures and practices designed to address compliance with the requirements set forth in this Corporate Compliance Program Agreement, with federal and state statutes and/or regulations concerning federal prescription drug distribution and FDA requirements. The Compliance Officer shall be a member of senior management of the Company, and shall report directly to the Chief Executive Officer of the Company. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Patterson Company's Board of Directors (hereinafter the "Board") or any authorized committee thereof, and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the Company as well as for any obligations created under the Corporate Compliance Program Agreement. Any non-compliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in the Corporate Compliance Program Agreement.

6. *Compliance Committee.* Prior to the effective date of the Non-Prosecution Agreement, the Company formed a Compliance Committee (hereafter "Compliance Committee") which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the compliance program. The Company shall maintain the Compliance Committee for the Term. The Compliance Committee shall include, at a minimum, the Compliance Officer and other members of senior management necessary to meet the requirements of the Corporate Compliance Program Agreement (e.g., senior executives of relevant departments, such as legal, regulatory, audit, human resources, and operations.) The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Company's risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

7. *Board of Directors Compliance Obligations.* Prior to the effective date of the Non-Prosecution Agreement, the Board formed a committee responsible for overseeing the Company's compliance program ("Board Committee"). The Company shall maintain the Board Committee for the Term. The Board Committee shall consist of no less than three (3) non-employee directors, including at least one (1) member of the Special Investigation Committee formed in response to the USAO-WDVA investigation for a minimum of twelve (12) months from the date of this Non-Prosecution Agreement. The Board Committee shall oversee the Company's compliance program, including at a minimum:

a. the Company's obligations under the Corporate Compliance Program Agreement

b. receiving updates about adoption and implementation of policies, procedures and practices designed to ensure compliance with the FDCA and FDA requirements, and

c. evaluating the effectiveness of the compliance program.

8. The Company shall continue to evaluate its current business to ensure that it is not currently receiving, distributing or handling misbranded or unapproved federal prescription drugs. Should the Company find it is receiving, distributing, or handling misbranded or unapproved federal prescription drugs, it shall take necessary steps to remediate any such conduct.

9. The Company shall continue to enhance its current training program to ensure that pertinent employees are familiar with the requirements of the FDCA and FDA requirements that could potentially apply to the Company's conduct.

10. The Company will put in place processes to (a) encourage employees to report suspected non-compliant activities by the Company, customers, or others and to (b) acknowledge or otherwise recognize employees for reporting confirmed non-compliant activity, as appropriate.

11. The Company will maintain, or as necessary establish, policies and procedures designed to ensure effective investigation of any complaints and/or potential deficiencies relating to compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA and FDA requirements. Such policies and procedures shall include, but are not limited to:

a. Training and providing guidance to all pertinent employees as to the requirement to report all information regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to the Compliance Officer, who in turn will review and determine whether corrective actions are required; and

b. Tracking allegations and remediation action plans regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to identify issues that may require corrective actions.

12. Within 60 days of the end of the Company's fiscal year, the Company's Chief Executive Officer will certify, under oath, to (a) the United States Attorney's Office during the Term and (b) the United States Probation Office for any period during which Animal Health International, Inc. is on probation, that (1) the Company fully complied with all federal laws and regulations pursuant to the Food, Drug, and Cosmetic Act ("FDCA") in the preceding year (or, in the instance of the first such certification, the period from execution of the Non-Prosecution Agreement through the end of the Company's fiscal year 2020), or in the alternative, (2) list all non-compliant activity and the steps taken by the company to remedy such non-compliant activity. Any listing of non-compliant activity shall not be considered by the government or the Probation Officer as a per se violation of the terms of probation or the Non-Prosecution Agreement. Instead, other factors will be taken into account, including whether the conduct violated policies the Company has adopted, whether the Company provided training addressing the subject matter of the reported conduct, whether it was an isolated or systemic occurrence, the Company's response, and any remedial actions taken after the Company learned of the conduct reported.

Non-Compliance

13. The Corporate Compliance Program Agreement is part of the Non-Prosecution Agreement and adherence to it will be an enforceable condition. Deliberate, intentional or knowing failure to comply with any part of the Corporate Compliance Program Agreement is a violation of the Non-Prosecution Agreement.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	Criminal No.
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before 7 days from the date of entry of a guilty plea, the defendant will voluntarily remit payment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant upon entry, and shall be made a part of the sentence and included in the judgment.

ENTERED THIS _____ DAY OF _____, 2020.

_____
UNITED STATES DISTRICT JUDGE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Please see attached disclosure statement.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Animal Health International, Inc. (AHI) Disclosure Statement

a. On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement and a fine, and AHI paid $41,250.

b. On April 18, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Visalia, California Veterinary Food- Animal Drug Retailer license for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

c. On June 18, 2013, the Missouri Division of Professional Regulation issued a drug distributor license to Animal Health International, Inc.'s (AHI) Salina, Kansas facility. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

d. On August 30, 2013, the California Board of Pharmacy cited Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failing to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

e. On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no misconduct allegations beyond the conduct in Arkansas, which led to the non-disciplinary order and fine.

f. In March 2017, the Colorado Board of Pharmacy issued a letter of admonishment to Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license following allegations that it failed to timely submit an application detailing a change in designated representative. AHI was required to pay the costs associated with the Board's order.

g. On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce misbranded veterinary prescription drugs to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

h. On July 20, 2020, Animal Health International, Inc. (AHI) in Boaz, AL entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an

administrative fine of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The facility in Boaz, Alabama facility, subject to discipline was AHI's Boaz, Alabama, wholesale drug distributor license.

i. On July 20, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy, in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas, wholesale drugdistributor license.

j. On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license. This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

k. On December 31, 2024, Animal Health International's Sioux Center, Iowa Wholesale Distributor facility entered into a Consent Order with the Illinois Department of Financial and Professional Regulation in which the facility's Illinois Wholesale Distributor license was reprimanded and fined $10,000. This action was based entirely on the Department of Justice case against AHI related to distribution activities predating current ownership. The Federal case was reported to State Boards during the investigation in July 2019 and again in February 2020 once the case was resolved.

l. On January 9, 2025, Animal Health International's ("AHI") Ceres, California Wholesale Distributor Facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 6 days in 2016, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

m. On January 9, 2025, Animal Health International's ("AHI") Roanoke, Texas Wholesale Distributor facility entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 165 days in 2014, the facility distributed prescription drugs into Oregon without an active wholesale distributor license. Pursuant to the Consent Order, AHI is required to pay a civil

penalty in the amount of $10,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. The activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice cases were reported to the appropriate state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

n. On January 9, 2025, Animal Health International's ("AHI") Twin Falls, Idaho pharmacy entered into a Consent Order with the Oregon Board of Pharmacy to resolve allegations that for approximately 3 days in 2016, the pharmacy dispensed prescriptions into Oregon without an active pharmacy license. Pursuant to the Consent Order, AHI is required to pay a civil penalty in the amount of $3,000. However, payment of the civil penalty is stayed for one year on the condition that AHI does not commit any similar violations. Please note that the activity at issue occurred shortly after AHI's current owners acquired the business in June 2015 and was included within the scope of the conduct considered by the Department of Justice in its case against AHI related to distribution activities that predated the current ownership. The Department of Justice case was reported to the state boards during the investigation in July 2019 and again in February 2020 once the case was resolved. A copy of the Oregon Consent Order is enclosed. Note also that the new owners addressed all licensure issues of the previous owner, and the licensure gaps were fully addressed by the end of 2016.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054

Name: Elanco US Inc
Address: 2500 Innovation Way N City: Greenfield, State: IN Zip: 46140

Name: Boehringer Ingelheim
Address: 900 Ridgebury Rd City: Ridgefield State: CT Zip: 06877

Name: Huvepharma, Inc.
Address: 525 Westpark Drive, Suite 230 City: Peachtree City State: GA Zip: 30269

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Colorado
Parent Company (if any): Patterson Companies, Inc.
Corporation/Organization Name: Animal Health International, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

	Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
	• **List of all Officers and Directors.**	✓	✓		
	• **List the top four corporation shareholders and their percent ownership.**	✓			
	• **List of all corporation shareholders and their percent ownership.**		✓		
	• **List of all partners and their percent ownership.**			✓	
	• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
	• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
N/A	• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
N/A	• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
	• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
	• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
	• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
N/A	• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
N/A	• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
	ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
	• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
	• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Animal Health International, Inc.

Facility Name

Kevin M Barry

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/6/25

Date

Board Use Only	Date Received: 5/9/25	Amount: $1000CC

Animal Health INTERNATIONAL
A Patterson Company

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515
State of Incorporation:	Minnesota

ANIMAL HEALTH INTERNATIONAL, INC. – Officer List

Corporate Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Phone Number:	970-353-2000
FEIN #:	84-0575063
State of Incorporation:	Colorado (5/16/1967)

Robert J. Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com
Steven M. Cunningham	**President**
Business Address:	2915 Rocky Mountain Avenue, Suite 400 Loveland, CO 80538
Business Phone:	970-353-2000
Email:	Facilitylicensing@pattersoncompanies.com
Kevin M. Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com
Leslie B. Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Effective 4/22/2025

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Animal Health International, Inc.

is a

Corporation

formed or registered on 05/16/1967 under the law of Colorado, has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 19871193550 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 05/06/2025 that have been posted, and by documents delivered to this office electronically through 05/08/2025 @ 06:42:52 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 05/08/2025 @ 06:42:52 in accordance with applicable law. This certificate is assigned Confirmation Number 17280636 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."



Renewal License

Wholesale Drug Permit

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

License No. WLS 6861
Receipt No. 00197164

Valid Until: 4/1/2026

ANIMAL HEALTH INTERNATIONAL INC
8711 WEST DOE AVE
VISALIA, CA 93291

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/07/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400 CN102114303-Stnd-GAWU-24-25	**CONTACT NAME:** Marsh	U.S. Operations & Technology
	PHONE (A/C, No, Ext): 866-966-4664	**FAX (A/C, No):**
	E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com	
	INSURER(S) AFFORDING COVERAGE	**NAIC #**
	INSURER A : Starr Indemnity & Liability Company	38318
INSURED Animal Health International, Inc. and Subsidiaries 822 7th Street, Suite 740 Greeley, CO 80631	**INSURER B :** Starr Specialty Insurance Company	16109
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** CHI-010764188-03 **REVISION NUMBER:** 1

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE	$ 2,000,000
	[ ] CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 0
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 10,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$ 4,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY			1000198195241 (AOS)	11/01/2024	11/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$ 3,000,000
A	X ANY AUTO			1000198196241 (MA)	11/01/2024	11/01/2025	BODILY INJURY (Per person)	$
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB [X] OCCUR			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE	$ 5,000,000
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$ 5,000,000
	DED [X] RETENTION $ 25,000							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			100 0005556 (AOS)	11/01/2024	11/01/2025	X PER STATUTE [ ] OTH-ER	
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [N]	N/A		100 0005558 (FL,MA)	11/01/2024	11/01/2025	E.L. EACH ACCIDENT	$ 1,000,000
B	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			100 0005559 (WI)	11/01/2024	11/01/2025	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits	See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance

CERTIFICATE HOLDER

Animal Health International, Inc.
and Subsidiaries
822 7th Street, Suite 740
Greeley, CO 80631

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. KO9121055

Application/License No. _____

Animal Health International (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 8711 West Doe Avenue, Visalia, CA 93291 (Address of Applicant/Principal), as PRINCIPAL, and Westchester Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 436 Walnut Street, Philadelphia, PA 19106 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 1, 2015 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this **24th** day of **August**, 20**15**.

APPLICANT/PRINCIPAL
Animal Health International

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY
Westchester Fire Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

ACKNOWLEDGMENT BY SURETY

STATE OF Missouri }
City of St. Louis } ss.

On this 24th day of August, 2015, before me personally appeared Cynthia L. Choren, known to me to be the Attorney-in-Fact of Westchester Fire Insurance Company, the corporation that executed the within instrument, and acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

Nancy L. Johnson
Notary Public in the State of Missouri
County of St. Charles

My Commission Expires: July 18, 2016

(Seal)

NANCY L. JOHNSON
Notary Public, Notary Seal
State of Missouri
St. Charles County
Commission # 12369080
My Commission Expires July 18, 2016

S-0230/GEEF 2/98

Power of Attorney

WESTCHESTER FIRE INSURANCE COMPANY

Know all men by these presents: That **WESTCHESTER FIRE INSURANCE COMPANY,** a corporation of the Commonwealth of Pennsylvania pursuant to the following Resolution, adopted by the Board of Directors of the said Company on December 11, 2006, to wit:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such persons written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and Vice Presidents of the Company in hereby authorized, for and on behalf of the Company, to delegate in writing any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested.

Does hereby nominate, constitute and appoint Cynthia L Choren, Debra C Schneider, Heidi A Notheisen, JoAnn R Frank, Karen L Roider, Pamela A Beelman, Sandra L Ham, all of the City of SAINT LOUIS, Missouri, each individually if there be more than one named, its true and lawful attorney-in-fact, to make, execute, seal and deliver on its behalf, and as its act and deed any and all bonds, undertakings, recognizances, contracts and other writings in the nature thereof in penalties not exceeding Thirty million dollars & zero cents ($30,000,000.00) and the execution of such writings in pursuance of these presents shall be as binding upon said Company, as fully and amply as if they had been duly executed and acknowledged by the regularly elected officers of the Company at its principal office,

IN WITNESS WHEREOF, the said Stephen M. Haney, Vice-President, has hereunto subscribed his name and affixed the Corporate seal of the said **WESTCHESTER FIRE INSURANCE COMPANY** this 7 day of April 2015.

WESTCHESTER FIRE INSURANCE COMPANY

Stephen M. Haney, Vice President

COMMONWEALTH OF PENNSYLVANIA
COUNTY OF PHILADELPHIA ss.

On this 7 day of April, AD. 2015 before me, a Notary Public of the Commonwealth of Pennsylvania in and for the County of Philadelphia came Stephen M. Haney ,Vice-President of the **WESTCHESTER FIRE INSURANCE COMPANY** to me personally known to be the individual and officer who executed the preceding instrument, and he acknowledged that he executed the same, and that the seal affixed to the preceding instrument is the corporate seal of said Company; that the said corporate seal and his signature were duly affixed by the authority and direction of the said corporation, and that Resolution, adopted by the Board of Directors of said Company, referred to in the preceding instrument, is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Philadelphia the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
KAREN E. BRANDT, Notary Public
City of Philadelphia, Phila. County
My Commission Expires Sept. 26, 2018

Notary Public

I, the undersigned Assistant Secretary of the **WESTCHESTER FIRE INSURANCE COMPANY,** do hereby certify that the original POWER OF ATTORNEY, of which the foregoing is a substantially true and correct copy, is in full force and effect.

In witness whereof, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of the Corporation, this 24th day of August, 2015.

William L. Kelly, Assistant Secretary

THIS POWER OF ATTORNEY MAY NOT BE USED TO EXECUTE ANY BOND WITH AN INCEPTION DATE AFTER April 07, 2017.

DocuGard #04546 contains a security pantograph, blue background, heat-sensitive ink, coin-reactive watermark, and microtext printing on border.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Animal Health International, Inc. MDEG License # (if applicable):

Physical Address: 8711 West Doe Avenue

City: Visalia State: CA Zip: 93291

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 651-686-1957 Website: https://www.animalhealthinternational.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Jaime Middle: Last: Gonzalez

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Dinuba State: Zip:

Telephone: [redacted] Email: jaime.gonzalez@pattersoncompanies.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Dinuba High School		08/1994 - 05/1998	
Address	**City**	**State**	**Zip**
340 E. Kern Street	Dinuba	CA	93618
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2016 - current	[redacted]	Dinuba	CA	[redacted]
01/2014 - 01/2019		Dinuba	CA	

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Animal Health International, Inc.			08/2018 - current
Business Address	**City**	**State**	**Zip**
8711 W. Doe Avenue	Dinuba	CA	93291
Phone	**Title**	**Number of Employed Hours**	
970-584-5314	Operations Manager	16,360	

Description of Duties

Mange daily functions of receiving, inventory and production. Manage daily operations of fleet deliveries, work with sales to service end users (customers). Ensure a secure functioning building, obey local and state laws.

Business Name			From - To (MM/YY – MM/YY)
Patterson Companies, Inc.			01/1999 - 08/2018
Business Address	**City**	**State**	**Zip**
800 Monte Vista Drive	Dinuba	CA	93618
Phone	**Title**	**Number of Employed Hours**	
559-595-1450	Employee/Supervisor/Department Manager	50,000 +	

Description of Duties

Managed and supervised daily functions of receiving and put-away. Ensuring product is being received properly by company policy, state and local laws.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6-4-2025
Date

I, Jaime Gonzalez, **certify that as the MDEG Administrator for**

Animal Health International, Inc.

that I (initial that you have read and meet the following requirements):

1. X Have a high school diploma or its equivalent;
2. X Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. X Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. X Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jaime Gonzalez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-4-25

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Animal Health International, Inc.
Pharmacy/Wholesaler License # (if applicable) WLS 6863
Physical Address 8711 W. Doe Ave
City Visalia State CA Zip 93291
Mailing Address (if different from physical address) 1031 Mendota Heights Road
City Saint Paul State MN Zip 55120
Telephone 970-656-1957 Website www.animalhealthinternational.com
Licensing Company Email facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First Jaime Middle _____ Last Gonzalez
Alias(es, nicknames, name changes, etc.) n/a
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X
Mailing Address [redacted]
City Dinuba State CA Zip [redacted]
Telephon[redacted] Email jaime.gonzalez@pattersoncompanies.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
DInuba High School		08/1994 05-1998	
Address	City	State	Zip
340 E. Kern St.	Dinuba	CA	93618
Diploma/Degree obtained, if any			
Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2016- current	[redacted]	Dinuba	CA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
01/2014-01/2019	[redacted]	Dinuba	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Animal Health International			08/2018-current	
Business Address		**City**	**State**	**Zip**
8711 W. Doe Ave		Dinuba	CA	93291
Phone	**Title**		**Number of Employed Hours**	
970-584-5314	Operation Manager		16,360	
Description of Duties				
Manage daily functions of receiving, inventory and production. Manage daily operations of fleet deliveries, work with sales to service end users (customers). Ensure a secure functioning building, obey local and state laws.				

Business Name			From - To (MM/YY – MM/YY)	
Patterson Companies			01-1999- 08-2018	
Business Address		**City**	**State**	**Zip**
800 Monte Vista Dr.		Dinuba	CA	93618
Phone	**Title**		**Number of Employed Hours**	
559-595-1450	Employee/Supervisor/Department Manager		50,000 +	
Description of Duties				
Managed and supervised daily functions of receiving and put-away. Ensuring product is being received properly by company policy, state and local laws.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

05/14/2025
Date

I, Jaime Gonzalez, **certify that as the designated representative for**

Animal Health International,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JG I am at least 21 years of age;
3. JG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jaime Gonzalez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-14-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jaime Gonzalez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-14-2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Tulare

I, Jaime Gonzalez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5-14-2025

Date

Subscribed and Sworn to before me this 14 day of May, 2025.

Notary Public Signature

NELDA GONZALEZ
Notary Public - California
Tulare County
Commission # 2408899
My Comm. Expires Jun 23, 2026

(Seal)

Animal Health INTERNATIONAL
2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Employee List

8711 West Doe Avenue
Visalia, CA 93291
License Number: WH01639

Legal Name

Aiello, Cassidy Ann
Aviles, Daniel
Avilez, Daniel
Baugh, Tina M
Bernardo, Lucio C
Bradley, Tania
Burgos, Angela M
Draper, Stefanie Lee
Eanes, Carrie D
Ekk, Darrin
Eller, Kenneth J
Elliott, Tracy Michelle
Espinola, Gracie Maria
Evangelo, Joseph
Gibbons, William
Gonzalez, Jaime
Grettner, Cherise K
Hernandez, Andrew
Hernandez, Clemente
Jacobsen, Rosalyn K
Jensen, Melissa
Johnson, Ashley Nicole
Jones, Dawn Nichole
Jones, Janet Lee
Julian, Esmeralda
Julian, Luis Miguel
Julian, Noe
Kinderknecht, Melinda
Macedo, Jacob
Macedo, James Matthew
Martinez, Richard A
Miner, John A
Montalvo, David
Moore, Julia Marie
Morales, Felipe
Mortensen, Ron
Mosqueda, Serena Deborah
Negus, Colton Charles
Nicholson, Hailey
Ornelas Gutierrez, Jesus Eduardo
Price, Margie
Quezada, Herlindo
Ragsdale, Jeffrey W
Ramos, Alejandro
Rising, Mary Bernadette
Rose, Albert Charles
Russell, Karen M
Saechao, Jim W
Saesee, Aikham
Saesee, Aishone
Salazar, Javier
Sanchez Espinoza, Brandon Jaimes
Sandoval, Jorge
Shockley Jr, Joseph Henry
Sosa, Leslie Eileen
Soto, Michael Jesse
Spate, Deborah A
Stacey, Suzanna Michelle
Swarm, Kevin M
Syvrud, Laurie Lee
Teixeira, Angela Marie
Vasquez, Adrian
Villa, Daniel
Villalobos Velasco, Alejandro
White, Joshua A
Williams, Johnny R
Wilson, Thomas F
Yoder, Walter O'Dell

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH [redacted] WRC	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: API Expeditors LLC

Physical Address: 40 SW 13th Street, #201

City: Miami State: Florida Zip: 33130

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 786-574-7400 Website: None

Name of Designated Representative (DR): Michael Robert Corcelli

Licensing Company Email: mr@apiexpeditors.com DR Email: mr@apiexpeditors.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Active Pharmaceutical Ingredients	☐ Warehouse
■ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/8/25

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Sinopep-Allsino Bio Pharmaceutical Co., Ltd.

Address: No.1378 Wenyi West Road, Room 1201 City: Lianyungang, China State: _____ Zip: _____

Name: Derivados Quimicos, SAU

Address: Strada Rivoltana KM 6/7 City: Rodano (MI) Italy Internati State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): N/A

Corporation/Organization Name: API Expeditors LLC

Mailing Address: 40 SW 13th Street, #201

City: Miami State: Florida Zip: 33130

Telephone: 786-574-7400 Email: mr@apiexpeditors.com

Contact Person Name: Michael Robert Corcelli

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

API Expeditors LLC

Facility Name

Michael Robert Corcelli

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

5-8-2025

Date

Board Use Only	Date Received: 5/22/25	Amount: $1000.00 297985343327

List of Individuals Associated with the Applicant

Michael Alexander Corcelli

Role: Employee, Agent

Title: Shipping & Warehouse Manager

Type: Employee

O. L. Smith

Role: Compliance Officer

Title: Compliance Officer

Type: Employee

Sharon Roberts

Role: Compliance Consultant

Title: Compliance Consultant

Type: Independent Contractor

Frier Levitt Law Firm

Role: Legal Counsel

Title: Regulatory and Compliance Attorneys

Type: Independent Contractor / Legal Advisor

API Expeditors LLC

Top Four Corporation Shareholders and Their Percent Ownership

Date: May 08, 2025

Name	Ownership Percentage	Title
Michael Corcelli	100%	Managing Member

State of Florida

Department of State

I certify from the records of this office that API EXPEDITORS LLC, is a Delaware limited liability company authorized to transact business in the State of Florida, qualified on January 31, 2025.

The document number of this limited liability company is M25000002214.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, and its status is active.

I further certify that said limited liability company has not filed a Certificate of Withdrawal.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourteenth day of February, 2025

Cord Byrd
Secretary of State

CR2E022 (01-11)

State of Florida

Department of State

I certify the attached is a true and correct copy of the application by API EXPEDITORS LLC, a Delaware limited liability company, authorized to transact business within the state of Florida on January 31, 2025 , as shown by the records of this office.

The document number of this limited liability company is M25000002214.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourteenth day of February, 2025

Cord Byrd
Secretary of State

CR2E022 (01-11)

Delaware

The First State

I, CHARUNI P. SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "API EXPEDITORS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-NINTH DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "API EXPEDITORS LLC" WAS FORMED ON THE THIRD DAY OF OCTOBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

C. P. Sanchez

Charuni P. Sanchez, Secretary of State

Authentication: 202806982

Date: 01-29-25

5387204 8300

SR# 20250297337

You may verify this certificate online at corp.delaware.gov/authver.shtml

Ron DeSantis, Governor

Melanie S. Griffin, Secretary

Florida dbpr

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS

THE Prescription Drug Wholesale Distributor HEREIN HAS REGISTERED UNDER THE PROVISIONS OF CHAPTER 499, FLORIDA STATUTES

API EXPEDITORS LLC

40 SW 13TH ST
SUITE 201
MIAMI FL 33130

LICENSE NUMBER: 2220335

EXPIRATION DATE: MAY 31, 2027

Always verify licenses online at MyFloridaLicense.com

ISSUED: 05/05/2025

Do not alter this document in any form.

This is your license. It is unlawful for anyone other than the licensee to use this document.

Ron DeSantis, Governor

Melanie S. Griffin, Secretary

Florida dbpr

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS

THE Certified Designated Representative HEREIN HAS REGISTERED UNDER THE PROVISIONS OF CHAPTER 499, FLORIDA STATUTES

CORCELLI, MICHAEL ROBERT

40 SW 13TH ST
MIAMI FL 33130

LICENSE NUMBER: 8812803

EXPIRATION DATE: DOES NOT EXPIRE

Always verify licenses online at MyFloridaLicense.com

ISSUED: 04/23/2025

Do not alter this document in any form.

This is your license. It is unlawful for anyone other than the licensee to use this document.

1670

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PR2761224

Application/License No. _____

API EXPEDITORS LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 40 SW 13TH ST STE 201 MIAMI, FL 33130 (Address of Applicant/Principal), as PRINCIPAL, and PLATTE RIVER INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of NEBRASKA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is PO BOX 5900 MADISON, WI 53705 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on MAY 6, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 13TH day of MAY, 2025.

APPLICANT/PRINCIPAL

COMPANY

Morelli
Authorized Representative

SURETY

PLATTE RIVER INSURANCE COMPANY CORPORATE SEAL NEBRASKA

Surety Company's Representative

ERIC FAUERBACH, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Not Needed
Nevada Resident Agent

Posted February 20, 2020

PLATTE RIVER INSURANCE COMPANY
POWER OF ATTORNEY

PR2761224
Bond Number

KNOW ALL MEN BY THESE PRESENTS, That the **PLATTE RIVER INSURANCE COMPANY,** a corporation of the State of Nebraska, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

Eric Fauerbach
Name of Individual

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

$ 100,000.00 for PR2761224 on behalf of API Expeditors LLC
Bond Amount — Bond Number — Principal

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **PLATTE RIVER INSURANCE COMPANY** at a meeting duly called and held on the 8th day of January, 2002.

"**RESOLVED,** that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, hy any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority herehy given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the **PLATTE RIVER INSURANCE COMPANY** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 1st day of January, 2020.

Attest:

Ryan J. Byrnes
Senior Vice President,
Chief Financial Officer and Treasurer

Suzanne M. Broadbent
Assistant Secretary

PLATTE RIVER INSURANCE COMPANY CORPORATE SEAL NEBRASKA

PLATTE RIVER INSURANCE COMPANY

John L. Sennott, Jr.
Chief Executive Officer and President

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

On the 1st day of January, 2020 before me personally came John L. Sennott, Jr., to me known, who being by me duly sworn, did depose and say: that he resides in the County of Hartford, State of Connecticut; that he is Chief Executive Officer and President of **PLATTE RIVER INSURANCE COMPANY,** the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

DAVID J. REGELE NOTARY PUBLIC STATE OF WISCONSIN

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

I, the undersigned, duly elected to the office stated below, now the incumbent in **PLATTE RIVER INSURANCE COMPANY,** a Nebraska Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 13th day of May, 20 25.

PLATTE RIVER INSURANCE COMPANY CORPORATE SEAL NEBRASKA

Andrew B. Diaz-Matos
Senior Vice President, General Counsel and Secretary

THIS DOCUMENT HAS BEEN GENERATED FOR A SPECIFIC BOND. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450.

PR-ePOA (Rev. 01-2020)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler API Expeditors LLC

Pharmacy/Wholesaler License # (if applicable) 2220335

Physical Address 40 SW 13th Street, #201

City Miami State Florida Zip 33130

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 786-574-7400 Website _____

Licensing Company Email mr@apiexpeditors.com

Section 2: Personal Information

First Michael Middle Robert Last Corcelli

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 40 SW 13th Street, 201

City Miami State Fl Zip [redacted]

Telephone [redacted] Email mr@apiexpeditors.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Miami		09/94 to 05/98	
Address	City	State	Zip
	Coral Gables	Florida	33124
Diploma/Degree obtained, if any			
Business Administration			

School Name		From - To (MM/YY – MM/YY)	
LaSalle Academy		09/90 to 06/94	
Address	City	State	Zip
612 Academy Ave	Providence	RI	02908
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			
04-08 to 3/2104-08 to 3/21			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04-21 to present	[redacted]	Miami	Fl	[redacted]
From - To (MM/YY – MM/YY)		City	State	
04-08 to 3/21		Miami	Fl	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
API Expeditors LLC			10/24 to present	
Business Address		**City**	**State**	**Zip**
40 SW 13th Street, #201		Miami	Florida	33130
Phone	**Title**		**Number of Employed Hours**	
786-574-7400	Certified Designated Representative		2,000	
Description of Duties				
As Managing Member, I oversee daily wholesale operations, including API procurement, storage, distribution, regulatory compliance, and recordkeeping. I ensure all activities meet state and federal requirements and supervise staff.				

Business Name			From - To (MM/YY – MM/YY)	
Stonegate Pharamcy			01/2022 to 12/2024	
Business Address		**City**	**State**	**Zip**
2501 W William Connor Dr, #203		Austin	Tx	78745
Phone	**Title**		**Number of Employed Hours**	
(512)707-2300	API Procurement Specialist		7,000	
Description of Duties				
While at Stonegate Pharmacy, I held a managerial role focused on API procurement, distribution logistics, and regulatory compliance. I was responsible for overseeing prescription drug handling, storage, and record keeping.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

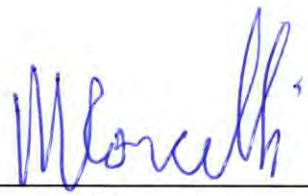
Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1, 3 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
07/24/2024	11/06/2024	RI	Newport	Newport County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-2024-01156		DISTRICT COURT		
Reason/Charge				
Disorderly Conduct				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
State of Rhode Island				
Name of Business/Industry/Entity				

Provide explanation below:

On November 6, 2024, a charge of disorderly conduct in the State of Rhode Island was resolved through a nolo contendere plea and placed on file pursuant to Rhode Island General Laws § 12-10-12(a). This was a non-domestic matter. After meeting all statutory conditions, the record was formally expunged under § 12-10-12(c) by court order. The expungement order sealed the record from public view, and there is no resulting conviction.



Original Signature (electronic, copies or stamps not accepted)

5/8/25

Date

DISTRICT COURT

ORDER FOR EXPUNGEMENT – FILING OF COMPLAINTS

State of Rhode Island v. **Defendant** Michael Corcelli	**Case Number** 21-2024-01156	**Case Type** Misdemeanor
	Bureau of Criminal Identification Number RI-@11863218	
Murray Judicial Complex 2nd Division District Court 45 Washington Square Newport RI 02840	**Date of Birth** [redacted]	
	Law Enforcement Arrest Number 24-19187-B-AR; 24-19187-B-AR; 24-19187-B-AR	
	Law Enforcement Agency Newport Police Department	

Charge	Disposition	Disposition Date
Simple Assault And/or Battery	Dismissed By Prosecution	11/06/2024
Simple Assault And/or Battery	Dismissed By Prosecution	11/06/2024
Disorderly Conduct	Plea Of Nolo Contendere	11/06/2024

All statutory conditions having been met, the above-mentioned charge(s) which was placed on file in accordance with G.L. 1956 § 12-10-12(a) is hereby ordered expunged pursuant to:

☒ G.L. 1956 § 12-10-12(c) Non-Domestic Abuse Filing

☐ G.L. 1956 § 12-10-12(d) Domestic Abuse Filing

All records relating to the above-referenced case shall be expunged and all index and other references to it removed from public inspection, and notice of the expungement shall be provided to the appropriate parties pursuant to the standards set forth in G.L. 1956 § 12-1.3-3(c).

Entered as an Order of the court on 5/7/2025.	**BY ORDER OF:** /s/ Maureen Palazzo Clerk

Copy 1 – Attorney General Copy 2 – Police Department Copy 3 – District Court Copy 4 – Defendant/Attorney

APPLICATION BY FOREIGN LIMITED LIABILITY COMPANY FOR AUTHORIZATION TO TRANSACT BUSINESS IN FLORIDA

IN COMPLIANCE WITH SECTION 605.0902, FLORIDA STATUTES, THE FOLLOWING IS SUBMITTED TO REGISTER A FOREIGN LIMITED LIABILITY COMPANY TO TRANSACT BUSINESS IN THE STATE OF FLORIDA:

1. API Expeditors LLC
(Name of Foreign Limited Liability Company; must include "Limited Liability Company," "L.L.C.," or "LLC.")

(If name unavailable, enter alternate name adopted for the purpose of transacting business in Florida. The alternate name must include "Limited Liability Company," "L.L.C," or "LLC.")

2. Delaware
(Jurisdiction under the law of which foreign limited liability company is organized)

3. _____
(FEI number, if applicable)

4. n/a
(Date first transacted business in Florida, if prior to registration.)
(See sections 605.0904 & 605.0905, F.S. to determine penalty liability)

5. 40 SW 13th Street
STE 201
Miami, Florida 33130
(Street Address of Principal Office)

6. 40 SW 13th Street
STE 201
Miami, Florida 33130
(Mailing Address)

7. Name and street address of Florida registered agent: (P.O. Box NOT acceptable)

Name: Michael Corcelli

Office Address: 40 SW 13th Street, STE 201

Miami (City), Florida 33130 (Zip code)

Registered agent's acceptance:

Having been named as registered agent and to accept service of process for the above stated limited liability company at the place designated in this application, I hereby accept the appointment as registered agent and agree to act in this capacity. I further agree to comply with the provisions of all statutes relative to the proper and complete performance of my duties, and I am familiar with and accept the obligations of my position as registered agent.

M Corcelli

(Registered agent's signature)

8. For initial indexing purposes, list names, title or capacity and addresses of the primary members/managers or persons authorized to manage [up to six (6) total]:

Title or Capacity:	Name and Address:	Title or Capacity:	Name and Address:
☐Manager	Name: Michael Corcelli	☐Manager	Name:
■Member	Address: 40 SW 13th Street	☐Member	Address:
☐Authorized	STE 201	☐Authorized	
Person	Miami, Florida 33130	Person	
☐Other	☐Other	☐Other	☐Other
☐Manager	Name:	☐Manager	Name:
☐Member	Address:	☐Member	Address:
☐Authorized		☐Authorized	
Person		Person	
☐Other	☐Other	☐Other	☐Other
☐Manager	Name:	☐Manager	Name:
☐Member	Address:	☐Member	Address:
☐Authorized		☐Authorized	
Person		Person	
☐Other	☐Other	☐Other	☐Other

Important Notice: Use an attachment to report more than six (6). The attachment will be imaged for reporting purposes only. Non-indexed individuals may be added to the index when filing your Florida Department of State Annual Report form.

9. Attached is a certificate of existence, no more than 90 days old, duly authenticated by the official having custody of records in the jurisdiction under the law of which it is organized. (If the certificate is in a foreign language, a translation of the certificate under oath of the translator must be submitted)

10. This document is executed in accordance with section 605.0203 (1) (b), Florida Statutes. I am aware that any false information submitted in a document to the Department of State constitutes a third degree felony as provided for in s.817.155, F.S.

Mcorcelli

Signature of an authorized person

Michael Corcelli

Typed or printed name of signee

API Expeditors LLC

Thank you for your order!

Your payment has been processed. Your order confirmation number is **#239H9CB3**

Your Registered Agent Details

Nevada

Registered Agents Inc
732 S 6TH ST STE R
LAS VEGAS, NV 89101

Start Date: 5/
End Date: 5/

Authorized individual on behalf of the Registered Agent: David Roberts
Special Instructions: When appointing us as your registered agent within the SilverFlume filing system, select "entity," ent full name, choose the exact match from the options below, then double check to make sure the name you selected is a "commercial" registered agent. Signed consent forms can be found in your Forms Library.

Whether you are trying to form a new company, change your existing Registered Agent, or registering your company to do bus in another state, we can help!

Terms of Service

I, Michael Corcelli, **certify that as the designated representative for**

API Expeditors LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MRC I am at least 21 years of age;
3. MRC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MRC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MRC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MRC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MRC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael Corcelli

Print Name (First, Last)

MCorcelli

Original Signature (electronic, copies or stamps not accepted)

5-8-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Corcelli

Print Name (First, Last)

MCorcelli

Original Signature (electronic, copies or stamps not accepted)

5-8-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami-Dade

I, Michael Corcelli, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

MCorcelli

Original Signature

5/8/2025

Date

Subscribed and Sworn to before me this 8 day of May, 2025

Flavia Rocha Agostini

Notary Public Signature

NOTARY PUBLIC STATE OF FLORIDA

FLAVIA ROCHA AGOSTINI
Commission # HH 620183
Expires February 3, 2029

The foregoing instrument was acknowledged before me this 8th day of May, 2025 by Michael R Corcelli on behalf of said firm. He has produced his Florida Driver's License as identification. (seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site API Expeditors LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 2220335

Physical Address 40 SW 13th Street, #201

City Miami State _____ Zip _____

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 786-574-7400 Website none

Licensing Company Email mr@apiexpeditors.com

Section 2: Personal Information

First Michael Middle Robert Last Corcelli

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 40 SW 13th Street, #201

City Miami State Fl Zip 33130

Telephone [redacted] Email mr@apiexpeditors..com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Miami		09/1990 - 06-1994	
Address	City	State	Zip
	Coral Gables	Florida	33124
Diploma/Degree obtained, if any			
Business Administration			

School Name		From - To (MM/YY – MM/YY)	
LaSalle Academy			
Address	City	State	Zip
612 Academy Ave	Providence	RI	02908
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04-21 to present	[redacted]	Miami	Fl	[redacted]
From - To (MM/YY – MM/YY)		City	State	
04-08 to 3/21		Miami	Fl	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
API Expeditors LLC			10/24 to present
Business Address	**City**	**State**	**Zip**
40 SW 13th Street, #201	Miami	Florida	33130
Phone	**Title**		
786-574-7400	Certified Designated Representative		

Description of Duties

As Managing Member, I oversee daily wholesale operations, including API procurement, storage, distribution, regulatory compliance, and recordkeeping. I ensure all activities meet state and federal requirements and supervise staff.

Business Name			From - To (MM/YY – MM/YY)
Stonegate Pharmacy			01/2022 to 12/2024
Business Address	**City**	**State**	**Zip**
2501 W William Connor Dr, #203	Austin	Tx	78745
Phone	**Title**		
(512)707-2300	Procurement Specialist		

Description of Duties

While at Stonegate Pharmacy, I held a managerial role focused on API procurement, distribution logistics, and regulatory compliance. I was responsible for overseeing prescription drug handling, storage, and record keeping.

Business Name			From - To (MM/YY – MM/YY)
Alexander Luxory Lenders LLC			02//14 to 12/21
Business Address	**City**	**State**	**Zip**
40 SW 13th Street	Miami	Floirda	33130
Phone	**Title**		
7864027548	Managing Member		

Description of Duties

Lend money to small businesses.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

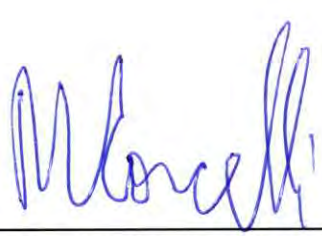
Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1, 3 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
07/24/2024	11/06/2024	RI	Newport	Newport County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-2024-01156		DISTRICT COURT		
Reason/Charge				
Disorderly Conduct				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
State of Rhode Island				
Name of Business/Industry/Entity				

Provide explanation below:

On November 6, 2024, a charge of disorderly conduct in the State of Rhode Island was resolved through a nolo contendere plea and placed on file pursuant to Rhode Island General Laws § 12-10-12(a). This was a non-domestic matter. After meeting all statutory conditions, the record was formally expunged under § 12-10-12(c) by court order. The expungement order sealed the record from public view, and there is no resulting conviction.



Original Signature (electronic, copies or stamps not accepted)

5/8/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Corcelli

Print Name (First, Last)

MCorcelli

Original Signature (electronic, copies or stamps not accepted)

5/8/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami Dade

I, Michael Corcelli, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

MCorcelli

Original Signature

5/8/25

Date

Subscribed and Sworn to before me this 8 day of May, 2025

Flavia Rocha Agostini

Notary Public Signature

NOTARY PUBLIC STATE OF FLORIDA

FLAVIA ROCHA AGOSTINI
Commission # HH 620183
Expires February 3, 2029

The foregoing instrument was acknowledged before me this 8th day of May, 2025 by Michael R. Corcelli on behalf of said firm. He has produced his Florida Driver's License as identification.

(Seal)

List of Employees

Michael Alexander Corcelli

Role: Employee, Agent

Title: Shipping & Warehouse Manager

Type: Employee

O. L. Smith

Role: Compliance Officer

Title: Compliance Officer

Type: Employee

Michael Robert Corcelli

Role: Certified Designated Representative

Role: Certified Designated Representative

Type: Sole Owner

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Frontier Dental Supply INC

Physical Address: 2709 N Rolling Rd Unit 138

City: Windsor Mill State: MD Zip: 21244

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 410-265-0040 Website: _____

Name of Designated Representative (DR): Jason Harber

Licensing Company Email: greeshma@frontierdental.ca DR Email: Jason@zeeklogistics.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Dental supplies	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Dental Clinics		■ Others: Wholesale distributor

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/27/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Septodont
Address: 205 Granite Run Dr #150 City: Lancaster State: PA Zip: 17601

Name: BBraun
Address: 824 12th Avenue City: Bethlehem State: PA Zip: 18018

Name: Baxster
Address: 1 Baxster Pkwy City: Deerfield State: IL Zip: 60015

Name: Cardinal Health
Address: 7000 Cardinal PL City: Dublin State: OH Zip: 43017

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Ontario, Canada
Parent Company (if any):
Corporation/Organization Name: Frontier Dental Supply INC
Mailing Address: 2709 N Rolling Rd Unit 138
City: Windsor Mill State: MD Zip: 21244
Telephone: 410-265-0040 Email: elisha@frontierdental.ca
Contact Person Name: Elisha Kalfa

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

FRONTIER DENTAL SUPPLY INC

Facility Name

ELISHA KALFA

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/27/24

Date

Board Use Only	Date Received: 2/3/25	Amount: $1000 CK 40243 ✓

FRONTIER DENTAL

OWNERSHIP INFORMATION

Name	Elisha Kalfa
Title	CEO & Founder
Address	2709 North Rolling Rd, Unit 138, Windsor Mills, Maryland 21244
Date of Birth	[redacted]
Company Name	Frontier Dental Supply INC
Percentage Owned	100%
Home address	[redacted]

Tel: 416-281-3681 | Fax: 866-471-5779 | info@frontierdental.ca
2709 North Rolling Rd, Unit 138, Windsor Mills, Maryland 21244

Transaction Number / Numéro de transaction: APP-A10786562282
Generated on: May 14, 2025, 09:29 / Généré le: 14 mai 2025, 09:29

Ontario

Ministry of Public and Business Service Delivery
Ministère des Services au public et aux entreprises

Certificate of Status

Attestation du statut juridique

Business Corporations Act

Loi sur les sociétés par actions

This is to certify that

La présente vise à attester que

FRONTIER DENTAL SUPPLY INC.

Corporation Name / Dénomination sociale

2499329

Ontario Corporation Number / Numéro de société de l'Ontario

is a corporation incorporated, amalgamated or continued under the laws of the Province of Ontario according to the electronic records maintained by the Ministry of Public and Business Service Delivery.

est, selon les dossiers électroniques du dossier du ministère des Services au public et aux entreprises, une société constituée, issue d'une fusion ou qui continue d'être exploitée en vertu des lois de la province de l'Ontario.

The corporation came into existence on January 08, 2016 and has not been dissolved.

La société a vu le jour le 08 janvier 2016 et n'a pas été dissoute.

V. Quintanilla W.

Director / Directeur
Business Corporations Act / Loi sur les sociétés par actions

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

V. Quintanilla W.

Director/Registrar

Copie certifiée conforme du dossier du ministère des Services au public et aux entreprises.

V. Quintanilla W.

Directeur ou registrateur

Details

Demographic Information

Name: Frontier Dental Supply Inc

Address Information

Address: 2709 North Rolling Road
Unit 138

City: Windsor Mill **State:** MD **Zip:** 21244

Maryland License\Permit Information

Number: D07174 **Type:** Distributor **Subtype:** **Status:** Active

Original Issued: 8/11/2022 **Date Renewed:** 5/29/2025 **Expires:** 5/31/2027

No Speciality Information

Board Orders

Clicking on the corresponding link will allow documents to be viewed.

No Related Documents

****Please refer to the Board's Formal Disciplinary Action page for the listing of all disciplinary actions.****

EVIDENCE OF COMMERCIAL PROPERTY INSURANCE

DATE (MM/DD/YYYY): 5/23/2025

THIS EVIDENCE OF COMMERCIAL PROPERTY INSURANCE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE ADDITIONAL INTEREST NAMED BELOW. THIS EVIDENCE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS EVIDENCE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE ADDITIONAL INTEREST.

PRODUCER NAME, CONTACT PERSON AND ADDRESS / **PHONE (A/C, No, Ext):** 630-595-5300 Arthur J. Gallagher Risk Management Services, LLC 2850 Golf Rd Rolling Meadows, IL 60008 License#: 0D69293 **FAX (A/C, No):** 630-694-4401 / **E-MAIL ADDRESS:** sara_aceves@ajg.com **CODE:** / **SUB CODE:** **AGENCY CUSTOMER ID #:**	**COMPANY NAME AND ADDRESS** / **NAIC NO:** 20281 Federal Insurance Company 15 Mountain View Road Warren, NJ 07059 IF MULTIPLE COMPANIES, COMPLETE SEPARATE FORM FOR EACH **POLICY TYPE**
NAMED INSURED AND ADDRESS FRONTIER DENTAL SUPPLY INC. 2709 NORTH ROLLING ROAD UNIT 138 Windsor Mill MD 21244	**LOAN NUMBER** / **POLICY NUMBER**: 3608-95-25-EUC **EFFECTIVE DATE**: 10/11/2024 / **EXPIRATION DATE**: 10/11/2025 / ☐ CONTINUED UNTIL TERMINATED IF CHECKED
ADDITIONAL NAMED INSURED(S)	**THIS REPLACES PRIOR EVIDENCE DATED:**

PROPERTY INFORMATION (ACORD 101 may be attached if more space is required) ☒ BUILDING OR ☒ BUSINESS PERSONAL PROPERTY

LOCATION / DESCRIPTION
Premises Annual Aggregate Limit Of Insurance: $14,000,000
Per Occurrence Limit Of Insurance: $ 14,000,000

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS EVIDENCE OF PROPERTY INSURANCE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

COVERAGE INFORMATION

PERILS INSURED: ☐ BASIC ☐ BROAD ☒ SPECIAL ☐

COMMERCIAL PROPERTY COVERAGE AMOUNT OF INSURANCE: $ 4,000,000 — DED: 10,000

	YES	NO	N/A		
☒ BUSINESS INCOME ☐ RENTAL VALUE	X			If YES, LIMIT: 10,000,000	Actual Loss Sustained; # of months:
BLANKET COVERAGE		X		If YES, indicate value(s) reported on property identified above: $	
TERRORISM COVERAGE	X			Attach Disclosure Notice / DEC	
IS THERE A TERRORISM-SPECIFIC EXCLUSION?			X		
IS DOMESTIC TERRORISM EXCLUDED?			X		
LIMITED FUNGUS COVERAGE	X			If YES, LIMIT: 50,000	DED: 10,000
FUNGUS EXCLUSION (If "YES", specify organization's form used)			X		
REPLACEMENT COST	X				
AGREED VALUE		X			
COINSURANCE		X		If YES, %	
EQUIPMENT BREAKDOWN (If Applicable)			X	If YES, LIMIT:	DED:
ORDINANCE OR LAW - Coverage for loss to undamaged portion of bldg	X			If YES, LIMIT: Included	DED: 10,000
- Demolition Costs	X			If YES, LIMIT: Included	DED: 10,000
- Incr. Cost of Construction	X			If YES, LIMIT: Included	DED: 10,000
EARTH MOVEMENT (If Applicable)			X	If YES, LIMIT:	DED:
FLOOD (If Applicable)			X	If YES, LIMIT:	DED:
WIND / HAIL INCL ☐ YES ☐ NO Subject to Different Provisions:			X	If YES, LIMIT:	DED:
NAMED STORM INCL ☐ YES ☐ NO Subject to Different Provisions:			X	If YES, LIMIT:	DED:
PERMISSION TO WAIVE SUBROGATION IN FAVOR OF MORTGAGE HOLDER PRIOR TO LOSS			X		

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

ADDITIONAL INTEREST

☐ CONTRACT OF SALE ☐ LENDER'S LOSS PAYABLE ☐ LOSS PAYEE
☐ MORTGAGEE

NAME AND ADDRESS

Evidence of Coverage

LENDER SERVICING AGENT NAME AND ADDRESS

AUTHORIZED REPRESENTATIVE

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The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. CIC1962408

Application/License No. _____

Frontier Dental Supply INC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2709 North Rolling Road, Windsor Mills MD 21244 (Address of Applicant/Principal), as PRINCIPAL, and CAPITOL INDEMNITY CORPORATION (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1600 Aspen Commons Suite 300 Middleton, WI 53562 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 15, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

A1SuretyBonds.com
11205 LEBANON RD #13
MOUNT JULIET, TN 37122

Surety Bond Receipt

Date: 5/15/2025

Frontier Dental Supply INC

[redacted]

Coral Gables Florida [redacted]

Nevada Prescription Drug Wholesaler Surety Bond

Thank you for your recent purchase! Attached you will find your , which you will need to sign if/where indicated and turn into the entity requiring the bond. We highly recommend you keep a copy of the bond for your records.

Bond Number:	CIC1962408
Bond Amount:	$100,000
Bond Premium:	$2,500.00
Shipping	$0.00
Credit Card fee for amounts over $1000:	$75.00
Payment Received:	$2,575.00

For future reference, when calling our office or in correspondence, please reference your **Account ID #** 212919

Please help us keep your information up to date by advising if there are any changes to your account (address, phone, email, etc.) Furthermore, if there has been any material change in ownership, business name or bond requirement, please let us know.

Thank you for using A1SuretyBonds.com for all of your bonding needs!

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of May, 2025.

APPLICANT/PRINCIPAL

Frontier Dental Supply INC

Authorized Representative

SURETY

CAPITOL INDEMNITY CORPORATION

Surety Company's Representative

Michael Neschke, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

CAPITOL INDEMNITY CORPORATION
POWER OF ATTORNEY

CIC1962408
Bond Number

KNOW ALL MEN BY THESE PRESENTS, That the **CAPITOL INDEMNITY CORPORATION,** a corporation of the State of Wisconsin, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

----------MICHAEL NESCHKE----------

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

---------- ALL WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED $20,000,000.00 ----------

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **CAPITOL INDEMNITY CORPORATION** at a meeting duly called and held on the 15th day of May, 2002.

"**RESOLVED**, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the **CAPITOL INDEMNITY CORPORATION** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 1st day of September, 2022.

Attest:

Ryan J. Byrnes
Senior Vice President,
Chief Financial Officer and Treasurer

Todd Burrick
Chief Underwriting Officer

CAPITOL INDEMNITY CORPORATION CORPORATE SEAL WISCONSIN

CAPITOL INDEMNITY CORPORATION

Adam L. Sills
Chief Executive Officer and President

STATE OF WISCONSIN
COUNTY OF DANE } S.S.

On the 1st day of September, 2022 before me personally came Adam L. Sills, to me known, who being by me duly sworn, did depose and say: that he resides in the County of New York, State of New York; that he is Chief Executive Officer and President of **CAPITOL INDEMNITY CORPORATION**, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

DAVID J. REGELE NOTARY PUBLIC STATE OF WISCONSIN

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN
COUNTY OF DANE } S.S.

I, the undersigned, duly elected to the office stated below, now the incumbent in **CAPITOL INDEMNITY CORPORATION**, a Wisconsin Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 15th day of May 2025

PLATTE RIVER INSURANCE COMPANY CORPORATE SEAL NEBRASKA

Suzanne M Broadbent
Secretary

THIS DOCUMENT HAS BEEN GENERATED FOR A SPECIFIC BOND. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450.

CIC-ePOA-M (Rev. 09-2022)

CapSpecialty
Especially now.

1600 Aspen Commons, Suite 300
Middleton, WI 53562
Phone: 800.475.4450
CapSpecialty.com

SURETY BOND SEAL AND SIGNATURE ADDENDUM
PLATTE RIVER INSURANCE COMPANY – CAPITOL INDEMNITY CORPORATION

CapSpecialty and its writing companies Platte River Insurance Company and Capitol Indemnity Corporation have authorized their Attorneys-in-Fact to affix Platte River Insurance Company and/or Capitol Indemnity Corporation's electronic corporate seal and electronic Attorney-In-Fact signatures to any bond executed on behalf of Platte River Insurance Company and/or Capitol Indemnity Corporation by any such Attorney-in-Fact by attaching this Addendum to said bond.

To the extent this Addendum is attached to a bond that is executed on behalf of Platte River Insurance Company and/or Capitol Indemnity Corporation by their Attorney-in-Fact, Platte River Insurance Company and/or Capitol Indemnity Corporation hereby agree that the seals below shall be deemed affixed to said bond to the same extent as if their raised corporate seal was physically affixed to the face of the bond. Additionally, Platte River Insurance Company and/or Capitol Indemnity Corporation authorize their Attorney-In-Fact to use electronic signatures to the same extent as if a wet signature was physically affixed to the face of the bond.

Dated this 1st day of September, 2022.

Platte River Insurance Company and Capitol Indemnity Corporation

PLATTE RIVER INSURANCE COMPANY CORPORATE SEAL NEBRASKA

CAPITOL INDEMNITY CORPORATION CORPORATE SEAL WISCONSIN

By: _____
Adam L. Sills, Chief Executive Officer and President

IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF AN ELECTRONCIALLY SEALED AND/OR SIGNED BOND, PLEASE CALL 860-494-4914 OR EMAIL SDRAKE@CAPSPECIALTY.COM. PLEASE REFERENCE THE BOND NUMBER IN ANY CORRESPONDENCE.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Frontier Dental Supply Inc MDEG License # (if applicable) _____

Physical Address 2709 N Rolling Rd, Unit 138

City Windsor Mill State MD Zip 21244

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email elisha@frontierdental.com, monika@frontierdental.com

Section 2: Personal Information

First Jason Middle Lee Last Harber

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITI [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 2709 N Rolling Rd, Unit 138

City Windsor Mill State MD Zip 21244

Telephone [redacted] Email Jason@zeeklogistics.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	X	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Bladensburg High School		9/90-5/97	
Address	City	State	Zip
4200 57th Ave	Bladensburg	MD	20710
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/21-Present	[redacted]	York	PA	[redacted]
02/20-02/21		Bladensburg	MD	
07/13-11/19		Stafford	VA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Frontier Dental Supply Inc			From - To (MM/YY – MM/YY): 10/20 - Present
Business Address: 2709 N Rolling Rd, Unit 138	City: Windsor Mill	State: MD	Zip: 21244
Phone: 410-255-0040	Title: Warehouse Manager		Number of Employed Hours: Full time (40 hr/week)
Description of Duties: Receiving & Inspection of products, Storage and Inventory Control, Order Processing and Wholesale Distribution, Returns and Product Disposition. Record keeping & federal and state regulatory compliance, Health & Safety. Staff training and oversight.			

Business Name: G&G Outfitters			From - To (MM/YY – MM/YY): 9/95-10/20
Business Address: 4901 Forbes Blvd	City: Lanham	State: MD	Zip: 20706
Phone: (301) 731-2099	Title: Warehouse Manager		Number of Employed Hours: Full time (40 hr/week)
Description of Duties: Inventory control, health & saftety, facility & equipment oversight, shipping & logistic coordination, Leadership, Order Fulfillment & Client Program Support, Receiving and shipping oversight, training staff.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

I, Jason Lee Harber, **certify that as the MDEG Administrator for**

Frontier Dental Supply Inc,

that I (initial that you have read and meet the following requirements):

1. X Have a high school diploma or its equivalent;
2. X Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. X Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. X Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jason

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/7/25

Date

Board Use Only	Date Received:

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
6/18/2011		Virginia	Arlington	Arlington County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge: DUI				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

On June 18, 2011, I was arrested, in Virginia, on suspicion of DUI. I subsequently plead guilty on March 3, 2012, in which my driving privileges were suspended for one year. Since this time, and before this incident, I have had no other criminal violations.

Original Signature (electronic, copies or stamps not accepted)

Date 8/7/25

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Frontier Dental Supply
Pharmacy/Wholesaler License # (if applicable): D07174
Physical Address: 2709 N. Rolling Road
City: Windsor Mill State: MD Zip: 21244
Mailing Address (if different from physical address):
City: State: Zip:
Telephone: 410-265-0040 Website: www.frontierdental.com
Licensing Company Email:

Section 2: Personal Information

First: Jason Middle: Lee Last: Harber
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or IT: [redacted] Sex: ■ M ☐ F ☐ X
Mailing Addres: [redacted]
City: York State: PA Zip: [redacted]
Telephone: [redacted] Email: jason@eekaylogistics.com
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Bladensburg High School		9/90-5/97	
Address	**City**	**State**	**Zip**
4200 57th Ave	Bladensburg	MD	20710
Diploma/Degree obtained, if any			
General Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/21-present	[redacted]	York	PA	[redacted]
01/20-2/21		Bladensburg	MD	
7/13-12/20		Stafford	VA	
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Frontier Dental Supply			10/20-present	
Business Address		City	State	Zip
2709 N. Rolling Road		Windsor Mill	MD	21244
Phone	Title		Number of Employed Hours	
202-812-9552	Warehouse Manager		6,825	
Description of Duties				
Manager Warehouse Staff, record keeping				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

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Description of Duties				

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Phone	Title		Number of Employed Hours	
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Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
6/18/2011	3/3/2012	VA	Arlington	Arlington
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
VA2060810L		General District Court		
Reason/Charge				
DUI				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Jason Harber				
Name of Business/Industry/Entity				

Provide explanation below:

On June 18, 2011, I was arrested, in Virginia, on suspicion of DUI. I subsequently plead guilty on March 3, 2012, in which my driving privileges were suspended for one year. Since this time, and before this incident, I have had no other criminal violations.

Original Signature (electronic, copies or stamps not accepted)

Date 5/11/2025

I, Jason Lee Harber, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JH I am at least 21 years of age;
3. JH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jason Harber
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/16/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jason Harber

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/16/24

Date

Please have this section completed in the presence of a Notary Public.

State of Maryland, ss. County of Baltimore County

I, Jason Lee Harber, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/16/2024

Date

Subscribed and Sworn to before me this 16th day of October 2024.

Michelle R Raines

Notary Public Signature

MICHELLE R RAINES
Notary Public - State of Maryland
Baltimore County
My Commission Expires Apr 5, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Frontier Dental Supply INC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 2709 N Rolling Rd Unit 138

City Windsor Mill State MD Zip 21244

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 410-265-0040 Website _____

Licensing Company Email greeshma@frontierdental.ca

Section 2: Personal Information

First Elisha Middle _____ Last Kalfa

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Coral Gables State FL Zip [redacted]

Telephon[redacted] Email elisha@frontierdental.ca

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Darchei Binah			09/01 – 07-04
Address	**City**	**State**	**Zip**
Toronto	Toronto	Ontario	
Diploma/Degree obtained, if any			
High School			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/72 - Cur	[redacted]	Coral Gables	FL	[redacted]
09/14 – 05/2		Markham ON	Ontario	
08/14 – 09/1		Markham	Ontario	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Frontier Dental Supply Inc			04/16 – current	
Business Address		**City**	**State**	**Zip**
2709 North Rolling Road		Baltimore	MD	21244
Phone	**Title**			
416-281-3681	Director			
Description of Duties				
Strategic Planning and Finance				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/27/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Elisha Khalfa

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/27/24

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami-Dade

I, Elisha Khalfa, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/27/24

Date

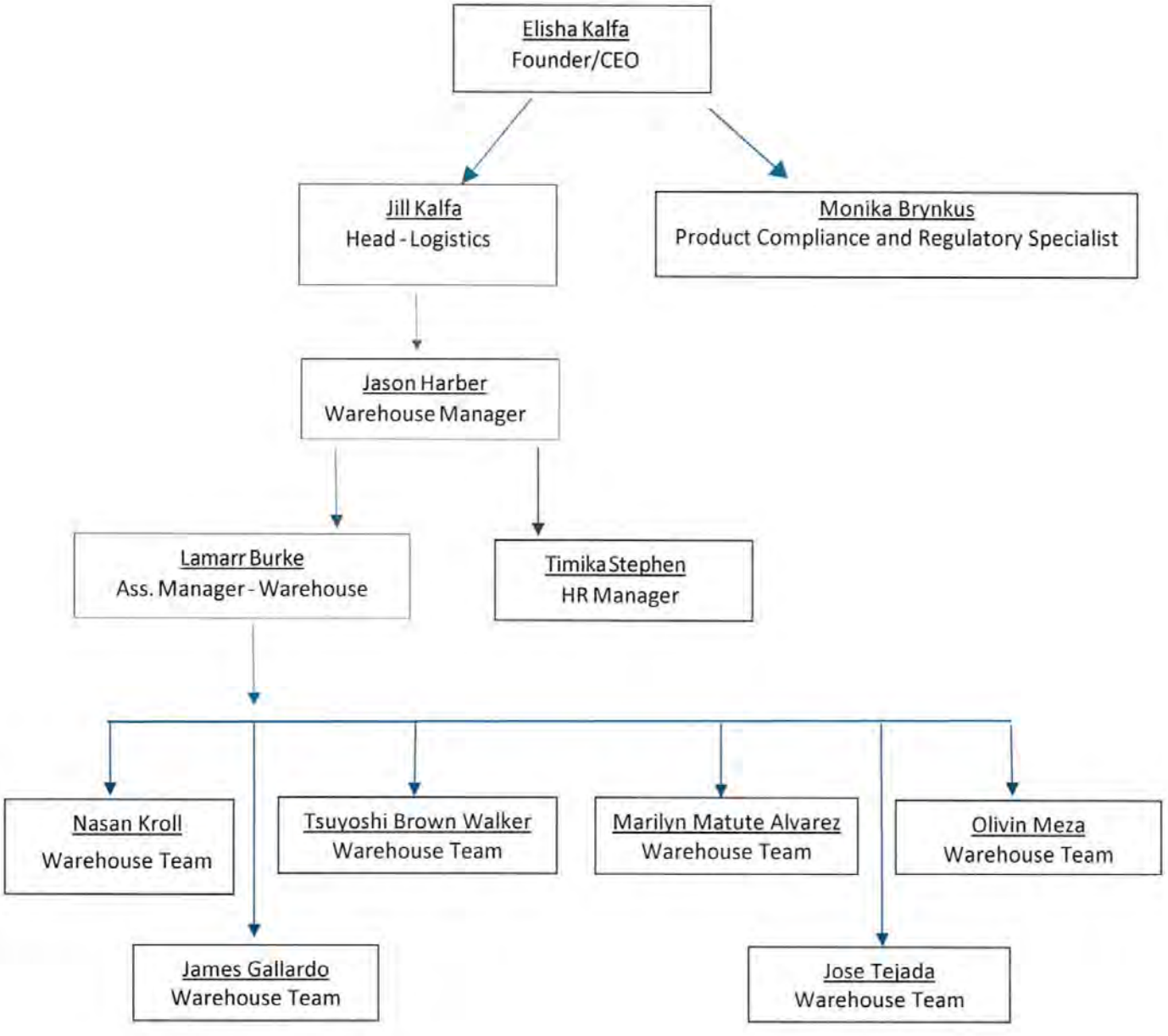
Subscribed and Sworn to before me this 27th day of November 2024.

Notary Public Signature

JASON GARCIA
Commission # HH 111010
Expires July 30, 2025 (Seal)
Bonded Thru Budget Notary Services

FRONTIER DENTAL

Organizational Chart



Tel: 416-281-3681 | Fax: 866-471-5779 | info@frontierdental.ca
2709 North Rolling Rd, Unit 138, Windsor Mill, Maryland 21244

MARYLAND
Department of Health
Larry J. Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Dennis R. Schrader, Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue, Baltimore, Maryland 21215-2299
Jennifer Hardesty, Board President, Deena Speights-Napata, Executive Director

Maryland Permit Number	:	D07174
Corporate Wholesale Distributor Name	:	Frontier Dental Supply Inc
Wholesale Distributor Name-Doing Business As (d/b/a) or Trade Name	:	
Street Address	:	2709 North Rolling Road, Unit 138, Windsor Mill, MD, 21244
Business Telephone Number	:	410-265-0040
Business Fax Number	:	N/A

License, Registration or Permit numbers issued by another state or federal authority (including States of Licensure):

Ohio: 0130000581 Exp: 06/30/2025

Maryland Pharmacy Permit Number	D07174	Expiration Date
CDS Registration Number	N/A	Expiration Date
DEA Registration Number	N/A	Expiration Date

Inspection Date	:	05/25/2023
Arrival Time	:	14:51
Departure Time	:	16:52
Type of Inspection	:	◉ Annual ○ Follow-up
Previous Date	:	08/11/2022
Name of Inspector	:	Taryn Daye/Nancy Richard

Hours of Operation

Monday: 7:30am-6:30pm	Tuesday: 7:30am-6:30pm	Wednesday: 7:30am-6:30pm	Thursday: 7:30am-6:30pm
Friday: 7:30am-6:30pm	Saturday: Closed	Sunday: Closed	

2. PERSONNEL (COMAR 10.34.22.02)

Name of Designated Representative who is the primary contact of the wholesale distributor with the Board and is actively involved in, and aware of, the daily operation of the wholesale distributor. COMAR 10.34.22.02(8)

Jason Lee Harber

◉ Yes ○ No — The Designated Representative is physically present, except for an authorized absence, at the facility of the wholesale distributor during regular business hours. COMAR 10.34.22.03D (3)

◉ Yes ○ No — The Designated Representative is a full time management level employee of the wholesale distributor. COMAR 10.34.22.03D (3)

Name of Immediate Supervisor of the Designated Representative :

Elisha Kalfa

Inspector's Comments:

None.

◉ Yes ○ No — The Immediate Supervisor is actively involved in, and aware of, the daily operations of the wholesale distributor. COMAR 10.34.22.03D (4)

◉ Yes ○ No — The Immediate Supervisor is a full time management level employee of the wholesale distributor. COMAR 10.34.22.03D(4)

○ Yes ◉ No — The wholesale distributor maintains a list of responsible individuals (officers, directors, managers, the designated representative, and others in charge if wholesale distribution, storage, and handling).

The list includes: (attach list) COMAR 10.34.22.07C

◉ Yes ○ No — The description of the duties of the responsible parties

◉ Yes ○ No — A summary of the qualifications of the responsible parties

Inspector's Comments:

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See attached job description/summary for Jason Lee Harber, Designated Representative.
Requested organization chart.
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3. PERSONNEL TRAINING

◉ Yes ○ No — All personnel employed in wholesale distribution have documented education and experience to assume the corresponding responsibilities. COMAR 10.34.22.04A

The Designated Representative:

◉ Yes ○ No — Is aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor, including applicable State and federal laws. COMAR 10.34.22.04C(1)

◉ Yes ○ No — Has had documented education sufficient to ensure that operations of the wholesale distributor are in compliance with applicable State and federal laws COMAR 10.34.22.04C(2); and

◉ Yes ○ No — Has received this education provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance with all applicable State and federal laws and regulations. COMAR 10.34.22.04C(2).

◉ Yes ○ No — Maintains current working knowledge of the requirements for wholesale distributors. COMAR 10.34.22.04C(3)

○ Yes ◉ No — Assures an ongoing training program for personnel to ensure compliance with applicable State and federal laws. COMAR 10.34.22.04C(3)

○ Yes ◉ No — Maintains all personnel training records and makes all records available for inspection. COMAR 10.34.22.04C(4)

4. STORAGE AND HANDLING OF PRESCRIPTION DRUG AND DEVICES

The facilities at which the prescription drugs or devices are stored, warehoused, handled, held, offered, marketed, or displayed COMAR 10.34.22.06A:

◉ Yes ○ No — Is of suitable size and construction to facilitate appropriate cleaning, maintenance and proper operation.

◉ Yes ○ No — Is maintained in a clean and orderly manner

◉ Yes ○ No — Is free from infestation by insects, rodents, birds, or vermin.

◉ Yes ○ No — The prescription drugs or devices storage area is equipped with:

◉ Yes ○ No ○ N/A — Proper Equipment

◉ Yes ○ No ○ N/A — Humidity Control

◉ Yes ○ No ○ N/A — Adequate Lighting

◉ Yes ○ No ○ N/A — Appropriate Sanitation

◉ Yes ○ No ○ N/A — Sufficient Space

◉ Yes ○ No ○ N/A — Appropriate Temperature

◉ Yes ○ No ○ N/A — Appropriate Ventilation

◉ Yes ○ No ○ N/A — The prescription drug or devices storage area is maintained at the appropriate temperature as established by labeling of the drug or device; or set forth in an official compendium; or at a controlled temperature that ensures identity, strength, quality and purity of the drug or devices are maintained. COMAR 10.34.22.06C

◉ Yes ○ No ○ N/A — The facility uses appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of prescription drugs or devices. COMAR 10.34.22.06C(3)

The wholesale distributor, upon receipt of a prescription drug or device, visually examines each outside shipping container to: COMAR 10.34.22.06D(1)

◉ Yes ○ No — Assure identity

◉ Yes ○ No — To prevent the acceptance of prescription drugs or devices that are contaminated or otherwise unfit for distribution

◉ Yes ○ No — The visual examination performed upon receipt of a prescription drug or device is adequate to reveal container damage that would suggest possible contamination or other damage to the contents. COMAR 10.34.22.06D(2)

The wholesale distributor carefully inspects each outgoing shipment to: COMAR 10.34.22.06D(2)

◉ Yes ○ No — Assure the identity of the prescription drug or device product

◉ Yes ○ No — Ensure there is no delivery of a prescription drug or device that has been damaged in storage or held under improper conditions

◉ Yes ○ No — The wholesaler distributor maintains records of the examination of incoming and outgoing prescription drug and device products. COMAR 10.34.22.06D(4)

◉ Yes ○ No — The wholesale distributor identifies, marks or has a quarantine area that physically separates prescription drugs and devices that are adulterated, damaged deteriorated, misbranded, outdated or in immediate or sealed secondary containers that have been opened from other prescription drugs and devices. COMAR 10.34.22.06E

Inspector's Comments:

Pest control services through Queen Bee,

5. SECURITY COMAR 10.34.22.06B

The facility is designed to prevent unauthorized entry through:

◉ Yes ○ No — Controlled access from outside the premises

◉ Yes ○ No — The outside perimeter of the premises is well lit.

◉ Yes ○ No — The entry into areas where prescription drugs and devices are held are limited to authorized personnel

The facility is equipped with:

◉ Yes ○ No — An alarm system to detect entry after hours.

◉ Yes ○ No — A security system that provides protection against theft and diversion.

◉ Yes ○ No — A security system to protect the integrity and confidentiality of data and documents.

◉ Yes ○ No — A video monitoring system for all entrances and exits, or alternate acceptable security.

◉ Yes ○ No — Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records.

◉ Yes ○ No — An inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting.

◉ Yes ○ No — An ongoing security data and documentation retention program which is readily available to the Board, an agent of the Board, or federal and other State law enforcement officials.

Inspector's Comments:

Alarm services through Crest Lock; Panel, door sensors, gate sensors, motion detectors and cameras throughout the warehouse and outside all entry ways.

6. PRESCRIPTION DRUG OR DEVICE DISTRIBUTION RECORDS COMAR 10.34.22.07

◉ Yes ○ No — The wholesale distributor maintains, for up to 3 years from the date of their creation, inventories and records of transactions regarding the receipt and distribution or disposition of prescription drugs and devices

The documentation of inventory and records of transactions include:

◉ Yes ○ No — The source of the prescription drugs and devices

◉ Yes ○ No — The name and principal address of the seller or transferor

◉ Yes ○ No — The address of the location from which the prescription drugs or devices were shipped

◉ Yes ○ No — The identity and quantity of the prescription drugs and devices received and distributed or disposed of

◉ Yes ○ No — The dates of receipt and distribution or other disposition of the prescription drugs or devices

◉ Yes ○ No ○ N/A — The pedigrees, if required by Health Occupations Article §12-6C-10, Annotated Code of Maryland, for prescription drugs that are wholesale distributed outside the normal distribution channel.

◉ Yes ○ No — The wholesale distributor makes records readily available for review at the inspection site, by computer or other means. If no:

◉ Yes ○ No	The wholesale distributor makes available within 5 business days of the request, records kept at a central location apart from the inspection site and not electronically retrievable
◉ Yes ○ No	The wholesale distributor has established and maintains procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting to the Board and the FDA.
◉ Yes ○ No	The wholesale distributor maintains a system and records for the mandatory reporting to the Board, the FDA and where applicable the DEA, significant inventory losses of prescription drugs and devices where it is known or suspected that diversion is occurring or has occurred.

The wholesale distributor has established, maintained, and adheres to written policies and procedures for:

◉ Yes ○ No	the receipt, security, storage, inventory and distribution of prescription drugs or devices
◉ Yes ○ No	identifying, recording and reporting losses or thefts
◉ Yes ○ No	correcting errors and inaccuracies in inventories

Inspector's Comments:

See attached Pedigree for Anesthetic Marcaine 0.5 1-200 EPI.
Reviewed incoming and outgoing invoices.

The wholesale distributor has included in the written policy and procedure:

◉ Yes ○ No ○ N/A	A procedure by which the oldest approved and unexpired stock of a prescription drug and device is distributed first
◉ Yes ○ No	Procedures to be followed for adequate handling of a recall and withdrawal of a prescription drug or device
◉ Yes ○ No	A procedure to ensure that the wholesale distributor is prepared for, protected against, and is able to handle a crisis that affects security or operation of a facility in the event of a strike, fire, flood, catastrophic health emergency, terrorist activities, other natural disaster or other situations of local, State or national emergency
○ Yes ◉ No	A procedure to ensure that an outdated prescription drug and device is segregated from other drugs or devices and either returned to the manufacturer or destroyed
○ Yes ◉ No	The wholesale distributor maintains documentation of the disposal of outdated prescription drugs or devices for up to 2 years after the disposition of the outdated prescription drugs or devices
◉ Yes ○ No	A procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels and packaging cannot be used in counterfeiting activities, which includes:
◉ Yes ○ No	all necessary documentation, maintained for a minimum of 3 years
◉ Yes ○ No	the appropriate witnessing of the destruction of any labels, packaging, immediate containers in accordance with applicable State and federal laws
◉ Yes ○ No ○ N/A	A procedure for identifying, segregating, investigating, and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, and suspect of being contraband, in the inventory and reporting of such discrepancies within 5 business days to the Board and appropriate federal or State agency upon discovery of such discrepancies.
○ Yes ○ No ◉ N/A	If the wholesale distributor performs prescription drug product salvaging and reprocessing, policies and procedures are in place to perform due diligence on transactions.
○ Yes ○ No ◉ N/A	If the wholesale distributor performs prescription device product salvaging or reprocessing, policies and procedures are in place to perform due diligence on transactions.

Inspector's Comments:

Reviewed policies and procedures in SOP black binder.

7. DUE DILIGENCE COMAR 10.34.22.07

○ Yes ◉ No	The wholesale distributor has had transactions with persons not licensed by the Board or not certified by a third party recognized by the Board. If yes, the wholesale distributor has policies and procedures to ensure:
○ Yes ○ No ◉ N/A	Verification of alternate licensure
○ Yes ○ No ◉ N/A	Verification of identity
○ Yes ○ No ◉ N/A	Verification of recent inspections by a state or third party entity recognized by the Board

INSPECTOR'S COMMENTS:

This distributor is located inside of a 3PL warehouse. 3PL company is Eekay Logistics formally Zeek Logistics which ships medical and dental supplies. Prescription medications are received directly from the manufactures and only distributed to dentist offices. No controlled medications at this location. Prescriptions are shipped through UPS and do not require overnight shipping. No refrigerated medications in stock. Electric shredder on site that is used to shred HIPPA and PHI documents.

Reviewed the prescription and quarantine areas; prescriptions are traced by lot numbers. The facility uses FIFO with in stock products. The room has security key pad to enter with motion detector and door sensor. The room is climate controlled. There are currently 6 prescription drugs on hand at the time of inspection.

Reviewed SOPs: 1.0-Back-up & Recovery; 2.0-Counterfiet or Misbranded Product Reporting; 3.0-Distribution Hold; 4.0-Drug Recalls; 5.0-Drug Rejection, Destruction or Disposal; 6.0-Good Documentation Practices; 7.0-Inventory Control; 8.0-Inventory Management; 9.0-Preventative Pest Control Program; 10.0-Product Returns; 11.0-Record Retention; 12.0-Reprocessing; 15.0-Emergency Plan; 18.0-Inventory disposal form.

During invoice review, prescriptions are being shipped into Ohio, Florida, New York and New Jersey. Ohio license was obtained and is current. Please ensure before shipping into another state that a license is required. Please provide the Board of Pharmacy with that information.

Please send Reversed distributor or manufacture process of damaged or outdated medications information to Taryn Daye by email taryn.daye@maryland.gov or fax at 410-384-4137 (Attention: Taryn) by 06/02/203. SOP in place but waiting for manufacture to give further instructions on this process currently.

Please send the organization chart to Taryn Daye by email taryn.daye@maryland.gov or fax at 410-384-4137 (Attention: Taryn) by 06/02/2023.

Please send the a copy of training for Designated Representative and a warehouse employee to Taryn Daye by email taryn.daye@maryland.gov or fax at 410-384-4137 (Attention: Taryn) by 06/02/2023.

Opening inspection was 08/11/2022.

Distribution license expiration date did not populate; 05/31/2025.

Inspector Signature: Taryn Daye

Designated Representative Name (Print): Jason Lee Harber

Date: 05/25/2023

Designated Representative Signature:

Received a copy of this inspection report:

Supporting Documents.
D07174_05252023_264_Job Description - Jason Harber Warehouse Manager.pdf
D07174_05252023_264_Septodont_PO0340888.pdf

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Medtronic USA, Inc. dba Medtronic Logistics LLC

Physical Address: 1480 Arthur St

City: Louisville State: CO Zip: 80027

Mailing Address (if different from physical address): Attn: Kay Knox 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: WWW.MEDTRONIC.COM

Name of Designated Representative (DR): ~~Maria Legy~~ Kelley Anderson

Licensing Company Email: kay.knox@cevalogistics.com DR Email: maria.legy@medtronic.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable:***

Date of Event/Arrest	Disposition Date	State	City	County
6/24/2017	3/20/2018	CO	Parker	Douglas County (Colorado)

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2017-3679	Colorado Board of Pharmacy

Reason/Charge
Failure to report change of designated representative within 30 days

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Medtronic Logistics LLC	Fine and surcharge

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Medtronic Logistics LLC (CO License WHI 6007) was disciplined for failure to timely report a change of Designated Representative within the require 30 day time period.

Terms of discipline: A fine with surcharge $1150. Medtronic Logistics LLC agreed to comply with Colorado regulations related to pharmacy businesses including timely reporting of Designated Representative changes with payment of associated fees going forward.

Rob M

Original Signature (electronic, copies or stamps not accepted)

9-24-24

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # ___3___. **Provide all the following *where applicable:***

Date of Event/Arrest	Disposition Date	State	City	County
4/3/2018	1/23/2019	CO	Parker	Douglas County (Colorado)

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
19-L-0013	Alabama State Board of Pharmacy

Reason/Charge
Failure to report Colorado disciplinary actions as required by Alabama regulations/rules

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Medtronic Logistics LLC	Consent Order with administrative fine $2000

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Count 1: (Alabama permit #194466)
Medtronic Logistics LLC, was disciplined for receiving Colorado Stipulation and Final Agency Order (2017-3679)

Count 2:
Medtronic Logistics LLC failed to report the Colorado Stipulation and Final Agency Order (2017-3679) on the Alabama 2019-2020 Renewal Application

Rob Ur
Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable:***

Date of Event/Arrest	Disposition Date	State	City	County
1/7/2021	7/12/2021	CO	Parker	Douglass County, (Colorado)
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2021-PHA-17242		Maine Board of Pharmacy		
Reason/Charge				
Failure to report disciplinary actions in CO and ME in timely manner				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Medtronic Logistics LLC		Consent Agreement $2000		
Name of Business/Industry/Entity				
Medtronic Logistics LLC				

Provide explanation below:

Medtronic Logistics LLC (Maine permit # WH70002083)

Issue 1
Medtronic Logistics LLC failed to report Colorado disciplinary action (2017-3679) to Maine within 10 days and did not reveal the same action at the time of renewal 12/12/2018. The Maine Board was not made aware of this action until 2/3/2020.

Issue 2
Medtronic Logistics LLC failed to report the Alabama disciplinary actions (19-L-0013) filed against the company within 10 days. The Maine Board of pharmacy was not made aware of this action until 7/18/2019.

Rob Un

Original Signature (electronic, copies or stamps not accepted)

9-24-24

Date

Medtronic

Medtronic Logistics LLC has experienced the below disciplinary actions:

- Case # 2017-3679 (Colorado) CLS Stipulation and fine ($1150) , Medtronic Logistics LLC, Parker CO, Lic # WHI.0006007
  - Failure to report change of designated representative for 13 months when required to do so within 30 days.
- Case # 19-L-0013 (Alabama) Consent Order with administrative fine $2000, Medtronic Logistics LLC, Parker CO, Lic # 194466
  - CO Case # 2017-3679 CLS Stipulation issued
  - Failure to disclose the Colorado case # 2017-3679 when renewing the 2019-2020 application.
- Case # 2021-PHA-17242 (Maine) Consent Agreement with reprimand and civil penalty $2000 issued to Medtronic Logistics LLC, Parker CO, Lic # WH70002083
  - Failure to report the Colorado case # 2017-3679 within 10 days of final disposition.
  - Failure to report the Colorado case # 2017-3679 on the Maine 2019-2020 renewal application
  - Failure to report the Alabama Case # 19-L-0013 to Maine within 10 days as required by 10 MRS 8003-G(2)(C)

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2017-3679

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MEDTRONIC LOGISTICS, LLC, REGISTRATION NO. WHI 6007,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medtronic Logistics, LLC ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2017-3679, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2017).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 7, 2006, being issued registration number WHI 6007, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 18501 Plaza Dr., Parker, CO 80134.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, thirteen (13) months transpired between May 31, 2016, date the previous designated representative ceased the position, and June 27, 2017, the date the application and fee were received.

6. Respondent Outlet was required to report a change of designated representative to the Board within thirty (30) days of such change.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board;

(k) Has failed to meet generally accepted standards of pharmacy practice.

12-42.5-303. Wholesaler license requirements.

(5) The designated representative of an applicant for a wholesaler license shall:

(i) Update all of the information required in this part 3 whenever changes occur.

Pharmacy Board Rules and Regulations

15.01.11 Minimum required information for registration.

b. Changes in any information in section 15.01.11 shall be submitted to the Board within thirty calendar days thereof.

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. Fine with Surcharge. Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall

impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one (1) lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board. Respondent Outlet shall write its registration number (WHI 6007) and the case number (2017-3679) on the check.

9. Compliance. Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. Other Requirements. Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. Advisements and Waivers. Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges.

c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. to appeal this Final Agency Order.

Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. Acknowledgments. The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none

of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. Violations. Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. Completion of Terms. Upon satisfactory completion of all terms and conditions set forth in this Final Agency Order, the Board shall release Respondent Outlet from the Final Agency Order, and Respondent Outlet's registration will be restored to active and unencumbered status.

15. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. Board Order. This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative

18. Effective Date. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

[signature] Dated: 3/20/18
Authorized Representative

License Compliance Analyst
Name / Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 3nd day of April, 2018.

State Board of Pharmacy

BY: [signature]
Wendy Anderson
Program Director

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
MEDTRONIC LOGISTICS LLC	)	BOARD OF PHARMACY
Wholesale Distributor Permit No. 194466	)	CASE NO: 19-L-0013

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Medtronic Logistics LLC (hereinafter referred to as "Medtronic") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act These allegations with particularity are set out in the Statement which is attached hereto as Exhibit "A."

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties have agreed to informally resolve this matter by the entry of this Consent Order the terms of which are as follows

1 The Board finds that Medtronic violated the applicable provisions based upon the conduct set out in each and every Count of the Statement

2 Medtronic shall pay to the Board an administrative fine in the amount of Two Thousand dollars ($2,000 00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board This obligation of payment to the Board shall not be dischargeable in bankruptcy and Medtronic shall not attempt to discharge the same in any bankruptcy proceeding

3. That Medtronic expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12) Code of Alabama (1975) §41-22-12 and §40-22-20 and Code of Alabama (1975) § 20-2-50 et seq and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review Medtronic further waives any objection to the attorney for the Board preparing, drafting or making this Order including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18

4 By execution of this Consent Order Medtronic hereby releases the Board its members, agents representatives, servants and employees from any and all liability claims, damages fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement

5 That Medtronic agrees that any further violation of the Alabama Pharmacy Practice Act the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may upon proof and hearing thereof result in further disciplinary sanctions against its license

6 That Medtronic acknowledges stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same Medtronic acknowledges stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion duress or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order

DONE this the 10th day of June 2019

Medtronic Logistics LLC

By [illegible]
Its [illegible]

DONE this the 19th day of June 2019

ALABAMA STATE BOARD OF PHARMACY

By [illegible]
Kenny Sanders R Ph President

By [illegible]
James S. Ward
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
MEDTRONIC LOGISTICS LLC	)	**BOARD OF PHARMACY**
Wholesale Distributor Permit No. 194466	)	**CASE NO: 19-L-0013**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Medtronic Logistics LLC
18501 E Plaza Drive
Parker, Colorado 80134

Pursuant to the provisions of Code of Alabama (1975). § 34-23-32 § 34-23-32 1 § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975). § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 15 2019 at 9:00 a.m at the State Board of Pharmacy Conference Room 111 Village Street Birmingham, Alabama 35242 and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Medtronic Logistics LLC (Medtronic) as a Wholesale Distributor should not be revoked suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that Medtronic has been guilty of the following, to-wit.

1 Board Rule 680-X-2.23 is entitled Drug Manufacturers Wholesale Distributors

2 Board Rule 680-X-2 23(3) provides that the Board of Pharmacy shall consider at a minimum certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama Those minimum factors

include

(a) Compliance with licensing requirements under previously granted license, if any

(b) Compliance with the requirements to maintain records required to be maintained

(c) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution

(d) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety

3 Board Rule 680-X-2 23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health

4 Board Rule 680-X-2 23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusa' to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1 000) for each violation

5 Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law

6. Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the

public safety or endangers the public health of the citizens of this state based upon the entry of a Stipulation and Final Agency Order by the Colorado State Board fo Pharmacy on Apnl 3, 2018 attached hereto as Exhibit "A" and/or your failure to notify the Colorado Board of a change in your designated representative for thirteen (13) months when required to do so in thirty (30) days

COUNT TWO

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your failure to disclose when required to do so on your 2019-2020 Renewal Application the Colorado discipline referenced above

At the aforesaid time and place and from time to time thereafter as may be directed by the Board you may be represented by an attorney if you so desire cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate

Dated this the 23rd day of January 2019

ALABAMA STATE BOARD OF PHARMACY

By Donna C Yeatman
Executive Secretary

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MEDTRONIC LOGISTICS LLC	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17242	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Medtronic Logistics LLC, for the renewal of its pharmaceutical wholesaler license. The parties to this Consent Agreement are: Medtronic Logistics LLC ("Medtronic"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since February 27, 2013, Medtronic has been licensed in Maine as a pharmaceutical wholesaler with a registered location of 18501 Plaza Drive, Parker, Colorado (license number WH70002083).

2. On April 3, 2018, the Colorado State Board of Pharmacy imposed discipline against Medtronic's Colorado registration (WHI 6007) pursuant to a Stipulation and Final Agency Order in Case No. 2017-3679.

3. Medtronic failed to report the Colorado discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On December 12, 2018, the Board received Medtronic's renewal application.

5. On that application, Medtronic responded "No" to the following question: "Since your last renewal, has any jurisdiction taken disciplinary action against any professional license you hold (except this license) or have held or denied your application for licensure?"

6. The Board accordingly renewed Medtronic's pharmaceutical wholesaler license.

7. On June 19, 2019, the Alabama State Board of Pharmacy imposed discipline against Medtronic's Alabama permit (194466) pursuant to a Consent Order in Case No.19-L-0013.

8. Medtronic failed to report the Alabama discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

9. On July 18, 2019, Medtronic reported to the Board for the first time that the Alabama State Board of Pharmacy had disciplined its permit.

10. On February 3, 2020, Medtronic reported to the Board for the first time that the Colorado State Board of Pharmacy had disciplined its registration.

11. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

12. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny Medtronic's application for renewal of its license to be a pharmaceutical wholesaler. In lieu of the denial, the Board also voted to offer Medtronic this Consent Agreement. Unless Medtronic either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME

04333-0035, by **July 12, 2021,** the preliminary denial of Medtronic's application for licensure as a pharmaceutical wholesaler will become final.

COVENANTS

13. Medtronic admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline as follows:

a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken; and

b. Pursuant to 10 M.R.S. § 8003(5-A)(A)(1), for making a misrepresentation to the Board on its December 12, 2018 application for renewal of licensure.

14. As discipline for the violation admitted to in paragraph 13 above, Medtronic agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of two thousand dollars ($2,000.00), which penalty is comprised of $1,500.00 for misrepresentation on its application and $500.00 for failing to report discipline within 10 days, payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, and must be submitted with the signed Consent Agreement.

15. Upon receipt of this signed Consent Agreement with the enclosed payment of the civil penalty from Medtronic, the Board will renew Medtronic's license contingent upon it meeting all other eligibility criteria.

16. Violation of any of the terms or conditions of this Consent Agreement by Medtronic shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

17. The Board and Medtronic agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Medtronic fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Medtronic, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving Medtronic. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Medtronic.

18. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

19. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

20. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

21. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

22. Medtronic acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 6/11/21

MEDTRONIC LOGISTICS LLC

By: [signature]

Print Name: Philip J Albert

Title: Vice President

DATED: 7/8/21

[signature]

BRADLEY S. HAMILTON, R.Ph., PRESIDENT
Maine Board of Pharmacy

DATED: 7/9/21

[signature]

JOHN NICHOLS
Assistant Attorney General

Please keep in mind that beyond what is provided in the Statutes and Rules, the Board does not have the authority under the practice act to provide practice opinions or legal advice.

Please review (or have an attorney review) the manufacturer section of the Statutes for the Pharmacy Board. Generally, devices that do not contain prescription drugs do not require licensure.

Kind regards,

On Thu, Oct 22, 2020 at 8:49 AM DPO_Licensing, DORA_ <dora_DPO_Licensing@state.co.us> wrote:

Customer Care Team

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

P: 303.894.7800 | F: 303.894.7693
1560 Broadway, Suite 1350, Denver, CO 80202
dora_dpo_licensing@state.co.us | www.colorado.gov/dora

COPY

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing
ATTN: Citation Coordinator
160 East 300 South
P.O. Box 146741
Salt Lake City, Utah 84114-6741

Telephone: (801) 530-6628
Fax: (801) 530-6511
Website: www.dopl.utah.gov

049003

CITATION

ISSUED TO: Medtronic USA Inc		
PROFESSION: Pharmacy Class C	LICENSE #: 16020162-1710	CASE #: 160584
DOB: / / N/A	DL #: N/A	SSN/EIN #: 46-1020994
BUSINESS ADDRESS: 1480 Arthur St	CITY: Louisville	STATE: CO ZIP: 80027
BUSINESS PHONE: (726) 890-3279	BUSINESS EMAIL: kay.knox@cevalogistics.com	
HOME ADDRESS: N/A	CITY: N/A	STATE: N/A ZIP: N/A
HOME PHONE: N/A	HOME EMAIL: N/A	
LOCATION OF OFFENSE: Medtronic USA Inc 1480 Arthur St Louisville, CO 80027		
	DATE OF OFFENSE: 4 / 3 / 2025	DATE ISSUED: 4 / 24 / 2025

OFFENSE CODE	DESCRIPTION
R156-17b-502(21)	(21) failing to provide consulting pharmacist, designated representative, responsible party, PIC, RDPIC, or DMPIC information to the Division within 30 days of a change in consulting pharmacist, designated representative, responsible party, PIC, RDPIC or DMPIC

REMARKS: On 4/3/2025, the Division received notification of a change in Designated Representative (DR) from the above facility. The previous DR on the submitted form was one that had not been reported to the Division. Upon investigation it was discovered that the previous DR, who associated with the company on 1/19/2021, in Division records left the company in 2/2023, with the previous DR on the submitted form starting in 2/2023. This means that the above facility failed to report the change in DR 762 days outside of the 30-day reporting window.

** Fine Pursuant to R156-17b-402(85)**

PERSON SERVED: Certified Mail 9589 0710 5270 2161 9950 00	SERVED BY: Zackary Christensen
☑ FINE $ 300.00	☑ CEASE AND DESIST ORDER

I ACKNOWLEDGE RECEIPT OF THIS CITATION AND CERTIFY THAT I HAVE READ AND UNDERSTAND THE RIGHTS ADVISEMENT CONTAINED BELOW AND HAVE BEEN PROVIDED A NOTICE OF RESPONSE.

RECIPIENT'S SIGNATURE _____ DATE / /

I CERTIFY THAT THE INFORMATION IN THIS CITATION IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

INVESTIGATOR'S SIGNATURE

READ CAREFULLY

1. If you wish to contest this citation at a hearing, you must notify the Division in writing within 20 calendar days of receipt. The hearing will be conducted according to Title 63 G, Chapter 4.
2. If you do not contest the citation within 20 calendar days of receipt, the citation will become a final order of the Division and is not subject to further agency review.
3. Failure to comply with a final order of the Division is a Class A misdemeanor. The Division may refuse to issue or renew or may suspend, revoke, or place on probation a license you hold or apply for.

RECIPIENT COPY

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medtronic Puerto Rico Operations (MPRI)
Address: P.O. Box 6001 City: Villalba State: PR Zip: 00766

Name: Medtronic Ireleand Manufacturing UC
Address: Parkmore Business Park West City: Galway State: Irelan Zip: IRE

Name: Medtronic Sophons
Address: 5744 Central Abe, Suite 100 City: Boulder State: CO Zip: 80301

Name: Medtronic Puerto Rico Operations CO
Address: Rd 31 KM 24 HM 4 Ceiba N Indus City: Juncos State: PR Zip: 00777

Section 4: Publicly Traded Corporation

State of Incorporation: Not Applicable
Parent Company (if any): Not Applicable
Corporation Name: Not Applicable
Mailing Address: Not Applicable
City: Not Applicable State: Not Applicabl Zip: Not Applicable
Telephone: Not Applicable Email: Not Applicable
Contact Person Name: Not Applicable
Date of SEC Registration: Not Applicable SEC Registration Number: Not Applicable Stock Exchange Symbol: Not Applica

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Medtronic Inc.
Corporation/Organization Name: Medtronic USA, Inc.
Mailing Address: 710 Medtronic Pkwy, LS245
City: Minneapolis State: MN Zip: 55432
Telephone: 508-261-6083 Email: rob.varner@medtronic.com
Contact Person Name: Robert Varner

Section 6: Partnership

Partnership Name: not applicable
Mailing Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable
Contact Person Name: not applicable

Section 7: Sole Owner

Owner's Name: not applicable
Business Name: not applicable
Business Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medtronic USA, Inc., dba Medtronic Logistics LLC, 1480 Arthur St, Louisville CO 80027

Facility Name

Robert Varner

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9-24-24

Date

Board Use Only	Date Received: 11/1/24	Amount: $1000 cc

New Search | Nevada, Louisville, CO Search | Back To Search Results

Establishment:
MEDTRONIC NAVIGATION, INC.
200 Medtronic Drive
Lafayette, CO 80026
Registration Number: 1723170
FEI Number*: 1000517638
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN US 55432
Owner/Operator Number: 2112641

Official Correspondent:
Rishi K Sinha
200 Medtronic Drive
Lafayette, CO 80026
Phone: 720-8902485

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Knox, Kay

From: Cast, Jennifer <jennifer.cast@medtronic.com>
Sent: Monday, February 5, 2024 3:58 PM
To: Knox, Kay; Cassady, Robert
Cc: Crates, William; Smrt, Eric; Ratchford, Debbie; Blount, Laura
Subject: RE: Louisville CO FDA registration.

NOTE: This message is from an EXTERNAL SENDER - be CAUTIOUS, particularly with links and attachments.
Please contact Information Security team for suspicious content/activity.

Hi Kay,

Arthur Ave. rolls up under the campus of: FDA Registration # 1000517638, 200 Medtronic Dr., Lafayette CO.

In January 2023 they moved from 826 Coal Creek, Louisville CO to a new building in Lafayette. Previously Arthur Ave. rolled up under the 826 Coal Creek address and establishment registration, we have just carried that same structure over for the new Lafayette address since this facility is actually closer to Arthur Ave. than 826 Coal Creek was and still meets the FDAs proximity requirements for a campus.

Does this help?

From: Cast, Jennifer
Sent: Thursday, February 1, 2024 9:10 AM
To: Knox, Kay <kay.knox@Cevalogistics.com>; Blount, Laura <laura.blount@medtronic.com>; Ratchford, Debbie <debbie.k.ratchford@medtronic.com>; Cassady, Robert <robert.b.cassady@medtronic.com>; Smrt, Eric <eric.c.smrt@medtronic.com>
Cc: Crates, William <William.Crates@Cevalogistics.com>
Subject: RE: Louisville CO FDA registration.

Ok, got it

Let me see who I can find at 1480 Arthur St, Louisville CO to talk to...stay tuned

---

From: Knox, Kay <kay.knox@Cevalogistics.com>
Sent: Thursday, February 1, 2024 8:13 AM
To: Cast, Jennifer <jennifer.cast@medtronic.com>; Blount, Laura <laura.blount@medtronic.com>; Ratchford, Debbie <debbie.k.ratchford@medtronic.com>; Cassady, Robert <robert.b.cassady@medtronic.com>; Smrt, Eric <eric.c.smrt@medtronic.com>
Cc: Crates, William <William.Crates@Cevalogistics.com>
Subject: [EXTERNAL] RE: Louisville CO FDA registration.

Thanks Jennifer, for the explanation.

Here's my problem with Maryland..... 1480 Arthur St, Louisville CO has been licensed in Maryland since 2012. The state now requires proof of FDA registration to renew the license. When I search the FDA medical device manufacturer website, I only find 2 sites in Colorado registered with the FDA. Neither is for Arthur St.

FDA Registration # 1000517638 is related to 200 Medtronic Dr., Lafayette CO. I need to be able to explain how this registration is related to 1480 Arthur St, Louisville CO.

Establishment:
MEDTRONIC NAVIGATION, INC.
200 Medtronic Drive
Lafayette, CO 80026
Registration Number: 1723170
FEI Number*: 1000517638
Status: Active
Date Of Registration Status: 2024

Establishment:
MEDTRONIC PERFUSION SYSTEMS
18501 E Plaza Dr
PARKER, CO 80134
Registration Number: 1718389
FEI Number*: 1718389
Status: Active
Date Of Registration Status: 2024

From: Cast, Jennifer <jennifer.cast@medtronic.com>
Sent: Thursday, February 1, 2024 8:30 AM
To: Knox, Kay <kay.knox@Cevalogistics.com>; Blount, Laura <Laura.blount@medtronic.com>; Ratchford, Debbie <debbie.k.ratchford@medtronic.com>; Cassady, Robert <robert.b.cassady@medtronic.com>; Smrt, Eric <eric.c.smrt@medtronic.com>
Subject: RE: Louisville CO FDA registration.

NOTE: This message is from an EXTERNAL SENDER - be CAUTIOUS, particularly with links and attachments.
Please contact Information Security team for suspicious content/activity.

++ Eric's Correct Email

From: Cast, Jennifer
Sent: Thursday, February 1, 2024 7:27 AM
To: Knox, Kay <kay.knox@Cevalogistics.com>; Blount, Laura <laura.blount@medtronic.com>; Ratchford, Debbie <debbie.k.ratchford@medtronic.com>; Cassady, Robert <robert.b.cassady@medtronic.com>; Eric.smrt@medtronic.com
Subject: RE: Louisville CO FDA registration.

Hi Kay,

1480 Arthur St, Louisville CO 80027: This is for **Mfg & Distribution** supporting Medtronic OUs: **CST, ENT, and NM.** Half of the inventory is already at Airways and we will move the rest in June. It will remain open as a Mfg after that but I believe they want to keep their DC Licensing to assist in Quarter Ends in the future.
1000517638 – Medtronic Navigation, Inc.

200 Medtronic Dr, Lafayette CO 80026: This is a new site I am told. And it is for **Covidien** – 1717344 & 3026612481.

I would consider these separate registrations due to separate businesses operating there. Not sure if that helps.

From: Knox, Kay <kay.knox@Cevalogistics.com>
Sent: Wednesday, January 31, 2024 2:14 PM
To: Blount, Laura <laura.blount@medtronic.com>; Ratchford, Debbie <debbie.k.ratchford@medtronic.com>; Cassady, Robert <robert.b.cassady@medtronic.com>; Cast, Jennifer <jennifer.cast@medtronic.com>; Eric.smrt@medtronic.com
Subject: [EXTERNAL] Louisville CO FDA registration.

Hello,

I need help understanding the FDA registration for Louisville CO so I can explain it to state Boards of Pharmacy, particularly Maryland.

The site I have been licensing has a street address 1480 Arthur St, Louisville CO 80027

Besides the Parker CO FDA registration, the only other FDA registration I find online in CO has the street address listed as 200 Medtronic Dr, Lafayette CO 80026.

Do these 2 sites fall under the same FDA similar to the one for Swinnea Rd and Airways Blvd?

Kind Regards,

KAY KNOX
Program Manager, Healthcare Regulatory Compliance
kay.knox@cevalogistics.com
Tel. 614-489-5164 M. 614-381-6730
4097 E Marquette Ave, Terre Haute IN 47805
www.cevalogistics.com



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Medtronic USA Inc. Officer List

Name	company title	Business Address
Robert Varner	President	4380 Swinnea Rd, Bldg B Memphis TN 38118
Dov Shenkman	Vice President	640 Orchard Ln. Glencoe IL 60022
Punit Menon	Vice President	4536 N Wildwood Ave. Shorewood, WI 53211

Medtronic

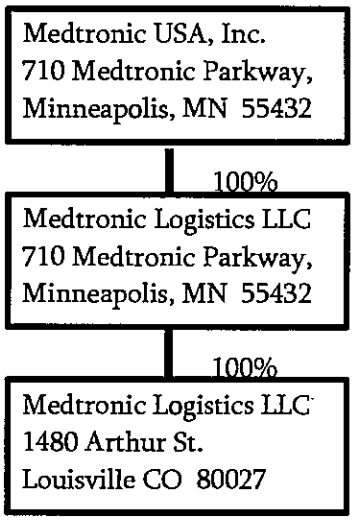
September 19, 2024

Nevada State Board of Pharmacy

985 Damonte Ranch PKWY, Suite 206
Reno, NV 89521

Medtronic USA, Inc. maintains 100% ownership of Medtronic Logistics LLC:

Organizational Chart



Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Medtronic USA, Inc.
Date Filed:	06/15/1984
File Number:	4R-233
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota
This certificate has been issued on:	12/18/2024



Steve Simon
Secretary of State
State of Minnesota



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FAQs, Glossary and Information

Summary

Details			
Name	MEDTRONIC USA, INC.		
Status	Good Standing	Formation date	12/23/1997
ID number	19971207212	Form	Foreign Corporation
Periodic report month	December	Jurisdiction	Minnesota
Principal office street address	710 Medtronic Pkwy, Minneapolis, MN 55432, US		
Principal office mailing address	710 Medtronic Pkwy, Minneapolis, MN 55432, US		

Registered Agent	
Name	Corporation Service Company
Street address	1900 W Littleton Blvd, Littleton, CO 80120, US
Mailing address	1900 W Littleton Blvd, Littleton, CO 80120, US

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FAQs, Glossary and Information

Summary

Details			
Name	Medtronic Logistics LLC		
Status	Good Standing	Formation date	12/16/2012
ID number	20121689956	Form	Foreign Limited Liability Company
Periodic report month	September	Jurisdiction	Minnesota
Principal office street address	710 Medtronic Pkwy, Minneapolis, MN 55432, US		
Principal office mailing address	710 Medtronic Pkwy, Minneapolis, MN 55432, US		

Registered Agent	
Name	Corporation Service Company
Street address	1900 W Littleton Blvd, Littleton, CO 80120, US
Mailing address	1900 W Littleton Blvd, Littleton, CO 80120, US

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Business Record Details »

Minnesota Business Name
Medtronic USA, Inc.

Business Type
Business Corporation (Domestic)

File Number
4R-233

Filing Date
06/15/1984

Renewal Due Date
12/31/2024

Number of Shares
1,000

Chief Executive Officer
Jennifer Kirk
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

MN Statute
302A

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2345 Rice Street
Suite 230
Roseville, MN 55113-5603
USA

Registered Agent(s)
Corporation Service Company

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	06/15/1984	Original Filing - Business Corporation (Domestic)	
	06/15/1984	Business Corporation (Domestic) Business Name (Business Name: MEDTRONIC MILACA, INC.)	

	Filing Date	Filing	Effective Date
☐	03/14/1989	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	10/06/1995	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	12/11/1997	Business Corporation (Domestic) Business Name (Business Name: Medtronic USA, Inc.)	
	12/11/1997	Business Corporation (Domestic) Restated Articles	
☐	10/29/1998	Merger - Business Corporation (Domestic)	
☐	04/10/2007	Global Registered Office and/or Agent - Business Corporation (Domestic)	
☐	9/16/2016	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	5/17/2018	Registered Office and/or Agent - Business Corporation (Domestic)	

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Business Record Details »

Minnesota Business Name
Medtronic Logistics LLC

Business Type
Limited Liability Company (Domestic)

File Number
618784400037

Filing Date
9/18/2012

Renewal Due Date
12/31/2025

Registered Agent(s)
Corporation Service Company

MN Statute
322C

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2345 Rice Street
Suite 230
Roseville, MN 55113-5603
USA

Manager
Greg Smith
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
USA

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	9/18/2012	Original Filing - Limited Liability Company (Domestic) (Business Name: Medtronic Logistics LLC)	
☐	9/16/2016	Registered Office and/or Agent - Limited Liability Company (Domestic)	
	1/1/2018	Conversion to 322C Due to Statute Mandate – Limited Liability Company (Domestic)	
☐	5/15/2018	Registered Office and/or Agent - Limited Liability Company (Domestic)	

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Medtronic Engineering the extraordinary

Memo to File

Author: Kay Knox

Date: May 24, 2024

Subject: Colorado Medical Device Manufacturer license not required.

To whom it may concern,

Medtronic has reviewed Colorado regulations and has determined licensure is not required for manufacture of medical devices within this state.

12-280-103. Definitions - rules

(13) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or similar or related article that is required under federal law to bear the label, "Caution: federal law requires dispensing by or on the order of a physician." "Device" also includes any component part of, or accessory or attachment to, any such article, whether or not the component part, accessory, or attachment is separately so labeled..

(16) (a) "Drug" means: (I) Substances recognized as drugs in the official compendia; (II) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals;..... (b) "Drug" does not include devices or their components, parts, or accessories.

(27) "Manufacturer" or "manufacturing drug outlet" means a person who manufactures drugs and includes a resident 503B outsourcing facility.

12-280-109. Drugs, devices, and other materials. (1) The board is responsible for the control and regulation of drugs, including the following: (a) The regulation of the sale at retail and the ispensing of drugs; (b) The specification of minimum professional and technical equipment, environment, supplies, and procedures for the compounding or dispensing of medications and drugs; (c) The control of the purity and quality of drugs. (2) The board is responsible for the control and regulation of the sale of devices at retail; except that the board shall not regulate the sale of any disposable veterinary device. The board may also exempt from regulation veterinary devices: (a) That are regulated by the FDA; or (b) For which the board determines regulation is unnecessary.

The Medtronic facility located at 1480 Coal Creek, Louisville CO manufactures medical devices which do not contain prescription drugs in the device or device packaging. The facility is registered with the FDA (# 1723170, FEI # 1000517638).

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 3/6/2025

Registration Number: 5003905 **Registered as:** Manufacturer and Wholesale

Name: MEDTRONIC USA, INC

DBA: MEDTRONIC LOGISTICS LLC

Address: 710 MEDTRONIC PARKWAY LC300, MINNEAPOLIS, MN 55432

Original Issue Date: 05/26/2010 **Expiration Date:** 01/31/2026

Current Issue Date: 01/17/2025

Disciplines: No

Additional Registered Addresses:
1851 E DEERE AVE, SANTA ANA, CA 92705
4620 NORTH BEACH ST, FORT WORTH, TX 76137
6743 SOUTHPOINT DR NORTH, JACKSONVILLE, FL 32216
2235 ROUTE 322, SUITE 200, SWEDESBORO, NJ 08085
4340 SWINNEA RD, MEMPHIS, TN 38118
7611 NORTHLAND DR, BROOKLYN PARK, MN 55432
18501 E PLAZA DR, PARKER, CO 80134
1480 ARTHUR ST, LOUISVILLE, CO 80027
5300 AIRWAYS BLVD, STE 101, MEMPHIS, TN 38116
201 INDUSTRIAL WAY, EATONTOWN, NJ 07724
4340 SWINNEA RD STE 39, MEMPHIS, TN 38118
1941 E BLAIR AVE, SANTA ANA, CA 92705

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0753236

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

710 MEDTRONIC PARKWAY LC300 MINNEAPOLIS, MN 55432-
4340 SWINNEA RD MEMPHIS,TN 38118-
6743 SOUTHPOINT DR NORTH JACKSONVILLE, FL 32216-
4620 NORTH BEACH ST FORT WORTH, TX 76137-
1851 E DEERE AVE SANTA ANA, CA 92705-
7611 NORTHLAND DR BROOKLYN PARK, MN 55432-
1480 ARTHUR ST LOUISVILLE, CO 80027-
18501 E PLAZA DR PARKER, CO 80134-

Reg. No.
5003905

MEDTRONIC USA, INC
MEDTRONIC LOGISTICS LLC
4097 E MARQUETTE AVE
TERRE HAUTE, IN 47805-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2026

Establishment Copy

New Jersey Department of Health
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369
609-826-4935

ADDENDUM TO CERTIFICATE OF REGISTRATION FOR A

WHOLESALE DRUG OR MEDICAL DEVICE BUSINESS PURSUANT TO N.J.S.A. 24:6B FOR THE PERIOD ENDING: January 31, 2026

Registered as: [X] manufacturer [X] wholesaler Registration No.: 5003905

The following are additional locations conducting Drug or Medical Device Business

9.	201 INDUSTRIAL WAY EATONTOWN, NJ 07724-	20.	, -
10.	4340 SWINNEA RD STE 39 MEMPHIS, TN 38118-	21.	, -
11.	1941 E BLAIR AVE SANTA ANA, CA 92705-	22.	
12.	~~5200 AIRWAYS BLVD, STE 101 MEMPHIS, TN 38116~~	23.	
13.	2235 ROUTE 322, SUITE 200 SWEDESBORO, NJ 08085-	24.	
14.		25.	, -
15.		26.	
16.		27.	
17.	, -	28.	
18.	, -	29.	, -
19.	, -	30.	

Cross out locations no longer being operated and add new locations in spaces provided.

Other Corrections: If name or address is incorrect, make necessary corrections below.

_____

_____

_____

_____

RETAIN LAST COPY FOR YOUR RECORD. MAIL WHITE COPY WITH YOUR FEE IN THE ENVELOPE PROVIDED.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 02/26/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 FAX (A/C, No): 212-948-5382
E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : Indemnity Insurance Company of North America	43575
INSURER C : ACE Fire Underwriters Insurance Company	20702
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Medtronic, Inc. and its subsidiaries
710 Medtronic Parkway
LC310
Minneapolis, MN 55432

COVERAGES **CERTIFICATE NUMBER:** CHI-010895207-01 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			SPL G24561288 008	05/01/2024	05/01/2026	EACH OCCURRENCE	$	5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	15,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$	15,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY			ISAH10832810	05/01/2024	05/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$	
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$	
	☐ DED ☐ RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			WLRC57196166 (AOS) (incl Stop Gap EL: MN,ND,OH,WA,WY)	05/01/2024	05/01/2025	X PER STATUTE ☐ OTH-ER		
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A					E.L. EACH ACCIDENT	$	1,000,000
B	(Mandatory in NH)			WLRC57196257 (MO,NC,NE,OK)	05/01/2024	05/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
A	If yes, describe under DESCRIPTION OF OPERATIONS below			SCFC57196518 (PA)	05/01/2024	05/01/2025	E.L. DISEASE - POLICY LIMIT	$	1,000,000
C	Workers Compensation continued			SCFC57196439 (WI)	05/01/2024	05/01/2025	Limit:		See Above
A	Excess Workers Compensation			WCUC57196567 (AZ) excess of $1M SIR	05/01/2024	05/01/2025	Limit:		1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance.
RE: 4340 Swinnea Rd, Memphis TN 38118; 6743 Southpoint Dr, Jacksonville FL 32216; 1480 Arthur St, Louisville CO 80027; 4620 N Beach St,. Ft Worth TX 76137; 18501 E Plaza Dr., Parker CO 80134; 7611 Northland Dr., Brooklyn Park MN 55428 5300 Airways Blvd, Suite 101, Memphis TN 38116; 2235 Route 322, Suite 200, Swedesboro NJ 08085

CERTIFICATE HOLDER
Medtronic Inc
Attn: LS370
710 Medtronic Parkway
Minneapolis, MN 55432

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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AGENCY CUSTOMER ID: CN103154363
LOC #: Minneapolis

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC	Medtronic, Inc. and its subsidiaries 710 Medtronic Parkway LC310 Minneapolis, MN 55432
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Professional Health Care Liability:
Policy # SPL G24561288 008
05/01/2024 - 05/01/2026
Carrier: ACE American Insurance Company
$2,000,000 Each Claim
$15,000,000 Aggregate

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SURETY RIDER

To be attached to and form a part of

Bond No. 190054165

dated effective October 2, 2023
(MONTH-DAY-YEAR)

executed by Medtronic USA, Inc. , as Principal,
(PRINCIPAL)

and by Liberty Mutual Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

ADDING COVERED LOCATIONS:

4340 Swinnea Rd, Memphis TN 38118
18501 E Plaza Dr., Parker CO 80134
6743 Southpoint Dr, Jacksonville FL 32216
4620 N Beach St,. Ft Worth TX 76137
5300 Airways Blvd, Suite 101, Memphis TN 38116
7611 Northland Dr., Brooklyn Park MN 55428
1480 Arthur St, Louisville CO 80027
2235 Route 322, Swedesboro NJ 08085

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective November 26, 2024
(MONTH-DAY-YEAR)

Signed and Sealed November 26, 2024
(MONTH-DAY-YEAR)

Medtronic USA, Inc.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Liberty Mutual Insurance Company
(SURETY)

By: Cynthia L. Choren
Cynthia L. Choren, Attorney-In-Fact
NV Non-Resident License No. 221080

S-0443/GEEF 10/99

Liberty Mutual. SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of November, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Marsh MSurety POA LMIC OCIC WAIC Multi Co_092024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 190054165

Application/License No. _____

Medtronic USA Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5300 Airways Blvd., Memphis, TN 38116 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 5, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of October, 2023.

APPLICANT/PRINCIPAL

Medtronic USA Inc

Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact

print name

NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Brittany D. Stuckel

Witness Heidi A. Notheisen

Countersigned by:

N/A

Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren

all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 5th day of October, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Marsh MSurety POA LMIC OCIC WAIC Multi Co_022021

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medtronic Logistics LLC — MDEG License # (If applicable): MP00768
Physical Address: 1480 Arthur St
City: Louisville — State: CO — Zip: 80027
Mailing Address (if different from physical address): 578 Highlands Circle
City: Erie — State: CO — Zip: 80516
Telephone: 763-237-4446 — Website: www.medtronic.com
Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Kalley — Middle: A — Last: Anderson
Alias(es; nicknames, name changes, etc.):
Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X
Mailing Address: [redacted]
City: Erie — State: CO — Zip: [redacted]
Telephone: 7632374446 — Email: kalley.a.anderson@medtronic.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Wisconsin-Madison		09/16 to 05/20	
Address	City	State	Zip
1415 Engineering Dr	Madison	WI	53706
Diploma/Degree obtained, if any			
BS Industrial and Systems Engineering			

School Name		From - To (MM/YY – MM/YY)	
Beker High School		09/12 to 05/16	
Address	City	State	Zip
12000 Hancock St SE	Becker	MN	55308
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
not applicable		Not applicable	
Address	City	State	Zip
Not applicable	Not applicable	NA	NA
Diploma/Degree obtained, if any			
Not applicable			

School Name		From - To (MM/YY – MM/YY)	
Not applicable		Not applicable	
Address	City	State	Zip
Not applicable	Not applicable	NA	NA
Diploma/Degree obtained, if any			
Not applicable			

School Name		From - To (MM/YY – MM/YY	
Not applicable		Not applicable	
Address	City	State	Zip
Not applicable	Not applicable	NA	NA
Diploma/Degree obtained, if any			
Not applicable			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/24to present	[redacted]	Erie	CO	[redacted]
From - To (MM/YY – MM/YY)		City	State	
11/22 to 2/24		Bloomfield	CO	
From - To (MM/YY – MM/YY)		City	State	
11/21 to 11/22		Denver	CO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
MEDTRONIC USA INC			11/2023 To Present	
Business Address		**City**	**State**	**Zip**
1480 ARTHUR ST		Loisville	CO	80027
Phone	**Title**		**Number of Employed Hours**	
303-242-9888	SR. LOGISTICS MANAGER		2760+	
Description of Duties				
MANAGER OF OPERATIONS (receiving, inventory control, material replenishment and shipping activities for this site)				

Business Name			From - To (MM/YY – MM/YY)	
Medtronic			11/21 To 09/2023	
Business Address		**City**	**State**	**Zip**
5920 Longbow Dr		Boulder	CO	80301
Phone	**Title**		**Number of Employed Hours**	
763-237-4446	Op Ex Engineer		3,840+	
Description of Duties				
Ran opex projects and program managed cost savings for the Boulder site				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Not applicable			Not applicable
Business Address	**City**	**State**	**Zip**
Not applicable	Not applicable	Not applic	Not applicab
Phone	**Title**	**Number of Employed Hours**	
Not applicable	Not applicable	Not applicable	
Description of Duties			
Not applicable			

Business Name			From - To (MM/YY – MM/YY)
Not applicable			Not applicable
Business Address	**City**	**State**	**Zip**
Not applicable	Not applicable	Not applic	Not applicab
Phone	**Title**	**Number of Employed Hours**	
Not applicable	Not applicable	Not applicable	
Description of Duties			
Not applicable			

Business Name			From - To (MM/YY – MM/YY)
Not applicable			Not applicable
Business Address	**City**	**State**	**Zip**
Not applicable	Not applicable	Not applic	Not applicab
Phone	**Title**	**Number of Employed Hours**	
Not applicable	Not applicable	Not applicable	
Description of Duties			
Not applicable			

Business Name			From - To (MM/YY – MM/YY)
Not applicable			Not applicable
Business Address	**City**	**State**	**Zip**
Not applicable	Not applicable	Not applic	Not applicab
Phone	**Title**	**Number of Employed Hours**	
Not applicable	Not applicable	Not applicable	
Description of Duties			
Not applicable			

Business Name			From - To (MM/YY – MM/YY)
Not applicable			Not applicable
Business Address	**City**	**State**	**Zip**
Not applicable	Not applicable	Not applic	Not applicab
Phone	**Title**	**Number of Employed Hours**	
Not applicable	Not applicable	Not applicable	
Description of Duties			
Not applicable			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Not applicable	Not applicable	NA	Not applicable	Not applicable

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
Not applicable	Not applicable

Reason/Charge
Not applicable

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Not applicable	Not applicable

Name of Business/Industry/Entity
Not applicable

Provide explanation below:

Not applicable

Original Signature (electronic, copies or stamps not accepted) Date

I, Kalley A Anderson, **certify that as the MDEG Administrator for**

Medtronic USA, Inc.,

that I (initial that you have read and meet the following requirements):

1. KA Have a high school diploma or its equivalent;
2. KA Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KA Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KA Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kalley A Anderson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only	Date Received:

Kalley A. Anderson [redacted]

pExecutive Profile

A results-driven engineer with top skills in lean six sigma methodologies, manufacturing operations and project management. Equipped to learn quickly, drive deliverables and achieve targets to support organizational growth.

Skills

Kaizen: Leading, planning, participating in quality, safety, and productivity events
Lean Six Sigma Green Belt Certification: 3M
Lean Six Sigma Black Belt Certification: Medtronic/MoreSteam
First Time Quality: Level I Coach
Leadership Trainings: Medtronic EDGE and Medtronic EMPOWER
Project Management: PMP Prep Course
Programming: Python, Java, SQL
Software: Microsoft Office Suite, SAP, Minitab, Power Bi, Microsoft Access, SolidWorks, BPCS

Experience

Medtronic, CO Campus | *Logistics Manager* **September 2023 - Present**

- Led project to change 3rd Party Logistics provider effectively moving 7,000 pallets of inventory in 6 months improving services levels by 80% and reducing costs by $1.3M/year.
- Created and executed on yearly strategic plan for the campus logistics organization with a $5M budget.
- Completed safety risk assessments across the campus to identify and reduce 45 high risk opportunities.
- Manage 53 head count (operators, supervisors, and engineers) across 4 shifts and 3 sites.
- Executed on the new warehouse design of a 50% reduction of dock doors, 10% storage space and 2 HC while maintaining operations at the same volumes.
- Supported transportation optimization projects that delivered $580K/year of savings.
- Implemented warehouse safety stock levels to ensure efficient flow of inventory to production and reduced line down absorption loss of $600K/year.

Medtronic, Boulder CO | *Sr. Operational Excellence Engineer* **November 2021 - September 2023**

- Executed FY22-FY23 plan to exceed goal of $14.65M of savings across labor, MUV, and PPV.
- Responsible for data analysis and reporting of KPIs and progress to executive leaders.
- Performed and implemented change management through project and resource management system roll out to track salaried staff utilization and project labor requirements.
- Led change management for the logistics team by spearheading the implementation of new tier management systems.
- Project managed roll out of an auto replenishment system to reduce the system work for material handlers and warehouse scheduler by 30%.
- Black Belt Project 1: Redesigned bottleneck process and rebalanced line to increase weekly output by 10% with $260K/year of labor efficiency savings.
- Black Belt Project 2: Warehouse inbound flow optimization to decrease unprocessed work by 50%, reducing overtime costs by $100K/year.

3M, Forest City IA | *Optimized Operations (O2) Rotational Engineer* **July 2021 – November 2021**

- Piloted new vision picking technology project with projected $400K/year savings.
- Led cross functional team including outside programming company based in India.
- Program manager for identifying improvement opportunities and ensuring implementation with a $2M/year goal.

3M, New Ulm MN | *Optimized Operations (O2) Rotational Engineer* **May 2020 – July 2021**

- Led Surface Mounted Technology (SMT) Line Yield Improvement project which reduced PCB rework by 10%, increased first pass yield from 60% to 85%, and had productivity savings of $240K/year.
- Reduced Solder Paste SKUs by 40% strategically reducing to 3 key suppliers.
- Created and led 5S Kaizen weekly program for 3 departments.
- New Product Introduction Co-Project Leader for transferring assembly process to New Ulm facility.
- Qualified 5 additional printed circuit boards to run on the SMT Line resulting in $60K/year savings.
- Created Power Bi reports to analyze productivity, efficiency, and yield for the department.

Education

University of Wisconsin-Madison | B.S. Industrial Engineering
Biology in Engineering and Six Sigma Certificates

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medtron ic Logistics LLC
Pharmacy/Wholesaler License # (if applicable): New application, License # not assigned yet
Physical Address: 1480 Arthur St
City: Louisville State: CO Zip: 80027
Mailing Address (if different from physical address): [redacted]
City: Erie State: CO Zip: [redacted]
Telephone: 763-237-4446 Website: www.medtronic.com
Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Kalley Middle: A Last: Anderson
Alias(es, nicknames, name changes, etc.): NA
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X
Mailing Address: [redacted]
City: Erie State: C O Zip: [redacted]
Telephone: 763-237-4446 Email: kalley.a.anderson@medtronic.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Wisconsin-Madison		09/16 to 05/20	
Address	**City**	**State**	**Zip**
1415 Engineering Dr	Madison	WI	53706
Diploma/Degree obtained, if any			
BS Industrial and Systems Engineering			
School Name		**From - To (MM/YY – MM/YY)**	
Beker High School		09/12 to 05/16	
Address	**City**	**State**	**Zip**
12000 Hancock St SE	Becker	MN	55308
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Not Applicable		Not Applicable	
Address	**City**	**State**	**Zip**
Not Applicable	Not Applicable	NA	NA
Diploma/Degree obtained, if any			
Not applicable			
School Name		**From - To (MM/YY – MM/YY)**	
Not Applicable		Not Applicable	
Address	**City**	**State**	**Zip**
Not Applicable	Not Applicable	NA	NA
Diploma/Degree obtained, if any			
Not Applicable			
School Name		**From - To (MM/YY – MM/YY)**	
Not Applicable		Not Applicable	
Address	**City**	**State**	**Zip**
Not Applicable	Not Applicable	NA	NA
Diploma/Degree obtained, if any			
Not Applicable			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/24 to present	[redacted]	Erie	CO	[redacted]
11/22 to 02/24		Bloomfield	CO	
11/21 to 11/22		Denver	CO	
Not Applicable	Not Applicable	Not Applicable	NA	NA
Not Applicable	Not Applicable	Not Applicable	NA	NA
Not Applicable	Not Applicable	Not Applicable	NA	NA
Not Applicable	Not Applicable	Not Applicable	NA	NA
Not Applicable	Not Applicable	Not Applicable	NA	NA
Not Applicable	Not Applicable	Not Applicable	NA	NA
Not Applicable	Not Applicable	Not Applicable	NA	NA

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Medtronic USA Inc.			From - To (MM/YY – MM/YY): 11/23 to present
Business Address: 1480 Arthur St	City: Louisville	State: CO	Zip: 80027
Phone: 3032429888	Title: Sr. Logistics Manager		Number of Employed Hours: 2760
Description of Duties: Manager of Operations (Receiving, Inventory Control, Material replenishment, and shipping activities for this site			

Business Name: Medtronic			From - To (MM/YY – MM/YY): 11/21 to 09/23
Business Address: 5920 Longbow Dr	City: Boulder	State: CO	Zip: 80301
Phone: 763-237-4446	Title: Op Ex Engineer		Number of Employed Hours: 3792
Description of Duties: General oversight of Operations to include receiving, inventory management, and shipping activities for this site.			

Business Name: Not Applicable			From - To (MM/YY – MM/YY): Not Applicable
Business Address: Not Applicable	City: Not Applicable	State: NA	Zip: NA
Phone: Not Applicable	Title: Not Applicable		Number of Employed Hours: Not Applicable
Description of Duties: Not Applicable			

Business Name: Not Applicable			From - To (MM/YY – MM/YY): Not Applicable
Business Address: Not Applicable	City: Not Applicable	State: NA	Zip: NA
Phone: Not Applicable	Title: Not Applicable		Number of Employed Hours: Not Applicable
Description of Duties: Not Applicable			

Business Name: Not Applicable			From - To (MM/YY – MM/YY): Not Applicable
Business Address: Not Applicable	City: Not Applicable	State: NA	Zip: NA
Phone: Not Applicable	Title: Not Applicable		Number of Employed Hours: Not Applicable
Description of Duties: Not Applicable			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)
Not Applicable		Not Applicable
Business Address: Not Applicable	City: Not Applicable	State: NA / Zip: NA
Phone: Not Applicable	Title: Not Applicable	Number of Employed Hours: Not Applicable
Description of Duties: Not Applicable		

Business Name		From - To (MM/YY – MM/YY)
Not Applicable		Not Applicable
Business Address: Not Applicable	City: Not Applicable	State: NA / Zip: NA
Phone: Not Applicable	Title: Not Applicable	Number of Employed Hours: Not Applicable
Description of Duties: Not Applicable		

Business Name		From - To (MM/YY – MM/YY)
Not Applicable		Not Applicable
Business Address: Not Applicable	City: Not Applicable	State: NA / Zip: NA
Phone: Not Applicable	Title: Not Applicable	Number of Employed Hours: Not Applicable
Description of Duties: Not Applicable		

Business Name		From - To (MM/YY – MM/YY)
Not Applicable		Not Applicable
Business Address: Not Applicable	City: Not Applicable	State: NA / Zip: NA
Phone: Not Applicable	Title: Not Applicable	Number of Employed Hours: Not Applicable
Description of Duties: Not Applicable		

Business Name		From - To (MM/YY – MM/YY)
Not Applicable		Not Applicable
Business Address: Not Applicable	City: Not Applicable	State: NA / Zip: NA
Phone: Not Applicable	Title: Not Applicable	Number of Employed Hours: Not Applicable
Description of Duties: Not Applicable		

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Not applicable	NA		Not applicable	Not applicable
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Not applicable		Not applicable		
Reason/Charge				
Not applicable				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Not applicable			Not applicable	
Name of Business/Industry/Entity				
Not applicable				

Provide explanation below:

This page not applicable

Original Signature (electronic, copies or stamps not accepted)

8/1/2025
Date

I, Kall g A Anderson, certify that as the designated representative for

Medtronic Logistics LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. __X_____ I am at least 21 years of age;
3. ____X___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____X___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____X___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. __X_____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____X___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kallie Anderson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/1/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kalley Anderson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/1/2025
Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Vigo

I, Kalley Anderson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/1/2025
Date

Subscribed and Sworn to before me this 4th day of Aug 2025

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Medtronic USA, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP00768

Physical Address: 1480 Arthur St

City: Louisville State: CO Zip: 80027

Mailing Address (if different from physical address): [redacted]

City: Erie State: CO Zip: [redacted]

Telephone: 763-237-4446 Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: kalley Middle: A Last: Anderson

Alias(es, nicknames, name changes, etc.): not applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Erie State: CO Zip: [redacted]

Telephone: 763-237-4446 Email: kalley.a.anderson@medtronic.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Wisconsin-Madison		09/2016 to 05/2020	
Address	City	State	Zip
1415 Engineering Dr.	Madison	WI	53706
Diploma/Degree obtained, if any			
BS Industrial and Systems Engineering			
School Name		From - To (MM/YY – MM/YY)	
Becker High School		09/2012 to 05/2016	
Address	City	State	Zip
12000 Hancock St SE	Becker	MN	55308
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
not applicable		notr applicable	
Address	City	State	Zip
not applicable	not applicable	NA	NA
Diploma/Degree obtained, if any			
not applicable			
School Name		From - To (MM/YY – MM/YY)	
not applicable		NOT APPLICABLE	
Address	City	State	Zip
not applicable	not applicable	NA	NA
Diploma/Degree obtained, if any			
Not Applicable			
School Name		From - To (MM/YY – MM/YY	
not applicable		not applicable	
Address	City	State	Zip
not applicable	not applicable	NA	NA
Diploma/Degree obtained, if any			
not applicable			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2024 TO PRES	[redacted]	ERIE	CO	[redacted]
11/2022 TO 2/2024		BLOOMFIELD	CO	
11/2021 TO 11/202		DENVER	CO	
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	NA	NA
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	NA	NA
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	NA	NA
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	NA	NA
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	NA	NA
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	NA	NA
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	NA	NA

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
MEDTRONIC USA INC			11/2023 TO PRESENT
Business Address	**City**	**State**	**Zip**
1480 ARTHUR ST	LOUISVILLE	CO	80027
Phone	**Title**		
3032429888	SR. LOGISTICS MANAGER		
Description of Duties			
MANAGER OF OPERATIONS (receiving, inventory control, material replenishment and shipping activities for this site)			

Business Name			From - To (MM/YY – MM/YY)
Medtronic			11/2021 to 09/2023
Business Address	**City**	**State**	**Zip**
5920 Longbow Dr	Boulder	CO	80301
Phone	**Title**		
7632374446	Op Ex Engineer		
Description of Duties			
Ran opex projects and program managed cost savings for the Boulder site			

Business Name			From - To (MM/YY – MM/YY)
3M			05/2020 to 09/2021
Business Address	**City**	**State**	**Zip**
1700 N Minnesota St	New Ulm	MN	56073
Phone	**Title**		
5073548271	Rotational Engineer		
Description of Duties			
PCBS manufacturing engineer who supported productivity and quality improvement projects			

Business Name			From - To (MM/YY – MM/YY)
not applicable (Attending college)			not applicable
Business Address	**City**	**State**	**Zip**
not applicable	not applicable	NA	NA
Phone	**Title**		
not applicabIre	not applicable		
Description of Duties			
not applicable			

Business Name			From - To (MM/YY – MM/YY)
not applicable			not applicable
Business Address	**City**	**State**	**Zip**
not applicable	not applicable	NA	NA
Phone	**Title**		
not applicable	not applicable		
Description of Duties			
not applicable			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
NA	NA	NA	NA	NA
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
NA		NA		
Reason/Charge				
NA				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
NA			NA	
Name of Business/Industry/Entity				
NA				

Provide explanation below:

NA

Original Signature (electronic, copies or stamps not accepted)

NA

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kalley Anderson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/28/2025
Date

Please have this section completed in the presence of a Notary Public.

State of Colorado, ss. County of Boulder

I, Kalley Anderson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/28/2025
Date

Subscribed and Sworn to before me this 28th day of March.

Notary Public Signature

JONAH DAHL
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID 20244025024
My Commission Expires: July 02, 2026

(Seal)

Employee ID	Legal Name - Last Name	Legal Name - First Name	Worker Type	Employee Type	Job Title
457056	McCurdy	Lynette	Employee	Regular	Project Coordinator III
297637	Mishra	Pratibha	Employee	Regular	Sr Supplier Qual Engineer
622512	Muradyan	Hailey	Contingent Worker		Manufacturing Contingent
129473	Nauman	Todd	Employee	Regular	Manufacturing Supervisor
579486	Patnamshetty	Girish Kumar	Contingent Worker		Engineering Contingent
238086	Phommachack	Touy	Employee	Regular	Manufacturing Tech II
237615	Ram	Saroeuth	Employee	Regular	Manufacturing Tech III
548704	Rayburn	James	Employee	Regular	Manufacturing Tech IV
571890	Richman	George	Contingent Worker		Engineering Contingent
98425	Riley	Randy	Employee	Regular	Technician IV
498666	Robinson	Gregory	Employee	Regular	Manufacturing Engineer II
623837	Schiller	Marie	Employee	Regular	Buyer/Planner
456597	Se	Hong	Employee	Regular	Manufacturing Tech II
551590	Sepulveda	Tiffany	Employee	Regular	Manufacturing Tech II
637140	SMITH	JUSTIN	Contingent Worker		Engineering Contingent
96182	Snyder	Scott	Employee	Regular	Prin Supplier Qual Engineer
581044	Sorensen	Blake	Employee	Regular	Ship/Rec/Stores Clerk II
500927	Sorensen	Cayden	Employee	Regular	Ship/Rec/Stores Clerk III
430560	Spence	Emily	Employee	Regular	Supplier Qual Engineer II
323383	Spencer	Kareem	Employee	Regular	Expeditor II
367005	Sujatha Karun	Rashmi	Employee	Regular	Sr Engineering Manager
508565	Sullivan	Andrea	Employee	Regular	Manufacturing Engineer II
89011	Taccogno	Anthony	Employee	Regular	Engineering Tech V
528515	Taccogno	Paige	Employee	Regular	Inventory Clerk II
589770	Tetamore	Gabriella	Contingent Worker		Manufacturing Contingent
351202	Torres	Randy	Employee	Regular	Technician III
571199	Touch	Anthony	Employee	Regular	Inventory Clerk II
527942	Ung	Sunny	Employee	Regular	Manufacturing Tech II
574856	Voelkel	Duke	Contingent Worker		Engineering Contingent
567109	Worasilpchai	Satiean	Employee	Regular	Sr Quality Engineer
232784	Xiong	Bobi	Employee	Regular	Manufacturing Tech IV

4QQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1. General Information

Facility Name: Medtronic USA, Inc. dba Medtronic Logistics LLC

Physical Address: 4620 N Beach St

City: Ft. Worth State: TX Zip: 76137

Mailing Address (if different from physical address): Attn: Kay Knox 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: WWW.MEDTRONIC.COM

Name of Designated Representative (DR): Mark Rainwater

Licensing Company Email: kay.knox@cevalogistics.com DR Email: mark.rainwater@medtronic.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/24/2017	3/20/2018	CO	Parker	Douglas County (Colorado)
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2017-3679		Colorado Board of Pharmacy		
Reason/Charge				
Failure to report change of designated representative within 30 days				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Medtronic Logistics LLC		Fine and surcharge		
Name of Business/Industry/Entity				
Medtronic Logistics LLC				

Provide explanation below:

Medtronic Logistics LLC (CO License WHI 6007) was disciplined for failure to timely report a change of Designated Representative within the require 30 day time period.

Terms of discipline: A fine with surcharge $1150. Medtronic Logistics LLC agreed to comply with Colorado regulations related to pharmacy businesses including timely reporting of Designated Representative changes with payment of associated fees going forward.

Rob Ur

Original Signature (electronic, copies or stamps not accepted)

9-24-24

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # ___3___. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
4/3/2018	1/23/2019	CO	Parker	Douglas County (Colorado)

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
19-L-0013	Alabama State Board of Pharmacy

Reason/Charge
Failure to report Colorado disciplinary actions as required by Alabama regulations/rules

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Medtronic Logistics LLC	Consent Order with administrative fine $2000

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Count 1: (Alabama permit #194466)
Medtronic Logistics LLC, was disciplined for receiving Colorado Stipulation and Final Agency Order (2017-3679)

Count 2:
Medtronic Logistics LLC failed to report the Colorado Stipulation and Final Agency Order (2017-3679) on the Alabama 2019-2020 Renewal Application

Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
1/7/2021	7/12/2021	CO	Parker	Douglass County, (Colorado)
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2021-PHA-17242		Maine Board of Pharmacy		
Reason/Charge				
Failure to report disciplinary actions in CO and ME in timely manner				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Medtronic Logistics LLC		Consent Agreement $2000		
Name of Business/Industry/Entity				
Medtronic Logistics LLC				

Provide explanation below:

Medtronic Logistics LLC (Maine permit # WH70002083)

Issue 1
Medtronic Logistics LLC failed to report Colorado disciplinary action (2017-3679) to Maine within 10 days and did not reveal the same action at the time of renewal 12/12/2018. The Maine Board was not made aware of this action until 2/3/2020.

Issue 2
Medtronic Logistics LLC failed to report the Alabama disciplinary actions (19-L-0013) filed against the company within 10 days. The Maine Board of pharmacy was not made aware of this action until 7/18/2019.

Rob U

Original Signature (electronic, copies or stamps not accepted)

9-24-24

Date

Medtronic

Medtronic Logistics LLC has experienced the below disciplinary actions:

- Case # 2017-3679 (Colorado) CLS Stipulation and fine ($1150) , Medtronic Logistics LLC, Parker CO, Lic # WHI.0006007
  - Failure to report change of designated representative for 13 months when required to do so within 30 days.
- Case # 19-L-0013 (Alabama) Consent Order with administrative fine $2000, Medtronic Logistics LLC, Parker CO, Lic # 194466
  - CO Case # 2017-3679 CLS Stipulation issued
  - Failure to disclose the Colorado case # 2017-3679 when renewing the 2019-2020 application.
- Case # 2021-PHA-17242 (Maine) Consent Agreement with reprimand and civil penalty $2000 issued to Medtronic Logistics LLC, Parker CO, Lic # WH70002083
  - Failure to report the Colorado case # 2017-3679 within 10 days of final disposition.
  - Failure to report the Colorado case # 2017-3679 on the Maine 2019-2020 renewal application
  - Failure to report the Alabama Case # 19-L-0013 to Maine within 10 days as required by 10 MRS 8003-G(2)(C)

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2017-3679

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MEDTRONIC LOGISTICS, LLC, REGISTRATION NO. WHI 6007,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medtronic Logistics, LLC ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2017-3679, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2017).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 7, 2006, being issued registration number WHI 6007, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 18501 Plaza Dr., Parker, CO 80134.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, thirteen (13) months transpired between May 31, 2016, date the previous designated representative ceased the position, and June 27, 2017, the date the application and fee were received.

6. Respondent Outlet was required to report a change of designated representative to the Board within thirty (30) days of such change.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board;

(k) Has failed to meet generally accepted standards of pharmacy practice.

12-42.5-303. Wholesaler license requirements.

(5) The designated representative of an applicant for a wholesaler license shall:

(i) Update all of the information required in this part 3 whenever changes occur.

Pharmacy Board Rules and Regulations

15.01.11 Minimum required information for registration.

b. Changes in any information in section 15.01.11 shall be submitted to the Board within thirty calendar days thereof.

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall

impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one (1) lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board. Respondent Outlet shall write its registration number (WHI 6007) and the case number (2017-3679) on the check.

9. **Compliance.** Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges.

c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. to appeal this Final Agency Order.

Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none

of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Completion of Terms.** Upon satisfactory completion of all terms and conditions set forth in this Final Agency Order, the Board shall release Respondent Outlet from the Final Agency Order, and Respondent Outlet's registration will be restored to active and unencumbered status.

15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. **Public Record**. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative

18. **Effective Date**. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

Lynette Ford
Authorized Representative

Dated: 3/20/18

License Compliance Analyst
Name / Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 3nd day of April, 2018.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MEDTRONIC LOGISTICS LLC	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit No. 194466	)	CASE NO: 19-L-0013
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Medtronic Logistics LLC (hereinafter referred to as "Medtronic") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties have agreed to informally resolve this matter by the entry of this Consent Order the terms of which are as follows:

1. The Board finds that Medtronic violated the applicable provisions based upon the conduct set out in each and every Count of the Statement.

2. Medtronic shall pay to the Board an administrative fine in the amount of Two Thousand dollars ($2,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and Medtronic shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Medtronic expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12) Code of Alabama (1975) §41-22-12 and §40-22-20 and Code of Alabama (1975) § 20-2-50 et seq and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review Medtronic further waives any objection to the attorney for the Board preparing drafting or making this Order including the waiver of any objection or right pursuant to Code of Alabama (1975) §41-22-18

4 By execution of this Consent Order Medtronic hereby releases the Board its members agents representatives servants and employees from any and all liability claims damages fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement

5 That Medtronic agrees that any further violation of the Alabama Pharmacy Practice Act the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may upon proof and hearing thereof result in further disciplinary sanctions against its license

6 That Medtronic acknowledges stipulates and agrees that it has read this Consent Order and that it fully understands the terms conditions and contents of the same Medtronic acknowledges stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion duress or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order

DONE this the 10th day of June 2019

Medtronic Logistics LLC

By Tracy Mercer
Its Director, Distribution Strategy

DONE this the 19th day of June 2019

ALABAMA STATE BOARD OF PHARMACY

By Kenny Sanders
Kenny Sanders, President

By
James [illegible]
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
MEDTRONIC LOGISTICS LLC	)	**BOARD OF PHARMACY**
Wholesale Distributor Permit No. 194466	)	**CASE NO: 19-L-0013**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: **Medtronic Logistics LLC**
18501 E Plaza Drive
Parker, Colorado 80134

Pursuant to the provisions of Code of Alabama (1975) § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975) § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on _____ 2019 at _____ m. at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Medtronic Logistics LLC (Medtronic) as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that Medtronic has been guilty of the following, to-wit:

1. Board Rule 680-X-2-.23 is entitled Drug Manufacturers' Wholesale Distributors.

2. Board Rule 680-X-2-.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors

include

(a) Compliance with licensing requirements under previously granted license, if any

(b) Compliance with the requirements to maintain records required to be maintained

(c) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution

(d) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety

3 Board Rule 680-X-2 23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health

4 Board Rule 680-X-2 23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no 100 Dollars ($1,000) for each violation

5 Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law

6 Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the

public safety or endangers the public health of the citizens of this state based upon the entry of a Stipulation and Final Agency Order by the Colorado State Board fo Pharmacy on April 3, 2018 attached hereto as Exhibit "A" and or your failure to notify the Colorado Board of a change in your designated representative for thirteen (13) months when required to do so in thirty (30) days

COUNT TWO

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit and or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your failure to disclose when required to do so on your 2019-2020 Renewal Application the Colorado discipline referenced above

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 23rd day of January 2019.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MEDTRONIC LOGISTICS LLC	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17242	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Medtronic Logistics LLC, for the renewal of its pharmaceutical wholesaler license. The parties to this Consent Agreement are: Medtronic Logistics LLC ("Medtronic"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since February 27, 2013, Medtronic has been licensed in Maine as a pharmaceutical wholesaler with a registered location of 18501 Plaza Drive, Parker, Colorado (license number **WH70002083).**

2. On April 3, 2018, the Colorado State Board of Pharmacy imposed discipline against Medtronic's Colorado registration (WHI 6007) pursuant to a Stipulation and Final Agency Order in Case No. 2017-3679.

3. Medtronic failed to report the Colorado discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On December 12, 2018, the Board received Medtronic's renewal application.

5. On that application, Medtronic responded "No" to the following question: "Since your last renewal, has any jurisdiction taken disciplinary action against any professional license you hold (except this license) or have held or denied your application for licensure?"

6. The Board accordingly renewed Medtronic's pharmaceutical wholesaler license.

7. On June 19, 2019, the Alabama State Board of Pharmacy imposed discipline against Medtronic's Alabama permit (194466) pursuant to a Consent Order in Case No.19-L-0013.

8. Medtronic failed to report the Alabama discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

9. On July 18, 2019, Medtronic reported to the Board for the first time that the Alabama State Board of Pharmacy had disciplined its permit.

10. On February 3, 2020, Medtronic reported to the Board for the first time that the Colorado State Board of Pharmacy had disciplined its registration.

11. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

12. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny Medtronic's application for renewal of its license to be a pharmaceutical wholesaler. In lieu of the denial, the Board also voted to offer Medtronic this Consent Agreement. Unless Medtronic either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME

04333-0035, by **July 12, 2021,** the preliminary denial of Medtronic's application for licensure as a pharmaceutical wholesaler will become final.

COVENANTS

13. Medtronic admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline as follows:

a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken; and

b. Pursuant to 10 M.R.S. § 8003(5-A)(A)(1), for making a misrepresentation to the Board on its December 12, 2018 application for renewal of licensure.

14. As discipline for the violation admitted to in paragraph 13 above, Medtronic agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of two thousand dollars ($2,000.00), which penalty is comprised of $1,500.00 for misrepresentation on its application and $500.00 for failing to report discipline within 10 days, payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, and must be submitted with the signed Consent Agreement.

15. Upon receipt of this signed Consent Agreement with the enclosed payment of the civil penalty from Medtronic, the Board will renew Medtronic's license contingent upon it meeting all other eligibility criteria.

16. Violation of any of the terms or conditions of this Consent Agreement by Medtronic shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

17. The Board and Medtronic agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Medtronic fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Medtronic, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving Medtronic. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Medtronic.

18. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

19. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

20. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

21. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

22. Medtronic acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 6/11/21

MEDTRONIC LOGISTICS LLC

By: _____

Print Name: Philip J Albert

Title: Vice President

DATED: 7/8/21

BRADLEY S. HAMILTON, R.Ph., PRESIDENT
Maine Board of Pharmacy

DATED: 7/9/21

JOHN NICHOLS
Assistant Attorney General

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medtronic Puerto Rico Operations (MPRI)
Address: P.O. Box 6001 City: Villalba State: PR Zip: 00766

Name: Medtronic Ireleand Manufacturing UC
Address: Parkmore Business Park West City: Galway State: Irelan Zip: IRE

Name: Medtronic Sophons
Address: 5744 Central Abe, Suite 100 City: Boulder State: CO Zip: 80301

Name: Medtronic Puerto Rico Operations CO
Address: Rd 31 KM 24 HM 4 Ceiba N Indus City: Juncos State: PR Zip: 00777

Section 4: Publicly Traded Corporation

State of Incorporation: Not Applicable
Parent Company (if any): Not Applicable
Corporation Name: Not Applicable
Mailing Address: Not Applicable
City: Not Applicable State: Not Applicabl Zip: Not Applicable
Telephone: Not Applicable Email: Not Applicable
Contact Person Name: Not Applicable
Date of SEC Registration: Not Applicable SEC Registration Number: Not Applicable Stock Exchange Symbol: Not Applica

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Medtronic Inc.
Corporation/Organization Name: Medtronic USA, Inc.
Mailing Address: 710 Medtronic Pkwy, LS245
City: Minneapolis State: MN Zip: 55432
Telephone: 508-261-6083 Email: rob.varner@medtronic.com
Contact Person Name: Robert Varner

Section 6: Partnership

Partnership Name: not applicable
Mailing Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable
Contact Person Name: not applicable

Section 7: Sole Owner

Owner's Name: not applicable
Business Name: not applicable
Business Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medtronic USA, Inc., dba Medtronic Logistics LLC, 1480 Arthur St, Louisville CO 80027

Facility Name

Robert Varner

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9-24-24

Date

Board Use Only	Date Received: 10/14/24	Amount: $1000-cc

New Search | Back To Search Results

Establishment:
Medtronic Neurosurgery
4620 North Beach Street
Fort Worth, TX 76137
Registration Number: 3015531529
FEI Number*: 3015531529
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN US 55432
Owner/Operator Number: 2112641

Official Correspondent:
Rishi K Sinha
200 Medtronic Drive
Lafayette, CO 80026
Phone: 720-8902485

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Medtronic USA Inc. Officer List

Name	company title	Business Address
Robert Varner	President	4380 Swinnea Rd, Bldg B Memphis TN 38118
Dov Shenkman	Vice President	640 Orchard Ln. Glencoe IL 60022
Punit Menon	Vice President	4536 N Wildwood Ave. Shorewood, WI 53211

September 19, 2024

Nevada State Board of Pharmacy

985 Damonte Ranch PKWY, Suite 206
Reno, NV 89521

Medtronic USA, Inc. maintains 100% ownership of Medtronic Logistics LLC:

Organizational Chart



Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Medtronic USA, Inc.
Date Filed:	06/15/1984
File Number:	4R-233
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 12/18/2024

Steve Simon
Secretary of State
State of Minnesota

Business Record Details »

Minnesota Business Name
Medtronic Logistics LLC

Business Type
Limited Liability Company (Domestic)

File Number
618784400037

Filing Date
9/18/2012

Renewal Due Date
12/31/2025

Registered Agent(s)
Corporation Service Company

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

MN Statute
322C

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2345 Rice Street
Suite 230
Roseville, MN 55113-5603
USA

Manager
Greg Smith
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
USA

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	9/18/2012	Original Filing - Limited Liability Company (Domestic) (Business Name: Medtronic Logistics LLC)	
☐	9/16/2016	Registered Office and/or Agent - Limited Liability Company (Domestic)	
	1/1/2018	Conversion to 322C Due to Statute Mandate – Limited Liability Company (Domestic)	
☐	5/15/2018	Registered Office and/or Agent - Limited Liability Company (Domestic)	

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Vulnerability Disclosure

 Nevada, Ft Worth , pg 15

Business Record Details »

Minnesota Business Name
Medtronic USA, Inc.

Business Type
Business Corporation (Domestic)

File Number
4R-233

Filing Date
06/15/1984

Renewal Due Date
12/31/2024

Number of Shares
1,000

Chief Executive Officer
Jennifer Kirk
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

MN Statute
302A

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2345 Rice Street
Suite 230
Roseville, MN 55113-5603
USA

Registered Agent(s)
Corporation Service Company

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	06/15/1984	Original Filing - Business Corporation (Domestic)	
☐	06/15/1984	Business Corporation (Domestic) Business Name (Business Name: MEDTRONIC MILACA, INC.)	

	Filing Date	Filing	Effective Date
☐	03/14/1989	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	10/06/1995	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	12/11/1997	Business Corporation (Domestic) Business Name (Business Name: Medtronic USA, Inc.)	
	12/11/1997	Business Corporation (Domestic) Restated Articles	
☐	10/29/1998	Merger - Business Corporation (Domestic)	
☐	04/10/2007	Global Registered Office and/or Agent - Business Corporation (Domestic)	
☐	9/16/2016	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	5/17/2018	Registered Office and/or Agent - Business Corporation (Domestic)	

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- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/medical-device-manufacturers-distributors.**
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey.** The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

MEDTRONIC LOGISTICS LLC ATTN KAY KNOX
4097 E MAROUETTE AVE
TERRE HAUTE IN 47805

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

MEDTRONIC USA INC DBA
MEDTRONIC LOGISTICS LLC
4620 N BEACH ST
FORT WORTH, TX 76137

Pursuant to Health and Safety Code, Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE MANUFACTURER

License # 1001111
Expires: March 6, 2027

NON-TRANSFERABLE

Commissioner

514956

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 02/26/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400	**CONTACT NAME:** Marsh | U.S. Operations & Technology **PHONE (A/C, No, Ext):** 866-966-4664 **FAX (A/C, No):** 212-948-5382 **E-MAIL ADDRESS:** Minneapolis.CertRequest@marsh.com
INSURED Medtronic, Inc. and its subsidiaries 710 Medtronic Parkway LC310 Minneapolis, MN 55432	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** ACE American Insurance Company — 22667 **INSURER B :** Indemnity Insurance Company of North America — 43575 **INSURER C :** ACE Fire Underwriters Insurance Company — 20702 **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CHI-010895207-01 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X **COMMERCIAL GENERAL LIABILITY** X CLAIMS-MADE ☐ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY ☐ PRO-JECT ☐ LOC OTHER:			SPL G24561288 008	05/01/2024	05/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	5,000,000 1,000,000 10,000 1,000,000 15,000,000 15,000,000
A	**AUTOMOBILE LIABILITY** X ANY AUTO OWNED AUTOS ONLY ☐ SCHEDULED AUTOS HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY			ISAH10832810	05/01/2024	05/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	1,000,000
	☐ **UMBRELLA LIAB** ☐ OCCUR **EXCESS LIAB** ☐ CLAIMS-MADE DED ☐ RETENTION $						EACH OCCURRENCE AGGREGATE	$ $	
B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		WLRC57196166 (AOS) (incl Stop Gap EL: MN,ND,OH,WA,WY) WLRC57196257 (MO,NC,NE,OK) SCFC57196518 (PA)	05/01/2024 05/01/2024 05/01/2024	05/01/2025 05/01/2025 05/01/2025	X PER STATUTE ☐ OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
C	Workers Compensation continued			SCFC57196439 (WI)	05/01/2024	05/01/2025	Limit:		See Above
A	Excess Workers Compensation			WCUC57196567 (AZ) excess of $1M SIR	05/01/2024	05/01/2025	Limit:		1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance.

RE: 4340 Swinnea Rd, Memphis TN 38118; 6743 Southpoint Dr, Jacksonville FL 32216; 1480 Arthur St, Louisville CO 80027; 4620 N Beach St,. Ft Worth TX 76137; 18501 E Plaza Dr., Parker CO 80134; 7611 Northland Dr., Brooklyn Park MN 55428 5300 Airways Blvd, Suite 101, Memphis TN 38116; 2235 Route 322, Suite 200, Swedesboro NJ 08085

CERTIFICATE HOLDER

Medtronic Inc
Attn: LS370
710 Medtronic Parkway
Minneapolis, MN 55432

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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AGENCY CUSTOMER ID: CN103154363
LOC #: Minneapolis

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC	Medtronic, Inc. and its subsidiaries 710 Medtronic Parkway LC310 Minneapolis, MN 55432
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Professional Health Care Liability:
Policy # SPL G24561288 008
05/01/2024 - 05/01/2026
Carrier: ACE American Insurance Company
$2,000,000 Each Claim
$15,000,000 Aggregate

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SURETY RIDER

To be attached to and form a part of

Bond No. 190054165

dated effective October 2, 2023
(MONTH-DAY-YEAR)

executed by Medtronic USA, Inc. , as Principal,
(PRINCIPAL)

and by Liberty Mutual Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

ADDING COVERED LOCATIONS:

4340 Swinnea Rd, Memphis TN 38118
18501 E Plaza Dr., Parker CO 80134
6743 Southpoint Dr, Jacksonville FL 32216
4620 N Beach St,. Ft Worth TX 76137
5300 Airways Blvd, Suite 101, Memphis TN 38116
7611 Northland Dr., Brooklyn Park MN 55428
1480 Arthur St, Louisville CO 80027
2235 Route 322, Swedesboro NJ 08085

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective November 26, 2024
(MONTH-DAY-YEAR)

Signed and Sealed November 26, 2024
(MONTH-DAY-YEAR)

Medtronic USA, Inc.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Liberty Mutual Insurance Company
(SURETY)

By: Cynthia L. Choren
Cynthia L. Choren, Attorney-In-Fact
NV Non-Resident License No. 221080

S-0443/GEEF 10/99

Liberty Mutual. SURETY

POWER OF ATTORNEY

Certificate No: 8204865

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechenically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of November, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Marsh MSurety POA LMIC OCIC WAIC Multi Co_092024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 190054165

Application/License No. _____

Medtronic USA Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5300 Airways Blvd., Memphis, TN 38116 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 5, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of October, 2023.

APPLICANT/PRINCIPAL

Medtronic USA Inc

Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact

print name

NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Brittany D. Stuckel

Witness Heidi A. Notheisen

Countersigned by:

N/A

Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren

all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 5th day of October 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Marsh MSurety POA LMIC OCIC WAIC Multi Co_022021

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medtronic USA, Inc. dba Medtronic Logistics LLC MDEG License # (if applicable): MP00769

Physical Address: 4620 N. Beach St.

City: Fort Worth State: TX Zip: 76137

Mailing Address (if different from physical address): Attn: Kay Knox, 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Mark Middle: Douglas Last: Rainwater

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 4620 N. Beach St.

City: Fort Worth State: TX Zip: [redacted]

Telephone: [redacted] Email: mark.d.rainwater@medtronic.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Texas A&M University			09/89 - 12/92
Address	**City**	**State**	**Zip**
120 Spence	College Station	TX	77843
Diploma/Degree obtained, if any			
Bachelor of Arts - Political Science			

School Name			From - To (MM/YY – MM/YY)
Austin College			09/88 - 05/89
Address	**City**	**State**	**Zip**
900 N. Grand Ave.	Sherman	TX	75090
Diploma/Degree obtained, if any			
N/A			

School Name			From - To (MM/YY – MM/YY)
Arlington High School			09/85 - 05/88
Address	**City**	**State**	**Zip**
818 W. Park Row	Arlington	TX	76013
Diploma/Degree obtained, if any			
High School Dipolma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
N/A			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/03 - Present	[redacted]	Pantego	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medtronic			10/08 - present	
Business Address		**City**	**State**	**Zip**
4620 N. Beach		Fort Worth	TX	76137
Phone	**Title**		**Number of Employed Hours**	
817-788-6588	Director Americas Depots		33,280	
Description of Duties				
Management of employees engaged in the receipt, diagnostics, repair and testing of medical equipment.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

N/A

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address		City	State / Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address		City	State / Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address		City	State / Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address		City	State / Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address		City	State / Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Oct 3, 2024
Date

I, Mark Rainwater, **certify that as the MDEG Administrator for**

Medtronic plc,

that I (initial that you have read and meet the following requirements):

MR 1. Yes Have a high school diploma or its equivalent;

MR 2. Yes Have

a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or

b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;

MR 3. Yes Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and

MR 4. Yes Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Rainwater

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Oct 3, 2024

Date

Board Use Only	Date Received: 10/4/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Medtronic USA, Inc. dba Medtronic Logistics LLC

Pharmacy/Wholesaler License # (if applicable) NA

Physical Address 4620 N. Beach

City Fort Worth State TX Zip 76137

Mailing Address (if different from physical address) Attn: Kay Knox, 4097 E Marquette Ave

City Terre Haute State IN Zip 47805

Telephone 614-489-5164 Website www.medtronic.com

Licensing Company Email kay.knox@cevalogistics.com

Section 2: Personal Information

First Mark Middle Douglas Last Rainwater

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 4620 N. Beach

City Fort Worth State TX Zip 76137

Telephon[redacted] Email mark.d.rainwater@medtronic.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Texas A&M University		09/89 - 12/92	
Address	**City**	**State**	**Zip**
120 Spence	College Station	TX	77843
Diploma/Degree obtained, if any			
Bachelor of Arts - Political Sciece			

School Name		From - To (MM/YY – MM/YY)	
Austin College		09/88 - 05/89	
Address	**City**	**State**	**Zip**
900 N. Grand Ave	Sherman	TX	75090
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Arlington High School		09/85-05/88	
Address	**City**	**State**	**Zip**
818 W. Park Row	Arlington	TX	76013
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/03 - Present	[redacted]	Pantego	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Medtronic			10/08 - Present	
Business Address		**City**	**State**	**Zip**
4620 N. Beach St		Fort Worth	TX	76137
Phone	**Title**		**Number of Employed Hours**	
817-788-6598	Director Americas Depots		33,280	
Description of Duties				
Management of employees engaged in the receipt, diagnostics, repair, and testing of medical equipment.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

N/A

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Oct 3, 2024
Date

I, Mark Rainwater, **certify that as the designated representative for**

Medtronic, plc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

mr 1. Yes I am at least 21 years of age;
mr 3. Yes I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
mra. Yes I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
mr 5. Yes I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
mr 6. Yes I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
mr 7. Yes I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Mark Rainwater
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Oct 3, 2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Rainwater

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Oct 8, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Tarrant

I, Mark Rainwater, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Oct 8, 2024

Date

Subscribed and Sworn to before me this 8th day of October 2024

Notary Public Signature

LORI JACK
My Notary ID # 11407275
Expires November 5, 2026
(Seal)

Medtronic Logistics LLC employee list, Ft. Worth TX, 10/11/24

- Shipping:
  - Billy Troy
  - Isidro Carrillo
  - Maria Melendez
- Receiving:
  - Kimberly Savage
  - Ruben Alvarez
- Quality:
  - Charlene Sandoval
  - Patricia Duran
  - Sonia Lemus

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH not applicable	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Medtronic USA, Inc dba Medtronic Logistics LLC

Physical Address: 2235 Route 322, Suite 200

City: Swedesboro State: NJ Zip: 08085

Mailing Address (if different from physical address): Not Applicable

City: Not Applicable State: NA Zip: NA

Telephone: 614-489-5164 Website: www.medtronic.com

Name of Designated Representative (DR): John N Bell

Licensing Company Email: kay.knox@cevalogistics.com DR Email: john.n.bell@medtronic.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
6/24/2017	3/20/18	CO	Parker	Douglas County (Colorado)
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2017-3679		Colorado Board of Pharmacy		
Reason/Charge				
Failure to report change of designated representative within 30 days				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Medtronic Logistics LLC		fine and surcharge		
Name of Business/Industry/Entity				
Medtronic Logistics LLC				

Provide explanation below:

Medtronic Logistics LLC is owned by Medtronic USA, Inc and was disciplined in 3 states.

Medtronic Logistics LLC (Colorado License WHI6007) was disciplined for failure to timely report a change of Designated Representative within the required 30 day time period.

Terms of discipline: A fine with surcharge $1150. Medtronic Logistics LLC agreed to comply with Colorado regulations related to pharmacy businesses including timely reporting of Designated Representative changes with payment of associated fees going forward.

Rob Ul

Original Signature (electronic, copies or stamps not accepted)

8-21-24

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 Provide all the following *where applicable:*

Date of Event/Arrest	Disposition Date	State	City	County
1/7/2021	7/12/21	CO	Parker	Douglas County (Colorado)

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2021-PHA-17242	Maine Board of Pharmacy

Reason/Charge
Failure to report disciplinary actions in CO and AL in a timely manner

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Medtronic Logistics LLC	Consent Agreement $2000

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Medtronic Logistics LLC (Maine Permit # WH70002083)

Issue #1
Medtronic Logistics LLC failed to report Colorado disciplinary action (2017-3679) to Maine within 10 days and did not reveal the same action at the time of renewal 12/12/2018. The Maine Board was not made aware of this action until 2/3/2020

Issue #2
Medtronic Logistics LLC failed to report the Alabama disciplinary actions (19-L-0013) filed against the company within 10 days. The Maine Board of Pharmacy was not made aware of this action until 7/18/2019.

Original Signature (electronic, copies or stamps not accepted)

8-21-24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 **Provide all the following *where applicable:***

Date of Event/Arrest	Disposition Date	State	City	County
4/3/2018	1/23/2019	CO	Parker	Douglass County, (Colorado)
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
19-L-0013		Alabama State Board of Pharmacy		
Reason/Charge				
Failure to report Colorado disciplinary actions as required by Alabama regulations/rules				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Medtronic Logistics LLC		Consent order with administrative fine $2000		
Name of Business/Industry/Entity				
Medtronic Logistics LLC				

Provide explanation below:

Count 1 (Alabama permit # 194466
Medtronic Logistics LLC was disciplined for receiving Colorado Stipulation and Final Agency Order (2017-3679)

Count 2
Medtronic Logistics LLC failed to report the Colorado Stipulation and Final Agency Order (2017-3679) on the Alabama 2019 -2020 renewal application

Original Signature (electronic, copies or stamps not accepted)

8-21-24
Date

Due to the sudden departure of Medtronic's licensing specialist, CEVA Logistics US, Inc. assumed responsibility for management of Medtronic licenses in July 2023. As part of the due diligence in this project, CEVA reviewed all state license verification sites to determine the extent of Medtronic licenses and to identify reportable disciplinary sanctions against the company. The below listed actions were revealed.

In an effort to establish and maintain an open dialogue, we are reporting the below actions.

Medtronic Logistics LLC has experienced the below disciplinary actions:

- Case # 2017-3679 (Colorado) CLS Stipulation and fine ($1150) , Medtronic Logistics LLC, Parker CO, Lic # WHI.0006007
    - Failure to report change of designated representative for 13 months when required to do so within 30 days.
- Case # 19-L-0013 (Alabama) Consent Order with administrative fine $2000, Medtronic Logistics LLC, Parker CO, Lic # 194466
    - CO Case # 2017-3679 CLS Stipulation issued
    - Failure to disclose the Colorado case # 2017-3679 when renewing the 2019-2020 application.
- Case # 2021-PHA-17242 (Maine) Consent Agreement with reprimand and civil penalty $2000 issued to Medtronic Logistics LLC, Parker CO, Lic # WH70002083
    - Failure to report the Colorado case # 2017-3679 within 10 days of final disposition.
    - Failure to report the Colorado case # 2017-3679 on the Maine 2019-2020 renewal application
    - Failure to report the Alabama Case # 19-L-0013 to Maine within 10 days as required by 10 MRS 8003-G(2)(C)

After the original disciplinary action was implemented, Medtronic implemented processes to ensure states were notified as required when a change of designated representatives occurred. Medtronic recently initiated a contractual agreement with CEVA Logistics US, Inc. (CEVA) to assume management responsibility of Medtronic licenses. CEVA follows established procedures to perform continued regulatory review of state regulations pertaining to manufacture and distribution of medical devices.

CEVA procedures and training documents may be provided upon request.

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2017-3679

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MEDTRONIC LOGISTICS, LLC, REGISTRATION NO. WHI 6007,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medtronic Logistics, LLC ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2017-3679, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2017).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 7, 2006, being issued registration number WHI 6007, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 18501 Plaza Dr., Parker, CO 80134.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, thirteen (13) months transpired between May 31, 2016, date the previous designated representative ceased the position, and June 27, 2017, the date the application and fee were received.

6. Respondent Outlet was required to report a change of designated representative to the Board within thirty (30) days of such change.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board;

(k) Has failed to meet generally accepted standards of pharmacy practice.

12-42.5-303. Wholesaler license requirements.

(5) The designated representative of an applicant for a wholesaler license shall:

(i) Update all of the information required in this part 3 whenever changes occur.

Pharmacy Board Rules and Regulations

15.01.11 Minimum required information for registration.

b. Changes in any information in section 15.01.11 shall be submitted to the Board within thirty calendar days thereof.

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall

impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one (1) lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board. Respondent Outlet shall write its registration number (WHI 6007) and the case number (2017-3679) on the check.

9. **Compliance**. Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. **Other Requirements**. Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers**. Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges.

c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. to appeal this Final Agency Order.

Respondent Outlet freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments**. The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none

of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Completion of Terms.** Upon satisfactory completion of all terms and conditions set forth in this Final Agency Order, the Board shall release Respondent Outlet from the Final Agency Order, and Respondent Outlet's registration will be restored to active and unencumbered status.

15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative

18. **Effective Date.** This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MEDTRONIC LOGISTICS LLC	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit No. 194466	)	CASE NO: 19-L-0013
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Medtronic Logistics LLC (hereinafter referred to as "Medtronic") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that Medtronic violated the applicable provisions based upon the conduct set out in each and every Count of the Statement.

2. Medtronic shall pay to the Board an administrative fine in the amount of Two Thousand dollars ($2,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and Medtronic shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Medtronic expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

ACCEPTED AND AGREED BY

Respondent Outlet

Authorized Representative Dated: 3/20/18

License Compliance Analyst
Name / Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 3nd day of April, 2018.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

(1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975) §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Medtronic further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Medtronic hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That Medtronic agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Medtronic acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Medtronic acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 10th day of June 2019

Medtronic Logistics LLC

By: Cathy Mercuro
Its: Sr. Manager, Compliance Oversight

DONE this the 19th day of June 2019

ALABAMA STATE BOARD OF PHARMACY

By: Kenny Sanders
Kenny Sanders, R Ph., President

By: James S. Ward
James S. Ward
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MEDTRONIC LOGISTICS LLC	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit No. 194466	)	CASE NO: 19-L-0013
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: **Medtronic Logistics LLC**
18501 E Plaza Drive
Parker, Colorado 80134

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 15, 2019 at 9:00 a.m. at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242 and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Medtronic Logistics LLC (Medtronic) as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that Medtronic has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors

include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to be maintained.

(c) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution.

(d) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

6. Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the

public safety or endangers the public health of the citizens of this state based upon the entry of a Stipulation and Final Agency Order by the Colorado State Board fo Pharmacy on April 3, 2018 attached hereto as Exhibit "A" and/or your failure to notify the Colorado Board of a change in your designated representative for thirteen (13) months when required to do so in thirty (30) days

COUNT TWO

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your failure to disclose when required to do so on your 2019-2020 Renewal Application the Colorado discipline referenced above.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 23rd day of January 2019

ALABAMA STATE BOARD OF PHARMACY

By: Donna C Yeatman
Executive Secretary

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MEDTRONIC LOGISTICS LLC	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17242	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Medtronic Logistics LLC, for the renewal of its pharmaceutical wholesaler license. The parties to this Consent Agreement are: Medtronic Logistics LLC ("Medtronic"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since February 27, 2013, Medtronic has been licensed in Maine as a pharmaceutical wholesaler with a registered location of 18501 Plaza Drive, Parker, Colorado (license number **WH70002083**).

2. On April 3, 2018, the Colorado State Board of Pharmacy imposed discipline against Medtronic's Colorado registration (WHI 6007) pursuant to a Stipulation and Final Agency Order in Case No. 2017-3679.

3. Medtronic failed to report the Colorado discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On December 12, 2018, the Board received Medtronic's renewal application.

5. On that application, Medtronic responded "No" to the following question: "Since your last renewal, has any jurisdiction taken disciplinary action against any professional license you hold (except this license) or have held or denied your application for licensure?"

6. The Board accordingly renewed Medtronic's pharmaceutical wholesaler license.

7. On June 19, 2019, the Alabama State Board of Pharmacy imposed discipline against Medtronic's Alabama permit (194466) pursuant to a Consent Order in Case No.19-L-0013.

8. Medtronic failed to report the Alabama discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

9. On July 18, 2019, Medtronic reported to the Board for the first time that the Alabama State Board of Pharmacy had disciplined its permit.

10. On February 3, 2020, Medtronic reported to the Board for the first time that the Colorado State Board of Pharmacy had disciplined its registration.

11. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

12. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny Medtronic's application for renewal of its license to be a pharmaceutical wholesaler. In lieu of the denial, the Board also voted to offer Medtronic this Consent Agreement. Unless Medtronic either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME

04333-0035, by **July 12, 2021,** the preliminary denial of Medtronic's application for licensure as a pharmaceutical wholesaler will become final.

COVENANTS

13. Medtronic admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline as follows:

a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken; and

b. Pursuant to 10 M.R.S. § 8003(5-A)(A)(1), for making a misrepresentation to the Board on its December 12, 2018 application for renewal of licensure.

14. As discipline for the violation admitted to in paragraph 13 above, Medtronic agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of two thousand dollars ($2,000.00), which penalty is comprised of $1,500.00 for misrepresentation on its application and $500.00 for failing to report discipline within 10 days, payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, and must be submitted with the signed Consent Agreement.

15. Upon receipt of this signed Consent Agreement with the enclosed payment of the civil penalty from Medtronic, the Board will renew Medtronic's license contingent upon it meeting all other eligibility criteria.

16. Violation of any of the terms or conditions of this Consent Agreement by Medtronic shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

17. The Board and Medtronic agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Medtronic fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Medtronic, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving Medtronic. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Medtronic.

18. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

19. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

20. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

21. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

22. Medtronic acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 6/11/21

MEDTRONIC LOGISTICS LLC

By: _____

Print Name: Philip J Albert

Title: Vice President

DATED: 7/8/21

_____

BRADLEY S. HAMILTON, R.Ph., PRESIDENT
Maine Board of Pharmacy

DATED: 7/9/21

_____

JOHN NICHOLS
Assistant Attorney General

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medtronic Puerto Rico Operations (MPri)
Address: P.O. Box 6001 City: Villalba State: PR Zip: 00766

Name: Medtronic Ireland Manufacturing UC
Address: Parkmore Business Park West City: Galway State: Ireland Zip: NA

Name: Medtronic Sophono
Address: 5744 Cerntral Ave, suite 100 City: Boulder State: CO Zip: 80301

Name: Medtronic Puerto Rico Operations CO
Address: Rd 31 KM 24HM 4 Ceiba N Indus` City: Juncos State: PR Zip: 00777

Section 4: Publicly Traded Corporation

State of Incorporation: Not applicable
Parent Company (if any): Not applicable
Corporation Name: Not applicable
Mailing Address: Not applicable
City: Not applicable State: NA Zip: NA
Telephone: Not applicable Email: Not applicable
Contact Person Name: Not applicable

Date of SEC Registration: Not applicable | SEC Registration Number: Not applicable | Stock Exchange Symbol: NA

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Medtronic USA Inc
Corporation/Organization Name: Medtronic USA, Inc dba Medtronic Logistics LLC
Mailing Address: 710 Medtronic Parkway, L 245
City: Swedesboro State: NJ Zip: 55432
Telephone: 508-261-6083 Email: rob.varner@medtronic.com
Contact Person Name: Robert Varner

Section 6: Partnership

Partnership Name: Not applicable
Mailing Address: Not applicable
City: Not applicable State: NA Zip: NA
Telephone: Not applicable Email: Not applicable
Contact Person Name: Not applicable

Section 7: Sole Owner

Owner's Name: Not applicable
Business Name: Not applicable
Business Address: Not applicable
City: Not applicable State: NA Zip: NA
Telephone: Not applicable Email: Not applicable

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** ✓	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** NA	✓			
• **List of all corporation shareholders and their percent ownership.** ✓		✓		
• **List of all partners and their percent ownership.** NA			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. ✓	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ ✓		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ ✓		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** NA	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ ✓	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). ✓	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. ✓		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. ✓		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medtronic USA, Inc. dba Medtronic Logistics LLC
Facility Name

Kay Knox
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9/23/2024
Date

Board Use Only	Date Received: 3/10/25	Amount: $1000 CK 00113885

Medtronic Logistics LLC. Officer List

Name	company title	Business Address
Robert Varner	President	4380 Swinnea Rd, Bldg B Memphis TN 38118
Dov Shenkman	Vice President	640 Orchard Ln. Glencoe IL 60022
Punit Menon	Vice President	4536 N Wildwood Ave. Shorewood, WI 53211

Medtronic ORG Chart:

Medtronic USA, Inc. maintains 100% ownership the site located in Swedesboro NJ:

Organizational Chart



Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Medtronic USA, Inc.
Date Filed:	06/15/1984
File Number:	4R-233
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 12/18/2024



Steve Simon
Secretary of State
State of Minnesota

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 3/6/2025

Registration Number: 5003905 **Registered as:** Manufacturer and Wholesale

Name: MEDTRONIC USA, INC

DBA: MEDTRONIC LOGISTICS LLC

Address: 710 MEDTRONIC PARKWAY LC300, MINNEAPOLIS, MN 55432

Original Issue Date: 05/26/2010 **Expiration Date:** 01/31/2026

Current Issue Date: 01/17/2025

Disciplines: No

Additional Registered Addresses:
1851 E DEERE AVE, SANTA ANA, CA 92705
4620 NORTH BEACH ST, FORT WORTH, TX 76137
6743 SOUTHPOINT DR NORTH, JACKSONVILLE, FL 32216
2235 ROUTE 322, SUITE 200, SWEDESBORO, NJ 08085
4340 SWINNEA RD, MEMPHIS, TN 38118
7611 NORTHLAND DR, BROOKLYN PARK, MN 55432
18501 E PLAZA DR, PARKER, CO 80134
1480 ARTHUR ST, LOUISVILLE, CO 80027
5300 AIRWAYS BLVD, STE 101, MEMPHIS, TN 38116
201 INDUSTRIAL WAY, EATONTOWN, NJ 07724
4340 SWINNEA RD STE 39, MEMPHIS, TN 38118
1941 E BLAIR AVE, SANTA ANA, CA 92705

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0753236

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

710 MEDTRONIC PARKWAY LC300 MINNEAPOLIS, MN 55432-
4340 SWINNEA RD MEMPHIS,TN 38118-
6743 SOUTHPOINT DR NORTH JACKSONVILLE, FL 32216-
4620 NORTH BEACH ST FORT WORTH, TX 76137-
1851 E DEERE AVE SANTA ANA, CA 92705-
7611 NORTHLAND DR BROOKLYN PARK, MN 55432-
1480 ARTHUR ST LOUISVILLE, CO 80027-
18501 E PLAZA DR PARKER, CO 80134-

Reg. No.
5003905

MEDTRONIC USA, INC
MEDTRONIC LOGISTICS LLC
4097 E MARQUETTE AVE
TERRE HAUTE, IN 47805-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2026

Establishment Copy

New Jersey Department of Health
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369
609-826-4935

ADDENDUM TO CERTIFICATE OF REGISTRATION FOR A

WHOLESALE DRUG OR MEDICAL DEVICE BUSINESS PURSUANT TO N.J.S.A. 24:6B FOR THE PERIOD ENDING: January 31, 2026

Registered as: [X] manufacturer [X] wholesaler Registration No.: 5003905

The following are additional locations conducting Drug or Medical Device Business

9. 201 INDUSTRIAL WAY EATONTOWN, NJ 07724-
10. 4340 SWINNEA RD STE 39 MEMPHIS, TN 38118-
11. 1941 E BLAIR AVE SANTA ANA, CA 92705-
12. ~~5200 AIRWAYS BLVD, STE 101 MEMPHIS, TN 38116~~
13. 2235 ROUTE 322, SUITE 200 SWEDESBORO, NJ 08085-
14.
15.
16.
17. , -
18. , -
19. , -
20. , -
21. , -
22.
23.
24.
25. , -
26.
27.
28.
29. , -
30.

Cross out locations no longer being operated and add new locations in spaces provided.

Other Corrections: If name or address is incorrect, make necessary corrections below.

RETAIN LAST COPY FOR YOUR RECORD. MAIL WHITE COPY WITH YOUR FEE IN THE ENVELOPE PROVIDED.

NV MDT Swedesboro Page 66

Business Record Details »

Minnesota Business Name

Medtronic USA, Inc.

Business Type
Business Corporation (Domestic)

File Number
4R-233

Filing Date
06/15/1984

Renewal Due Date
12/31/2025

Number of Shares
1,000

Chief Executive Officer
Jennifer Kirk
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

MN Statute
302A

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2780 Snelling Avenue N
Suite 101
Roseville, MN 55113
USA

Registered Agent(s)
Corporation Service Company

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	06/15/1984	Original Filing - Business Corporation (Domestic)	
	06/15/1984	Business Corporation (Domestic) Business Name (Business Name: MEDTRONIC MILACA, INC.)	

NV MDT Swedesboro Page 67

	Filing Date	Filing	Effective Date
☐	03/14/1989	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	10/06/1995	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	12/11/1997	Business Corporation (Domestic) Business Name (Business Name: Medtronic USA, Inc.)	
	12/11/1997	Business Corporation (Domestic) Restated Articles	
☐	10/29/1998	Merger - Business Corporation (Domestic)	
☐	04/10/2007	Global Registered Office and/or Agent - Business Corporation (Domestic)	
☐	9/16/2016	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	5/17/2018	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	10/2/2024	Global Registered Office and/or Agent - Business Corporation (Domestic)	

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Vulnerability Disclosure

NV MDT Swedesboro Page 68

Business Record Details »

Minnesota Business Name

Medtronic Logistics LLC

Business Type
Limited Liability Company (Domestic)

File Number
618784400037

Filing Date
9/18/2012

Renewal Due Date
12/31/2025

Registered Agent(s)
Corporation Service Company

MN Statute
322C

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2780 Snelling Avenue N
Suite 101
Roseville, MN 55113
USA

Manager
Greg Smith
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
USA

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

Filing History

Filing History

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NV MDT Swedesboro Page 69

	Filing Date	Filing	Effective Date
☐	9/18/2012	Original Filing - Limited Liability Company (Domestic) (Business Name: Medtronic Logistics LLC)	
☐	9/16/2016	Registered Office and/or Agent - Limited Liability Company (Domestic)	
	1/1/2018	Conversion to 322C Due to Statute Mandate – Limited Liability Company (Domestic)	
☐	5/15/2018	Registered Office and/or Agent - Limited Liability Company (Domestic)	
☐	10/2/2024	Global Registered Office and/or Agent - Limited Liability Company (Domestic)	

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NV MDT Swedesboro Page 62

Mail to: PO Box 308 Trenton, NJ 08646

STATE OF NEW JERSEY
DIVISION OF REVENUE

Overnight to: 33 West State St. 5th Floor Trenton, NJ 08608-1214

"FEE REQUIRED" PUBLIC RECORDS FILING FOR NEW BUSINESS ENTITY

Fill out all information below INCLUDING INFORMATION FOR ITEM 11, and sign in the space provided. Please note that once filed, this form constitutes your original certificate of incorporation/formation/registration/authority, and the information contained in the filed form is considered public. Refer to the instructions for delivery/return options, filing fees and field-by-field requirements. Remember to remit the appropriate fee amount. Use attachments if more space is required for any field, or if you wish to add articles for the public record.

1. **Business Name:** Medtronic Logistics LLC

2. **Type of Business Entity:** F L C
(See Instructions for Codes, Page 21, Item 2)

3. **Business Purpose :** Distribution of medical devices.
(See Instructions, Page 22, Item 3)

4. **Stock** (Domestic Corporations only; LLCs and Non-Profit leave blank):

5. **Duration** (If Indefinite or Perpetual, leave blank): FLC

6. **State of Formation/Incorporation** (Foreign Entities Only):
Minnesota

7. **Date of Formation/Incorporation** (Foreign Entities Only):
September 18, 2012

FILED
JAN 14 2013
STATE TREASURER

8. **Contact Information:**
Registered Agent Name: The Corporation Trust Company

Registered Office:
(Must be a New Jersey street address)
Street 820 Bear Tavern Road
City West Trenton Zip 08628

Main Business or Principal Business Address
Street 710 Medtronic Parkway, LC300
City Minneapolis State MN Zip 55432

9. **Management** (Domestic Corporations and Limited Partnerships Only)
- For-Profit and Professional Corporations list initial Board of Directors, minimum of 1;
- Domestic Non-Profits list Board of Trustees, minimum of 3;
- Limited Partnerships list all General Partners.

0600395061

Name	Street Address	City	State	Zip

The signatures below certify that the business entity has complied with all applicable filing requirements pursuant to the laws of the State of New Jersey.

10. **Incorporators** (Domestic Corporations Only, minimum of 1)

Name	Street Address	City	State	Zip

Signature(s) for the Public Record (See instructions for Information on Signature Requirements)

Signature	Name	Title	Date
Anne M. Ziebell	Anne M. Ziebell	Assistant Secretary	1/10/13

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 02/26/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 **FAX (A/C, No):** 212-948-5382
E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : Indemnity Insurance Company of North America	43575
INSURER C : ACE Fire Underwriters Insurance Company	20702
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Medtronic, Inc. and its subsidiaries
710 Medtronic Parkway
LC310
Minneapolis, MN 55432

COVERAGES **CERTIFICATE NUMBER:** CHI-010895207-01 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X **COMMERCIAL GENERAL LIABILITY** X CLAIMS-MADE ☐ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY ☐ PRO-JECT ☐ LOC OTHER:			SPL G24561288 008	05/01/2024	05/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 5,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 15,000,000 $ 15,000,000
A	**AUTOMOBILE LIABILITY** X ANY AUTO ☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS ☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY			ISAH10832810	05/01/2024	05/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
	☐ **UMBRELLA LIAB** ☐ OCCUR ☐ **EXCESS LIAB** ☐ CLAIMS-MADE ☐ DED ☐ RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? **(Mandatory in NH)** Y/N N If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		WLRC57196166 (AOS) (incl Stop Gap EL: MN,ND,OH,WA,WY) WLRC57196257 (MO,NC,NE,OK) SCFC57196518 (PA)	05/01/2024 05/01/2024 05/01/2024	05/01/2025 05/01/2025 05/01/2025	X PER STATUTE ☐ OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C	Workers Compensation continued			SCFC57196439 (WI)	05/01/2024	05/01/2025	Limit:	See Above
A	Excess Workers Compensation			WCUC57196567 (AZ) excess of $1M SIR	05/01/2024	05/01/2025	Limit:	1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance.
RE: 4340 Swinnea Rd, Memphis TN 38118; 6743 Southpoint Dr, Jacksonville FL 32216; 1480 Arthur St, Louisville CO 80027; 4620 N Beach St,. Ft Worth TX 76137; 18501 E Plaza Dr., Parker CO 80134; 7611 Northland Dr., Brooklyn Park MN 55428 5300 Airways Blvd, Suite 101, Memphis TN 38116; 2235 Route 322, Suite 200, Swedesboro NJ 08085

CERTIFICATE HOLDER
Medtronic Inc
Attn: LS370
710 Medtronic Parkway
Minneapolis, MN 55432

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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AGENCY CUSTOMER ID: CN103154363
LOC #: Minneapolis

ADDITIONAL REMARKS SCHEDULE

AGENCY MARSH USA LLC	NAMED INSURED Medtronic, Inc. and its subsidiaries 710 Medtronic Parkway LC310 Minneapolis, MN 55432
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Professional Health Care Liability:
Policy # SPL G24561288 008
05/01/2024 - 05/01/2026
Carrier: ACE American Insurance Company
$2,000,000 Each Claim
$15,000,000 Aggregate

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SURETY RIDER

To be attached to and form a part of

Bond No. 190054165

dated effective October 2, 2023
(MONTH-DAY-YEAR)

executed by Medtronic USA, Inc. , as Principal,
(PRINCIPAL)

and by Liberty Mutual Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

ADDING COVERED LOCATIONS:

4340 Swinnea Rd, Memphis TN 38118
18501 E Plaza Dr., Parker CO 80134
6743 Southpoint Dr, Jacksonville FL 32216
4620N Beach St., Ft Worth TX 76137
5300 Airways Blvd, Suite 101, Memphis TN 38116
7611 Northland Dr., Brooklyn Park MN 55428
1480 Arthur St, Louisville CO 80027
2235 Route 322, Suite 200 Swedesboro NJ 08085

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective November 26, 2024
(MONTH-DAY-YEAR)

Signed and Sealed November 26, 2024
(MONTH-DAY-YEAR)

Medtronic USA, Inc.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Liberty Mutual Insurance Company
(SURETY)

By: _____
Cynthia A. Choren, Attorney-In-Fact
NV Non-Resident License No. 221080

S-0443/GEEF 10/99

Liberty Mutual. SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of November, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 190054165

Application/License No. _____

Medtronic USA Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5300 Airways Blvd., Memphis, TN 38116 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 5, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of October, 2023.

APPLICANT/PRINCIPAL

Medtronic USA Inc

Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact

print name

NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Brittany D. Stuckel

Witness Heidi A. Notheisen

Countersigned by:

N/A

Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 9204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint,

Cynthia L. Choren

all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 5th day of October, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medtronic USA, Inc. dba Medtronic Logistics LLC MDEG License # (if applicable): NA

Physical Address: 2235 Route 322, Suite 200

City: Swedesboro State: NJ Zip: 08085

Mailing Address (if different from physical address): Attn: Kay Knox 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: John Middle: Newton Last: Bell

Alias(es, nicknames, name changes, etc.): not applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 2235 Route 322, Suite 200

City: Swedesboro State: IN Zip: [redacted]

Telephone: [redacted] Email: john.n.bell@medtronic.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pennsylvanie State University - PCT		8/92 to 08/94	
Address	**City**	**State**	**Zip**
1 College Ave	Williamsport	PA	17701
Diploma/Degree obtained, if any			
Bachelor's degree			

School Name		From - To (MM/YY – MM/YY)	
Allegany College of Maryland		08/91 to 08/92	
Address	**City**	**State**	**Zip**
12401 Willowbrook Rd	Cumberland	MD	21502
Diploma/Degree obtained, if any			
none			

School Name		From - To (MM/YY – MM/YY)	
Somerset Area High School		08/87 to 05/91	
Address	**City**	**State**	**Zip**
645 S Columbus Ave	Somerset	PA	15501
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
not applicable		not applicable	
Address	**City**	**State**	**Zip**
not applicable	not applicable	NA	NA
Diploma/Degree obtained, if any			
not applicable			

School Name		From - To (MM/YY – MM/YY	
not applicable		not applicable	
Address	**City**	**State**	**Zip**
not applicable	not applicable	NA	NA
Diploma/Degree obtained, if any			
not applicable			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2017 to Present	[redacted]	Swedesboro	NJ	[redacted]
1986-2017		Somerset	PA	
not applicable	not applicable	not applicable	not applica	not applicabl
not applicable	not applicable	not applicable	not applica	not applicabl
not applicable	not applicable	not applicable	not applica	not applicabl
not applicable	not applicable	not applicable	not applica	not applicabl
not applicable	not applicable	not applicable	not applica	not applicabl
not applicable	not applicable	not applicable	not applica	not applicabl
not applicable	not applicable	not applicable	not applica	not applicabl
not applicable	not applicable	not applicable	not applica	not applicabl

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medtronic IUSA, Inc, dba Medtronic Logistics LLC			03/24 to Present	
Business Address		City	State	Zip
2235 Route 322, Suite 200		Swedesboro	NJ	08085
Phone	Title		Number of Employed Hours	
800-633-8766	Distribution Manager		1184	
Description of Duties				
Management of all Distribution Operations				

Business Name			From - To (MM/YY – MM/YY)	
Medtronic USA, Inc			09/21 to 03/24	
Business Address		City	State	Zip
710 Medtronic Parkway		Minneapolis	MN	55432
Phone	Title		Number of Employed Hours	
800-633-5766	Distribution Manager		5216	
Description of Duties				
Management of Distribution Operations				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	not applic	not applicabl
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	not applica	not applicabl
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	not applic	not applicabl
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	not applica	not applicabl
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	not applica	not applicabl
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	not applica	not applicabl
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	not applica	not applicabl
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	not applica	v
Phone	Title		Number of Employed Hours	
not applicable			not applicable	
Description of Duties				
not applicable				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
not applicable	not applicable	not applic	not applicable	not applicable
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
not applicable		not applicable		
Reason/Charge				
not applicable				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
not applicable			not applicable	
Name of Business/Industry/Entity				
not applicable				

Provide explanation below:

not applicable

John Newton Bell

Original Signature (electronic, copies or stamps not accepted)

04/22/2025

Date

I, John Newton Bell, **certify that as the MDEG Administrator for** Medtronic USA Inc., **that I (initial that you have read and meet the following requirements):**

1. ✓ Have a high school diploma or its equivalent;
2. ✓ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ✓ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ✓ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JOHN BELL
Print Name (First, Last)

John Newton Bell
Original Signature (electronic, copies or stamps not accepted)

04/22/2025
Date

Board Use Only	Date Received: 5/22/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medtronic USA, Inc. dba Medtronic Logistics LLC

Pharmacy/Wholesaler License # (if applicable): Not applicable

Physical Address: 2235 Route 300, Suite 200

City: Swedesboro State: NJ Zip: 08085

Mailing Address (if different from physical address): Attn Kay Knox, 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: John Middle: Newton Last: Bell

Alias(es, nicknames, name changes, etc.): not applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Swedesboro State: NJ Zi[redacted]

Telephone: [redacted] Email: john.n.bell@medtronic.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pennsylvania State University - ACT		08/62 to ~~05/94~~ Present	
Address	**City**	**State**	**Zip**
1 college Ave	Williamsport	PA	17701
Diploma/Degree obtained, if any			
Degree			

School Name		From - To (MM/YY – MM/YY)	
Allegany College of Marylanc		08/961 to 08/92	
Address	**City**	**State**	**Zip**
12401 Wellowbrook Rd	Cumberland	MD	21502
Diploma/Degree obtained, if any			
none			

School Name		From - To (MM/YY – MM/YY)	
Somerset area High School		08/87 to 05/91	
Address	**City**	**State**	**Zip**
645 S Columbia Ave	Somerset	PA	15501
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Not applicable		Not applicable	
Address	**City**	**State**	**Zip**
Not applicable	Not applicable	NA	NA
Diploma/Degree obtained, if any			
Not applicable			

School Name		From - To (MM/YY – MM/YY)	
Not applicable		Not applicable	
Address	**City**	**State**	**Zip**
Not applicable	Not applicable	NA	NA
Diploma/Degree obtained, if any			
Not applicable			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2017 - present	[redacted]	Swedesboro	NJ	[redacted]
From - To (MM/YY – MM/YY)		City	State	
1996-2017	[redacted]	Somerset	PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
not applicable	not applicable	not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
not applicable	not applicable	Scottsdale	AZ	85254
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Medtronic USA, Inc. dba Medtronic Logistics LLC			03/24-09/24	
Business Address		City	State	Zip
2235 Route 322, Suite 200		Swedesboro	NJ	08/085
Phone	Title		Number of Employed Hours	
303-530-6270	Sr Operations Manager		1184	
Description of Duties				
Oversight of all inventory control and distribution operations				

Business Name			From - To (MM/YY – MM/YY)	
Medtronic USA			09/21 - 03/24	
Business Address		City	State	Zip
710 Medtronic Parkway		Minneapolis	MN	55432
Phone	Title		Number of Employed Hours	
800-633-5766	Distribution Manahger		5216	
Description of Duties				
Management of Distribution Operations				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
Not Applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		V	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

John Newton Bell
Original Signature (electronic, copies or stamps not accepted)

04/22/2025
Date

I, John Bell, **certify that as the designated representative for**

Medtronic USA, Inc. dba Medtronic Logistics LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JOHN BELL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/22/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JOHN BELL

Print Name (First, Last)

John Newton Bell

Original Signature (electronic, copies or stamps not accepted)

04/22/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Gloucester

I, JOHN NEWTON BELL, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

John Newton Bell

Original Signature

04/22/2025

Date

Subscribed and Sworn to before me this 22nd day of April 2025

Notary Public Signature

ANESHA FORMAN
Notary Public, State of New Jersey
Commission # 50173971
My Commission Expires 10/05/2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Medtronic USA Inc dba Medtronic Logistics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NA

Physical Address: 3735 Rowtec 300, Suite 300

City: Swedesboro State: NJ Zip: 08085

Mailing Address (if different from physical address): Attn Kay Knox 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: www.medtronic.com

Licensing Company Email: Kay.Knox@cervalogistics.com

Section 2: Personal Information

First: Robert Middle: Warren Last: Varner

Alias(es, nicknames, name changes, etc.): Rob

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Savannah State: TN Zip: [redacted]

Telephone: [redacted] Email: rob.varner@medtronic.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		NA

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Memphis		08/87 - 12/92	
Address	City	State	Zip
	Memphis	TN	
Diploma/Degree obtained, if any			
B.B.A.			

School Name		From - To (MM/YY – MM/YY)	
Bishop Byrne H.S.		09/83 - 05/87	
Address	City	State	Zip
Closed	Memphis	TN	38116
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
NA			
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/20 - 09/24	[redacted]	Savannah	TN	[redacted]
05/12 - 09/20		Grand Junction	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
NA				

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Medtronic			From - To (MM/YY – MM/YY): 01/89 - 09/24
Business Address: 4340 Swinnea Rd.	City: Memphis	State: TN	Zip: 38118
Phone: 901-246-4308	Title: VP - Distribution & Logistics		
Description of Duties: Americas Distribution & Transportation Management			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties: N/A			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

N A

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

NA

Original Signature (electronic, copies or stamps not accepted)

9-17-24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Varner
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 9-17-24

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

I, Mishia Y. Thomas, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 9-17-24

Subscribed and Sworn to before me this 17th day of September.

Notary Public Signature

MISHIA Y THOMAS
TENNESSEE NOTARY PUBLIC
My Comm Exp. November 29, 2027
COUNTY OF SHELBY
(Seal)

Rob Varner Driver's license copy





NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Medtronic USA Inc dba Medtronic Logistics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) NA

Physical Address 2235 Route 130, Ste 200

City Swedesboro State NJ Zip 08085

Mailing Address (if different from physical address) attn Kay Knox 4097 E Marquette Ave

City Terre Haute State IN Zip 47805

Telephone 614-489-5164 Website www.medtronic.com

Licensing Company Email Kay.Knox@cevalogistics.com

Section 2: Personal Information

First Dov Middle _____ Last Shenkman

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Glencoe State IL Zip [redacted]

Telephone [redacted] Email dov.shenkman@medtronic.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wayne State University, Detroit, Michigan		12/1992	
Address	**City**	**State**	**Zip**
42 W Warren Ave	Detroit	MI	48202
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Ben Gurion University of the Negev		10/1986	
Address	**City**	**State**	**Zip**
David Ben Gurion Blvd 1	Be'er Sheva	Israel	
Diploma/Degree obtained, if any			
Bachelors Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
N A			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2005 - present	[redacted]	Glencoe	IL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N A

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Medtronic				From - To (MM/YY – MM/YY): 04/2022 - present
Business Address: 710 Medtronic Parkway		City: Fridley	State: MN	Zip: 55418
Phone: 763-541-4000	Title: Vice President			
Description of Duties: Vice President Supply Chain				

Business Name: Walgreens				From - To (MM/YY – MM/YY): 08/12-04/22
Business Address: 108 Wilmot Road		City: Deerfield	State: IL	Zip: 60015
Phone: 800-925-4733	Title: Group Vice President			
Description of Duties: Supply Chain				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

N A

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties	NA		

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

This Page Not Applicable

Original Signature (electronic, copies or stamps not accepted)

09/19/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dov Shenkman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/19/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Anoka

I, Dov Shenkman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

19 Sept 2024
Date

Subscribed and Sworn to before me this 19 day of September, 2024.

Karickson
Notary Public Signature

KRISTIN INGRID ERICKSON
NOTARY PUBLIC
MINNESOTA
(Seal)
My Commission Expires Jan. 31 2027

Dov Shenkman Driver's license:





NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Medtronic USA, Inc. dba Medtronic Logistics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Not Assigned

Physical Address: 2235 Route 322, Suite 200

City: Swedesboro State: NJ Zip: 08085

Mailing Address (if different from physical address): Attn: Kay Knox 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Punit Middle: Last: Menon

Alias(es, nicknames, name changes, etc.): not applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Shorewood State: WI Zip: [redacted]

Telephone: [redacted] Email: punit.menon@medtronic.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of South Carolina		08/98 to 05/0	
Address	City	State	Zip
1244 Blossom St	Columbia	SC	29208
Diploma/Degree obtained, if any			
Masters in International Business			
School Name		From - To (MM/YY – MM/YY)	
Manipal Institute of Technology (Mangalore University)		08/90 to 06/96	
Address	City	State	Zip
Udipi-Kamkala Rd., Eshwar Nagar	Manipal	India	576104
Diploma/Degree obtained, if any			
Bachelors in Engineering			
School Name		From - To (MM/YY – MM/YY)	
Naval Public School		08/86 to 05/90	
Address	City	State	Zip
Satya Marg, Block D 1, Chanakyapuri,	New Delhi	Delhi	110021
Diploma/Degree obtained, if any			
High School diploma			
School Name		From - To (MM/YY – MM/YY)	
not applicable		not applicable	
Address	City	State	Zip
not applicable	not applicable	NA	NA
Diploma/Degree obtained, if any			
not applicable			
School Name		From - To (MM/YY – MM/YY	
not applicable		not applicable	
Address	City	State	Zip
not applicable	not applicable	NA	NA
Diploma/Degree obtained, if any			
not applicable			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/16 to present	[redacted]	Shorewood	WI	[redacted]
From - To (MM/YY – MM/YY)		City	State	
10/15 to 07/16		Oakland	MI	
From - To (MM/YY – MM/YY)		City	State	
09/09 to 09/15		Oak Creek	MI	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
not applicable	not applicable	not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
not applicable	not applicable	not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
not applicable	not applicable	not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
not applicable	not applicable	not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
not applicable	not applicable	not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
not applicable	not applicable	not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
not applicable	not applicable	not applicable	NA	NA

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Medtronic Inc.			1/23 to present
Business Address	**City**	**State**	**Zip**
710 Medtronic Parkway	Minneapolis	MN	55432
Phone	**Title**		
763-514-4000	VP Global Logistics Distribution and Trade		
Description of Duties			
Responsible for all strategic planning and operations related to logistics, distribution, and trade for Medtronic			

Business Name			From - To (MM/YY – MM/YY)
Johnson Controls, Inc. (JCI)			10/18 to 12/22
Business Address	**City**	**State**	**Zip**
5757 N Green Bay Ave	Milwaukee	WI	53209
Phone	**Title**		
414-524-1200	VP Global Logistics Distribution and Trade		
Description of Duties			
Responsible for all strategic planning and operations related to logistics, distribution, and trade for JCI			

Business Name			From - To (MM/YY – MM/YY)
Rockwell Automation			08/16 to 10/18
Business Address	**City**	**State**	**Zip**
1201 S Second St	Milwaukee	WI	53204
Phone	**Title**		
414-382-2000	Director, NA Logistics, Distribution & Trade		
Description of Duties			
Responsible for all operations related to logistics, distribution, and trade for North America for Rockwell Automation			

Business Name			From - To (MM/YY – MM/YY)
Volkswagen Group of America			09/15 to 06/16
Business Address	**City**	**State**	**Zip**
3800 Hamlin Rd	Auburn Hills	MI	48326
Phone	**Title**		
800-822-8987	GM Materials Management		
Description of Duties			
Responsible for materials planning and deployment of product across North America for Volkswagen distribution centers			

Business Name			From - To (MM/YY – MM/YY)
CNH Industial			10/12 to 08/15
Business Address	**City**	**State**	**Zip**
2701 Oakes Rd	Sturtevant	WI	53177
Phone	**Title**		
877-422-7344	Director, Materials Management, Service Parts		
Description of Duties			
Responsible for materials planning and deployment of product across North America for CNH Industrial distribution centers			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title			
not applicable	not applicable			
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title			
not applicable	not applicable			
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title			
not applicable	not applicable			
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title			
not applicable	not applicable			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title			
not applicable	not applicable			
Description of Duties				
not applicable				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
NA	NA	NA	NA	NA
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
NA		NA		
Reason/Charge				
NA				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
NA			NA	
Name of Business/Industry/Entity				
NA				

Provide explanation below:

NA

N/A

Original Signature (electronic, copies or stamps not accepted)

NA

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

PUNIT MENON
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/22/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

error not 22SEP2024
I, ~~Mishia Y. Thomas~~, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

error not 22SEP2024

Original Signature

22 SEP 2024
Date

Subscribed and Sworn to before me this 22nd day of Sept 2024.

Notary Public Signature

MISHIA Y THOMAS
TENNESSEE NOTARY PUBLIC
My Comm Exp. November 29, 2027
COUNTY OF SHELBY
(Seal)


DRIVER LICENSE
REGULAR
WISCONSIN
SEP 72



Medtronic Employee List - Woolwich N.J.

Legal Name - Last Name	Legal Name - First Name
Haile	Darran
Audet	Katrina
Santiago Cruz	Rebeca
Mitchell	Deborah
Bell	John
Batson	Michael
Regalbuto	Alexis
Mercer	Jon
O'Mealia	Danielle
Goins	Carl
Acello	Michael
Brauer	Aaron
Lee	Francis
Foster	Stephen
Toby	Joseph
Showalter	Chelsea
Williams	Ryan
Mckinnie	Rosina
Bakarr Bangura	Abu
Alfred	Albens
Ayala	Ana
Kay	Alec
Hessing	Beth
Peralta	Ana
Frazier	Andrew
Santa	Angel
Harris	Anna
Monval	Arisdove
Alzate	Augusto
Rodriguez	Anthony
Thomas	Besthi
Taje	Arturo
Rodriguez	Camila
Averiett	Bruce
Fokam Kamga	Boris
Raval	Brijesh
Patterson	Crawford
Siverio	Carmen
Reinmuth	Christian
Turenne	Claudette
Foraker	Corrina
Santiago	David
Jones	Deborah
Rumph	DeMario
Henson	Divine
Hanrahan	Debra
Brown	Deaijah
Vilson	Daphne
Miller	Donovan
Davis	Evelyn
Mathis	Jerome

Davis	Donye
Quinones	Edan
Perpilus	Francky
Rodriguez	Edgardo
Duffy	Josiah
Solarte Almarza	Fiorella
Vilson	Fabienne
Lattimore	Jayda
Rodriguez	Gabriela
George	Gifford
Venosa Mendoza	Graciela
Foraker	Hailey
Joseph	Henold
Perkins	Jacob
VanMorter	Ivory
Peirce	James
Pierre	Jamesly
Bonhomme	Jean
Lopez Escobar	Jenner
Rousseau	Jean
White	Jeremiah
Torres	Jesus
Alamo Figueroa	Johanna
Guy	John
Hagan	Johnathon
Hurtado	Jose
Satiriche	Karohn
Ortega-Chirinos	Jose
Ortiz	Jose
Goodhall	Kahseim
Adams	Justice
Gilmore	Kareem
Simon	Katiana
Maranzano	Kenneth
Spence	Kayeal
Spence	Leroy
Goodale	Kevin
Dieudonne	Kettia
Macabudbud	MaJoan
Guerra-Hernandez	Marcelo
O'Brien	Kevin
Mills	Lorraine
Orellana	Marco
Ross	Kristi
Long	Kyle
Baptiste	Lovely
Scott	Lisa
Torres	Luis
Thomas	Margaret
Hill	Marcus
Kenneh	Mohamed
Landrau Ferrer	Mariely
Williams	Michael
Preston	Simone
Farinelli	Michael

NEW JERSEY DEPARTMENT OF HEALTH CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE PUBLIC HEALTH AND FOOD PROTECTION PROGRAM P.O. BOX 369, TRENTON, NJ 08625-0369 609-826-4935	**REPORT OF INSPECTION** Assignment No **17919** Inspection End Date **12/09/2024**

Registration #	Category	Inspection Type	Evaluation
5003905	**Wholesale Drug/Medical Device**	**Initial**	**Satisfactory**

Name of Owner or Corporation	Trade Name	Activity
Medtronic USA, Inc.		**Wholesaler/Warehouse**

Establishment Street Address	City	ZIP	County
2235 Route 322, Suite 200	**Swdesboro**	**08085**	**Gloucester**

Establishment Mailing Address (if different)	Phone Number	Fax Number

Name and Title of Inspecting Official	REHS Lic. #	Operational Status	Embargo	Reinspect on or After
Ryan Reighn, REHI	**B-2407**	**Operational**	**No**	

Name and Title of Designated Representative	Email
John Bell, Distribution Manager	**john.n.bell@medtronic.com**

Products

☒ Prescription Drugs ☐ OTC Drugs ☐ Class I Medical Devices ☐ Class II Medical Devices ☐ Class III Medical Devices
☐ Drug-Device ☐ API ☐ Veterinary Drugs ☐ No Products Stored/Handled Onsite

TIME/ACTIVITY REPORT (1-TRAVEL, 2-INSPECTION, 3-ADMINISTRATION, 4-PERSONAL) TOTAL HOURS:

DATE	CODE	BEGIN	END	CODE	BEGIN	END	CODE	BEGIN	END
12/09/2024	1	10:30	11:00	2	11:00	12:30	1	12:30	13:30
	3	13:30	14:00						

		YES	NO	N/A
	N.J.A.C. 8:21-3A.7 Personnel Requirements			
	Personnel employed by a wholesale distributor have appropriate education and/or experience to assume responsibility for positions related to compliance with State registration requirements	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.8 Facility *Facilities at which drugs are stored, warehoused, handled, held, offered, marketed or displayed:*			
(a) 1	Of suitable size and construction to facilitate cleaning, maintenance, and proper operations	☒	☐	☐
(a) 2	Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions	☒	☐	☐
(a) 3	Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened	☒	☐	☐
(a) 4	Maintained in a clean and orderly condition	☒	☐	☐
(a) 5	Free from infestation by insects, rodents, birds, or vermin of any kind	☒	☐	☐
Note				

		YES	NO	N/A
	N.J.A.C. 8:21-3A.9 Security			
(a)	Facility is secured from unauthorized entry	☒	☐	☐
(a) 1	Access from outside premises is kept to a minimum and is well controlled	☒	☐	☐
(a) 2	The outside perimeter of the premises is well-lighted	☒	☐	☐
(a) 3	Entry into areas where drugs are held shall be limited to authorized personnel	☒	☐	☐
(b)	All facilities are equipped with an alarm system to detect entry after hours	☒	☐	☐
(c)	Facilities are equipped with a security system that provides suitable protection against theft and diversion. When applicable, the security system provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.10 Storage			
(a)	All drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, of the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).	☒	☐	☐
(b)	If no storage requirements are established for a drug, the drug is held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected	☒	☐	☐
(c)	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs are utilized to document proper storage of drugs	☒	☐	☐
(d)	For prescription drugs a record is maintained that includes the date, time, thermometer temperature, and the initials of the person recording the data	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.11 Examination of Materials			
(a)	Upon receipt, each outside shipping container is visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination is adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	☒	☐	☐

		YES	NO	N/A
(b)	Each outgoing shipment is carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.12 Returned, Damaged and Outdated Drugs			
(a)	Outdated, damaged, deteriorated, misbranded, or adulterated drugs are quarantined and physically separated from other drugs until they are destroyed or returned to their supplier	☒	☐	☐
(b)	Drugs whose immediate or sealed outer or sealed secondary containers have been opened or used are identified as such, quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier	☒	☐	☐
(c)	If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.13 Recordkeeping			
(a)	Inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs are maintained	☒	☐	☐
(a) 1	Source of drugs, name and principal address of the seller or transferor, and address from which drugs were shipped are maintained	☒	☐	☐
(a) 2-3	Identity and quantity of drugs received and distributed/disposed, date of receipt and distribution, disposal.	☒	☐	☐
(a) 5	A complete and accurate annual record of all stock of drugs on hand.	☒	☐	☐
(d)	An ongoing listing of all retail and wholesale establishments with whom they do business.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.14 Due Diligence *Firm is performing due diligence of other wholesale establishments with whom they do business, which requires that prior to the initial purchase or acquisition of drugs from another wholesale distributor, a wholesale distributor shall obtain the following information from the selling wholesale distributor:*			
(a) 1	Copies of all state and Federal regulatory licenses and registrations	☒	☐	☐
(a) 2	The wholesale distributor's most recent facility inspection reports	☐	☐	☒
(a) 3	A list of other names under which the wholesale distributor is doing business or by which the wholesale distributor was formerly known	☒	☐	☐

		YES	NO	N/A
(a) 4	A list of corporate officers and managerial employees and designated representatives	☒	☐	☐
(a) 5	A verification of the selling wholesale distributor's status as an authorized distributor of record, if applicable.	☒	☐	☐
(b)	At least annually, a wholesale distributor that purchases drugs from another wholesale distributor updates the information set forth in (a) 1-5 above.	☒	☐	☐
(c)	No purchases were placed from any storage facility, manufacturer or wholesale distributor not having a current license or registration within the jurisdiction of the establishment location from where product is purchased.	☒	☐	☐
(d)	No purchase or acquisition has been made from a firm that has not provided complete information as set forth in (a) 1-5 above.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.15 Availability of Records and Inventories			
(a)	Records and inventories, including those related to salvage and reprocessing, are made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation	☒	☐	☐
(b)	Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means are readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable are made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.16 Policies and Procedures			
(a)	Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of drugs	☒	☐	☐
(a)	Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories	☒	☐	☐
(a) 1	Firm has a procedure where oldest stock is distributed first.	☒	☐	☐
(a) 2	Firm has a procedure for handling recalls/withdrawals of drugs.	☒	☐	☐
(a) 3	Firm has a procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster	☒	☐	☐
(a) 4	Firm has a procedure for handling return of outdated drugs; segregation and written documentation of disposal, by either returning the drug to the manufacturer or destruction of the drug. This documentation shall be maintained for 2 years after disposition of the outdated drugs.	☒	☐	☐

NEW JERSEY REPORT OF INSPECTION

		YES	NO	N/A
Note				
	N.J.A.C. 8:21-3A.17 List of Responsible Persons			
	A current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of drugs is maintained at the firm	☒	☐	☐
	Description of duties and qualifications of personnel is maintained at the firm	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.19 Salvage; Reprocessing			
	Salvaging and reprocessing operation is in compliance with 21 CFR 207, 210, 211	☐	☐	☒
Note				

Inspecting Official

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive

Physical Address: 120 Phyllis Drive

City: Croydon State: PA Zip: 19021

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 215-613-3001 Website: www.pci.com

Name of Designated Representative (DR): William G Rhim Jr

Licensing Company Email: compliance.PCIPharma@gmail.c DR Email: william.rhim@pci.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Tabs, Capsules, Injectables	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:
N/A

Original Signature (electronic, copies or stamps not accepted)

11/06/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Packaging Coordinators, Inc.

Corporation/Organization Name: PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive

Mailing Address: 120 Phyllis Drive

City: Croydon State: PA Zip: 19021

Telephone: 215-613-3670 Email: compliance.PCIPharma@gmail.com

Contact Person Name: William G Rhim Jr

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive
Facility Name

William G Rhim Jr
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/06/24
Date

Board Use Only	Date Received: 3/18/25	Amount: Ck $1000 1359

pci PHARMA SERVICES

List of Corporate Officers

Full Name: Salim Haffar
Title/Position: Chief Executive Officer
Work Address: 4880 Linden Road, Rockford, IL 61109
Phone Number: [redacted]
Email Address: Salim.Haffar@pci.com
Ownership Percentage: 0%

Full Name: Tom Wim Frans De Weerdt
Title/Position: Chief Financial Officer
Work Address: 4880 Linden Road, Rockford, IL 61109
Phone Number: [redacted]
Email Address: Tom.DeWeerdt@pci.com
Ownership Percentage: 0%

Full Name: Jeannie Metzinger
Title/Position: Chief Quality and Compliance Officer
Work Address: 4880 Linden Road, Rockford, IL 61109
Phone Number: [redacted]
Email Address: Jeannie.Metzinger@pci.com
Ownership Percentage: 0%

Full Name: Brad Payne
Title/Position: Chief Operating Officer
Work Address: 4880 Linden Road, Rockford, IL 61109
Phone Number: [redacted]
Email Address: Brad.Payne@pci.com
Ownership Percentage: 0%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PACKAGING COORDINATORS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF JUNE, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PACKAGING COORDINATORS, LLC" WAS FORMED ON THE TWENTY-SEVENTH DAY OF APRIL, A.D. 2012.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5118926 8300

SR# 20253067829

Authentication: 203944305

Date: 06-13-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Pennsylvania
Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version 4.0.0

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive 120 Phyllis Drive; Croydon, PA 19021

Certificate(s): **3000010631** issued: 06/20/2024 expires: 7/31/2026

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

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Assembly Version 4.0.18274.4

Database Version Could not retrieve database version. Check that the database is registered as a Data-tier Application.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 06/30/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Philadelphia PA Office 100 North 18th Street 16th Floor Philadelphia PA 19103 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE		NAIC #
Packaging Coordinators, Inc. 3001 Red Lion Road Philadelphia PA 19114 USA	INSURER A:	Travelers Property Cas Co of America	25674
	INSURER B:	Travelers Commercial Casualty Co	40282
	INSURER C:	Illinois Union Insurance Company	27960
	INSURER D:	Federal Insurance Company	20281
	INSURER E:		
	INSURER F:		

COVERAGES **CERTIFICATE NUMBER:** 570113986689 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
D	X COMMERCIAL GENERAL LIABILITY			36055286	06/19/2025	06/19/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	Excluded
	OTHER:							
A	AUTOMOBILE LIABILITY			HJCAP-9P529099-TIL-25 CA, IL, NH, WI	06/19/2025	06/19/2026	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
D	X UMBRELLA LIAB X OCCUR			79837169	06/19/2025	06/19/2026	EACH OCCURRENCE	$15,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$15,000,000
	DED RETENTION							
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			UB1R0291502512K AOS	06/19/2025	06/19/2026	X PER STATUTE OTH-ER	
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH) N/A If yes, describe under DESCRIPTION OF OPERATIONS below			UB1R02810425I2R AZ, MA, WI	06/19/2025	06/19/2026	E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000
C	Products Liability			G71151864008 Claims Made SIR applies per policy terms & conditions	06/19/2025	06/19/2026	Each Occurrence Aggregate Limit	$10,000,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: 120 Phyllis Drive, Suite A, Croydon, PA 19021. Evidence of Coverage.

CERTIFICATE HOLDER

Packaging Coordinators, Inc.
3001 Red Lion Road
Philadelphia PA 19114 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570113986689

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ACORD®

EVIDENCE OF PROPERTY INSURANCE

DATE (MM/DD/YYYY) 06/30/2025

THIS EVIDENCE OF PROPERTY INSURANCE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE ADDITIONAL INTEREST NAMED BELOW. THIS EVIDENCE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS EVIDENCE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE ADDITIONAL INTEREST.

AGENCY

PHONE (A/C, NO, Ext): (866) 283-7122

Aon Risk Services Central, Inc.
Philadelphia PA Office
100 North 18th Street
16th Floor
Philadelphia PA 19103 USA

FAX (A/C No): (800) 363-0105

E-MAIL ADDRESS:

CODE: SUB CODE:

AGENCY CUSTOMER ID #: 570000082283

COMPANY

Affiliated FM Insurance Co.

INSURED

Packaging Coordinators, Inc.
3001 Red Lion Road
Philadelphia PA 19114 USA

LOAN NUMBER

POLICY NUMBER 1153210

EFFECTIVE DATE 06/19/2025

EXPIRATION DATE 06/19/2026

☐ CONTINUED UNTIL TERMINATED IF CHECKED

THIS REPLACES PRIOR EVIDENCE DATED:

Holder Identifier : 570113986679

Certificate No :

PROPERTY INFORMATION

LOCATION/DESCRIPTION

RE: 120 Phyllis Drive, Suite A, Croydon, PA 19021.

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS EVIDENCE OF PROPERTY INSURANCE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

COVERAGE INFORMATION

PERILS INSURED ☐ BASIC ☐ BROAD ☐ SPECIAL ☒ ALL RISK - subject to exclusions

	COVERAGES/PERILS/FORMS	AMOUNT OF INSURANCE	DEDUCTIBLE
Commercial Property Coverage	Loss Limit	$ 250,000,000	$ 250,000
	Terrorism	Included	
	Business Income	Included	

REMARKS (Including Special Conditions)

Evidence of Coverage.

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

ADDITIONAL INTEREST

NAME AND ADDRESS

Packaging Coordinators, Inc.
3001 Red Lion Road
Philadelphia PA 19114 USA

☐ ADDITIONAL INSURED ☐ LENDER'S LOSS PAYABLE ☐ LOSS PAYEE
☐ MORTGAGEE

LOAN #

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

ACORD 27 (2016/03)

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AGENCY CUSTOMER ID: 570000082283

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Packaging Coordinators, Inc.
POLICY NUMBER	
See Certificate Number: 570113986679	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570113986679	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 27 FORM TITLE: Evidence of Property Insurance

Additional Coverages

Flood- $100,000,000 aggregate
Earth Movement- $100,000,000 aggregate

Deductibles:
1. Earthquake
A. $100,000 (per location for all coverages provided)
Except for locations in California, USA: 5% for Property Damage and Business Interruption combined subject to a minimum of USD 250,000 per location

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D

H114-257 (rev. 12 22)

Commonwealth of Pennsylvania
Department of Health (DOH)
(717) 787-4779 FAX (717)-231-4790

Drug, Device, & Cosmetic Program
2525 North 7th Street, Suite 210D
Harrisburg, PA. 17110

DRUG, DEVICE, & COSMETIC COMPLIANCE INSPECTION REPORT

FIRM NAME: Packaging Coordinators LLC	DATE: 6/17/2024	PA DOH REGISTRATION: Pending	EXP. DATE
ADDRESS: 120 Phyllis Drive	CHANGE ☐	PA DOH LICENSE: Pending	EXP. DATE
CITY: Croydon PA ZIP CODE: 19021	COUNTY: Bucks	FDA REGISTRATION: MA	EXP. DATE
OWNER/PARENT (if different than above)	LEAD PERSON INTERVIEWED: Jacqueline Colon	DEA REGISTRATION: N/A	EXP. DATE
PHONE: 267-326-7623	TITLE: GM.	PA CS LICENSE: N/A	EXP. DATE
HOURS OF OPERATION: M-F 6AM - 12MIDNIGHT	ID OF PERSON INTERVIEWED: PA DL 31490373	PA DOS LICENSE: N/A	EXP. DATE
TOTAL EMPLOYEES/FACILITY SIZE: 25-30	INSPECTOR NAME: L. Pitcher	OTHER REGISTRATION	EXP. DATE

Initial Inspection	X	Type of Action Pursuant to:	X
Investigation/Compliance Follow-up		New	
Disaster			

X Controlled Substance, Drug, Device, & Cosmetic Act, Act 64 of 1972
Wholesale Prescription Drug Distributors License Act, Act 145 of 1992
Noncontrolled Substance Registration & Reporting Act
Other

TYPE of FIRM		PRODUCTS		SUBTYPE		MISC.
	Manufacturer-Drugs	X	Prescription Drugs (RX)		Contract manufacturer	Contract distributor
	Manufacturer-Devices		Controlled Substances		Wholesaler	
	Manufacturer-Cosmetics		List I Chemicals		Intra-company transfers	3/PL
	Transfiller/Mfr. Medical Gases		OTC Drugs/Medicinals	X	3PL/Third Party logistics	Currently not istocked
	Relabeler/Repackager		Cosmetics/Cosmeceuticals		DME	wholesaling / will
X	Distributor-Drugs		Veterinary-Prescription		Optical	check with corp.
	Distributor-Medical Gases		Veterinary- OTC		Dental Lab	
	Distributor-Devices		Medical Gases		Prosthetics	
	Distributor-Cosmetics		RX Devices		Orthotics	
	Retailer-Medical Gases		OTC Devices		Assisted Hearing Devices	
	Retailer-Drugs, Medicinals,		Biologics/Blood Products		Reprocessor/Reuser	
	Practitioner/Institution		Radiation Emitting product		Samples	
	Medicated Feed Plant/Agri.		Medicated Feed		Clinical Trial/Investigation	
	Research/Training		API (Active Pharm Ingred.)		Foreign Import/Export	
	Other:		Other:		Other:	

FACILITY, PHYSICAL CONTROLS, & STAFF		STOCK, RECORDS, & POLICIES		QUALITY CONTROL	
"X" denotes firm meets standard in this area. "N" denotes deficiency in this area. " / " denotes not applicable					
X	Physical Condition	X	Inventory control/Errors	X	Adulterated/Expired
X	Adequate Equipment	X	Suspect Product Policy	X	Misbranded
X	Physical Security	X	Recall Policy	X	Contraband
X	Staff Security/Limited Access	X	Return Goods Policy		*Manufacturing/Repack Only*
X	Temperature system/Logs	N	Emergency Policy/Reporting		Adherence to GMP
X	Ventilation/Humidity	N	Track and Trace System		Validation: Equipment
X	Running Water/Restroom	X	Receiving Records/Pedigree		Raw Materials
X	Cleanliness/Pest-Free	X	Distributing Records		Intermediaries
X	Quarantine/Hold Area	X	Authorized trading/transfer		Finished Prod.
X	Appropriate Storage	X	Disposal/Destruction Records	X	Sterile/X Contamination
X	Registration/Licenses	/	Controlled Substance Rec	X	Product Label/Identifiers
X	Perm. Site (deed/lease > 6m)	/	Labels/Prescription Order	X	Batch Record/Lot No.
X	Qualified Staff & Supervision		Other:	X	Other:
X	Name/ID/qualifications of manager: Jacqueline Colon 3yrs Experience ID PA DL 31490373D				

- Designated supervisor to change to ~~[illegible]~~ New supervisor
- will send updated IWFO - Personnel standard ref.
Policy/Procedures standards not but Emergency policy - add notification to PA Dept Health
Records/copy/Track/Trace meet standards except need to clear Transaction statement
- Discussed - whether wholesale license is needed.

PASS **FAIL** or **PASS-pending** (pending corrections noted above & date corrections must be made 7/17/24)

Signature of Inspector

Signature of Firm Representative

Date 6/17/24

Commonwealth of Pennsylvania
Department of Health (DOH)
(717) 787-4779 FAX (717)-231-4790

Drug, Device, & Cosmetic Program
2525 North 7th Street, Suite 210D
Harrisburg, PA. 17110

DRUG, DEVICE, & COSMETIC COMPLIANCE INSPECTION REPORT

FIRM NAME: Packaging Coordinators LLC	DATE: 6/17/2024 CHANGE ☐	PA DOH REGISTRATION: Pending	EXP. DATE
ADDRESS: 120 Phyllis Drive,		PA DOH LICENSE: Pending	EXP. DATE
CITY: Chalfont PA ZIP CODE: 18914	COUNTY: Bucks	FDA REGISTRATION: MA	EXP. DATE
OWNER/PARENT (if different than above)	LEAD PERSON INTERVIEWED: Jacqueline Colon	DEA REGISTRATION: N/A	EXP. DATE
PHONE: 267-326-7623	TITLE: GM	PAT & T LICENSE: N/A	EXP. DATE
HOURS OF OPERATION: M-F 6AM - 12 MIDNIGHT	ID OF PERSON INTERVIEWED: PA DL 34903720	PA DOS LICENSE: N/A	EXP. DATE
TOTAL EMPLOYEES FACILITY SIZE: 25-30	INSPECTOR NAME: L. Ritchie	OTHER REGISTRATION	EXP. DATE

Initial Inspection	X	Type of Action Pursuant to:	X	Controlled Substance, Drug, Device, & Cosmetic Act, Act 64 of 1972
Investigation/Compliance		NEW		Wholesale Prescription Drug Distributors License Act, Act 145 of 1992
Follow-up				Noncontrolled Substance Registration & Reporting Act
Disaster				Other

TYPE of FIRM		PRODUCTS		SUBTYPE		MISC.
	Manufacturer-Drugs	X	Prescription Drugs (RX)		Contract manufacturer	Contract distributor
	Manufacturer-Devices		Controlled Substances		Wholesaler	
	Manufacturer-Cosmetics		List I Chemicals		Intra-company transfers	3/PL
	Transfiller/Mfr. Medical Gases		OTC Drugs/Medicinals	X	3PL/Third Party logistics	
	Relabeler/Repackager		Cosmetics/Cosmeceuticals		DME	Currently not stocked
X	Distributor-Drugs		Veterinary-Prescription		Optical	
	Distributor-Medical Gases		Veterinary-OTC		Dental Lab	wholesaling I will
	Distributor-Devices		Medical Gases		Prosthetics	
	Distributor-Cosmetics		RX Devices		Orthotics	check with corp.
	Retailer-Medical Gases		OTC Devices		Assisted Hearing Devices	
	Retailer-Drugs, Medicinals,		Biologics/Blood Products		Reprocessor/Reuser	
	Practitioner/Institution		Radiation Emitting product		Samples	
	Medicated Feed Plant/Agri.		Medicated Feed		Clinical Trial/Investigation	
	Research/Training		API (Active Pharm Ingred.)		Foreign Import/Export	
	Other:		Other:		Other:	

FACILITY, PHYSICAL CONTROLS, & STAFF		STOCK, RECORDS, & POLICIES		QUALITY CONTROL		KEY NOTES
"X" denotes firm meets standard in this area. "N" denotes deficiency in this area. " / " denotes not applicable						
X	Physical Condition	X	Inventory control/Errors	X	Adulterated/Expired	
X	Adequate Equipment	X	Suspect Product Policy	X	Misbranded	
X	Physical Security	X	Recall Policy	X	Contraband	
X	Staff Security/Limited Access	X	Return Goods Policy		*Manufacturing/Repack Only*	
X	Temperature system/Logs	X	Emergency Policy/Reporting		Adherence to GMP	
X	Ventilation/Humidity	N	Track and Trace System		Validation: Equipment	
X	Running Water/Restroom	X	Receiving Records/Pedigree		Raw Materials	
X	Cleanliness/Pest-Free	X	Distributing Records		Intermediaries	
X	Quarantine/Hold Area	X	Authorized trading/transfer		Finished Prod.	
X	Appropriate Storage	X	Disposal/Destruction Records	X	Sterile/X Contamination	
X	Registration/Licenses	/	Controlled Substance Rec	X	Product Label/Identifiers	
X	Perm. Site (deed/lease > 6m)	/	Labels/Prescription Order	X	Batch Record/Lot No.	
X	Qualified Staff & Supervision		Other:	X	Other:	
X	Name/ID/qualifications of manager:	Jacqueline Colon 3½ yrs Experience ID PA DL 34903720				

- Designated supervisor to change to ~~[illegible] 34449378~~ New supervisor will send updated IWFO. Personnel standard met.
Policy/Procedures standards met but Emergency policy - add notification to PA Dept Health
Record keeping/Track/Trace Meet Standards except Need to clear on Transaction statement
- Discussed - whether wholesale license is needed.

PASS **FAIL** or **PASS-pending** (pending corrections made noted above & date corrections must be made 7/17/24)

Signature of Inspector — Signature of Firm Representative — Date 6/17/24

State of Delaware
Secretary of State
Division of Corporations
Delivered 02:05 PM 04/27/2012
FILED 01:50 PM 04/27/2012
SRV 120483763 - 5118926 FILE

CERTIFICATE OF FORMATION

OF

CP USA, LLC

This Certificate of Formation of CP USA, LLC (the "LLC"), is being duly executed and filed by Richard Goldstein, as an authorized person, to form a limited liability company under the Delaware Limited Liability Company Act (6 Del C. § 18-101, *et seq*).

FIRST: The name of the limited liability company formed hereby is CP USA, LLC.

SECOND: The address of the registered office of the LLC in the State of Delaware is c/o Corporation Services Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

THIRD: The name and address of the registered agent for service of process on the LLC in the State of Delaware is Corporation Services Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

FOURTH: The name and address of the authorized person is Richard B. Goldstein, Fried, Frank, Harris, Shriver & Jacobson LLC, One New York Plaza, New York, New York 10004.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation this 27th day of April, 2012.

/s/ Richard B. Goldstein
Richard B. Goldstein
Authorized Person

State of Delaware
Secretary of State
Division of Corporations
Delivered 08:01 PM 06/19/2012
FILED 08:01 PM 06/19/2012
SRV 120755957 - 5118926 FILE

CERTIFICATE OF AMENDMENT

OF THE

CERTIFICATE OF FORMATION

OF

CP USA, LLC

1. The name of the limited liability company is CP USA, LLC (the "Company").

2. The Certificate of Formation of the Company is hereby amended as follows:

   a. FIRST: The name of the limited liability company formed hereby is Packaging Coordinators, LLC.

   b. The following is hereby deleted in its entirety:

      FOURTH: The name and address of the authorized person is Richard B. Goldstein, Fried, Frank, Harris, Shriver & Jacobson LLC, One New York Plaza, New York, New York 10004.

3. This Certificate of Amendment shall be effective upon filing.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Amendment of the Certificate of Formation of CP USA, LLC this 19th day of June, 2012.

CP USA, LLC

By: _____
Name: William T. Mitchell, III
Title: President and Chief Executive Officer

PACKAGING COORDINATORS, INC.
3001 Red Lion Road
Philadelphia, PA 19114

DELAWARE CONSENT TO USE OF NAME

PACKAGING COORDINATORS, INC.
PACKAGING COORDINATORS, LLC

June 19, 2012

Delaware Secretary of State:

Packaging Coordinators, Inc. hereby gives consent to use of name to:

CP USA, LLC, who is filing a Certificate of Amendment to its Certificate of Formation in Delaware.

By: PACKAGING COORDINATORS, INC.

Name: William T. Mitchell, III
Title: President and Chief Executive Officer

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF INCORPORATION OF "PACKAGING COORDINATORS, INC.", FILED IN THIS OFFICE ON THE FOURTH DAY OF MAY, A.D. 2012, AT 12:34 O'CLOCK P.M.

Jeffrey W. Bullock, Secretary of State

5143207 8100

131415697

AUTHENTICATION: 0974443

DATE: 12-12-13

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 2339436

Application/License No. _____

PACKAGING COORDINATORS, INC., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
120 Phyllis Drive Croydon, PA 19021, as
Address of Applicant/Principal
PRINCIPAL, and SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION, a
Surety Company
corporation organized under the laws of the state of MO
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1200 Main Street Suite 800 Kansas City, MO 64105-2478 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 16, 2024.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of October, 2024.

APPLICANT/PRINCIPAL
PACKAGING COORDINATORS, INC.

COMPANY

Authorized Representative

SURETY
SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION

Surety Company's Representative

Anne Potter, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Jacob Neerenberg

Witness Krista Laxton

SIGNED and SEALED in the presence of:

Witness Valorie Spates

Witness Sandra Diaz

Countersigned by:

Nevada Resident Agent N/A

Posted February 20, 2020

SWISS RE CORPORATE SOLUTIONS

.E CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION ("SRCSAIC")
RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION ("SRCSPIC")
PORT INSURANCE CORPORATION ("WIC")

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT SRCSAIC, a corporation duly organized and existing under laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, and SRCSPIC, a corporation organized and existing under the laws of the State of Missouri and having its principal office in the City of Kansas City, Missouri, and WIC, organized under the laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, each does hereby make, constitute and appoint:

SANDRA DIAZ, DEBRA A. DEMING, PETER HEALY, JENNIFER JAKAITIS, SUSAN A. WELSH, ANNE POTTER, FRANCESCA KAZMIERCZAK, FRANCES RODRIGUEZ, BEVERLY A. WOOLFORD, VALORIE SPATES, AKLIMA NOORHASSAN, PABLO GARCIA HORCAJO and VILMA GONZALEZ

JOINTLY OR SEVERALLY

Its true and lawful Attorney(s)-in-Fact, to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

ONE HUNDRED TWENTY FIVE MILLION ($125,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both SRCSAIC and SRCSPIC at meetings duly called and held on the 18th of November 2021 and WIC by written consent of its Executive Committee dated July 18, 2011.

"RESOLVED, that any two of the President, any Managing Director, any Senior Vice President, any Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is, authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Corporation bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Corporation; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Corporation may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Corporation when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."





By _____
Erik Janssens, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC & Senior Vice President of WIC

By _____
Gerald Jagrowski, Vice President of SRCSAIC & Vice President of SRCSPIC & Vice President of WIC



IN WITNESS WHEREOF, SRCSAIC, SRCSPIC, and WIC have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers

this 29TH day of MARCH, 20 24

State of Illinois
County of Cook SS

Swiss Re Corporate Solutions America Insurance Corporation
Swiss Re Corporate Solutions Premier Insurance Corporation
Westport Insurance Corporation

On this 29TH day of MARCH, 20 24, before me, a Notary Public personally appeared Erik Janssens, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC and Senior Vice President of WIC and Gerald Jagrowski, Vice President of SRCSAIC and Vice President of SPCSPIC and Vice President of WIC, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

OFFICIAL SEAL
CHRISTINA MANISCO
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires March 28, 2026

Christina Manisco, Notary

I, Jeffrey Goldberg, the duly elected Senior Vice President and Assistant Secretary of SRCSAIC and SRCSPIC and WIC, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said SRCSAIC and SRCSPIC and WIC, which is still in full force and effect.
IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 18th day of October, 20 24

Jeffrey Goldberg, Senior Vice President &
Assistant Secretary of SRCSAIC and
SRCSPIC and WIC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PCI Pharma Services dba Packaging Coordinators, LLC-Phyllis Drive

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 20 Phyllis Drive

City Croydon State PA Zip 19021

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone _____ Website www.pci.com

Licensing Company Email _____

Section 2: Personal Information

First Abilio Middle _____ Last Goncalves

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Bensalem State PA Zip [redacted]

Telephone [redacted] Email Billy.goncalves@pci.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	X *

* BG 05/30/2025

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mary Mount		82-83	
Address: N/A	City: Montreal	State: PQ	Zip: N/A
Diploma/Degree obtained, if any: High school degree			
School Name: Pius		From - To (MM/YY – MM/YY): 83-85	
Address: N/A	City: Montreal	State: PQ	Zip: N/A
Diploma/Degree obtained, if any: Associates degree			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2004-> 2025	[redacted]	Bensalem	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)
PCL Packaging Coordinators LLC		2002 > Present
Business Address	City	State / Zip
3001 Red Lion RD	Philadelphia	PA / 19114
Phone	Title	Number of Employed Hours
2156133629	SR. Manager	23+ years
Description of Duties		
Warehouse SR. Manager		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone	Title	Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone	Title	Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone	Title	Number of Employed Hours
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	City	State / Zip
Phone	Title	Number of Employed Hours
Description of Duties		

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

05/30/2025
Date

I, Abilio Goncalves, **certify that as the designated representative for**

PCI Pharma Services (Packaging Coordinators LLC) 120 Ethlyn Drive Cragdow 19021

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Abilio Goncalves

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/30/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Abribio Gonzalez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/03/2025

Date

Please have this section completed in the presence of a Notary Public.

State of PA, ss. County of Montgomery

I, Jessica Welda, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

June 3, 2025

Date

Subscribed and Sworn to before me this 3 day of June 2025

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Packaging Coordinators LLC MDEG License # (if applicable) _____

Physical Address 3001 Red Lion Rd

City Philadelphia State PA Zip 19114

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone _____ Website www.pci-com

Licensing Company Email Regulatory-PHL@pci-com

Section 2: Personal Information

First Abilio Middle _____ Last Goncalves

Alias(es, nicknames, name changes, etc.) Billy

Date of Birth [redacted] SSN or ITIN _____ Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Bensalem State PA Zip [redacted]

Telephone [redacted] Email Billy.Goncalves@PCI.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	X

BG
05/30/2025

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
ST-PIXUS			1983 - 1985	
Address		City	State	Zip
N/A		Montreal	PQ	N/A
Diploma/Degree obtained, if any				
Associates				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2004-2015	[redacted]	Ben Salem	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

1984

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: PCI Pharma Services			From - To (MM/YY – MM/YY): 2003 - present
Business Address: 3001 Red Lion Rd	City: Philadelphia	State: PA	Zip: 19114
Phone: 215 613-3629	Title: SR. Warehouse Manager		Number of Employed Hours: 44,352
Description of Duties: Warehouse Manager			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

05/30/2025
Date

I, Abilio Goncalves, **certify that as the MDEG Administrator for** PCI Packaging Coordinators LLC,

that I (initial that you have read and meet the following requirements):

1. ✓ Have a high school diploma or its equivalent;
2. ✓ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. ✓ An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ✓ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ✓ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Abilio Goncalves

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/30/2025

Date

Board Use Only	Date Received: 6/30/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 120 Phyllis Drive

City: Croydon State: PA Zip: 19021

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 215-613-3001 Website: www.pci.com

Licensing Company Email:

Section 2: Personal Information

First: Abilio Middle: Last: Goncalves

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Bensalem State: PA Zip: [redacted]

Telephone: [redacted] Email: Billy.Goncalves@PCi.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
MaryMount			80-83	
Address		City	State	Zip
		Montreal	PQ	N/A
Diploma/Degree obtained, if any				
High School degree				
School Name			From - To (MM/YY – MM/YY)	
Diploma			83-85	
Address		City	State	Zip
N/A		Montreal	PQ	N/A
Diploma/Degree obtained, if any				
Associates degree				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2004-2025	[redacted]	Bensalem	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: PCI Packaging Coordinators LLC			From - To (MM/YY – MM/YY): 2022 - Present
Business Address: 3001 Red Lion Rd	City: Philadelphia	State: PA	Zip: 19114
Phone: 2156133629	Title: SR. Manager		
Description of Duties: Warehouse SR. Manager			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

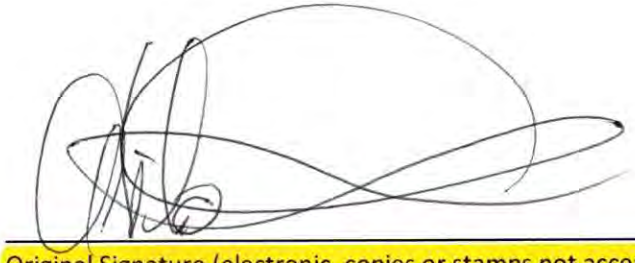
Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A



Original Signature (electronic, copies or stamps not accepted)

05/30/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Abiliz Gonzalez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/03/2025

Date

Please have this section completed in the presence of a Notary Public.

State of PA, ss. County of Montgomery

I, ~~Jeannie Motzinger~~ Jessica Weldon, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

June 3, 2025

Date

Subscribed and Sworn to before me this 3 day of June, 2025.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 120 Phyllis Drive

City: Croydon State: PA Zip: 19021

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 215-613-3001 Website: www.pci.com

Licensing Company Email: compliance.PCIPharma@gmail.com

Section 2: Personal Information

First: Tom Middle: Wim Frans Last: De Weerdt

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: St Petersburg State: FL Zip: [redacted]

Telephon[redacted] Email: tom.deweerdt@pci.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Chicago Booth School of Busine		2010 - 2012	
Address	**City**	**State**	**Zip**
5807 S Woodlawn Ave	Chicago	IL	60637
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
ULEKITO		1998-1999	
Address	**City**	**State**	**Zip**
	Brussels, Belgium		
Diploma/Degree obtained, if any			
Master in Applied Inf Tech.			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/23 - 01/23	[redacted]	St. Petersburg	FL	[redacted]
		St. Petersburg FL	FL	
08/10 - 04/23		Chicago	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive			
Business Address	**City**	**State**	**Zip**
120 Phyllis Drive	Croydon	PA	19021
Phone	**Title**		
815-484-8900	Chief Financial Officer		
Description of Duties			
Oversees Financial operations			

Business Name		From - To (MM/YY – MM/YY)	
Man Sa Pack. Solutions		05/17-01/21	
Business Address	**City**	**State**	**Zip**
1515 W. 22nd St.	Oakbrook	IL	60523
Phone	**Title**		
	CFO		
Description of Duties			
CFO			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Dec 3, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tom Wim Frans De Weerdt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Dec 3, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of PA, ss. County of Philadelphia

I, Tom Wim Frans De Weerdt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Dec 3, 2024

Date

Subscribed and Sworn to before me this 3 day of Dec 2024.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 120 Phyllis Drive

City: Croydon State: PA Zip: 19021

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 215-613-3001 Website: www.pci.com

Licensing Company Email: compliance.PCIPharma@gmail.com

Section 2: Personal Information

First: Brad (Middle): Last: Payne

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Bainbridge Island State: WA Zip: [redacted]

Telephone: [redacted] Email: brad.payne@pci.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Shoreline High School			09/78-06/82	
Address	**City**		**State**	**Zip**
18560 1st Ave.	Shoreline		WA	98155
Diploma/Degree obtained, if any				
High School Diploma				
School Name			**From - To (MM/YY – MM/YY)**	
University of Washington			09/82-06/86	
Address	**City**		**State**	**Zip**
1410 NE Campus Pkwy	Seattle		WA	98195
Diploma/Degree obtained, if any				
BS Chemical Engineering				
School Name			**From - To (MM/YY – MM/YY)**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/24-Present	[redacted]	Cape Coral	FL	[redacted]
01/21-03/24		Bainbridge Island	WA	
5/19-1/21		Philadelphia	PA	
01/18–4/19		Philadelphia	PA	
06/13-01/18		Nyon, Switzerland	VD	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive			01/18-Present
Business Address	**City**	**State**	**Zip**
120 Phyllis Drive	Croydon	PA	19021
Phone	**Title**		
815-484-8900	Chief Operating Officer		
Description of Duties			
Chief Operating Officer, oversee operations and supply chain for PCI			

Business Name			From - To (MM/YY – MM/YY)
Becton Dickinson/CareFusion			06/13-01/18
Business Address	**City**	**State**	**Zip**
Park - A4, Sarl Terro Bonne, Rtede Crassier 17	Nyon, Switzerland	VD	1262
Phone	**Title**		
+41 21 556 30 00	Sr. Vice President Operations		
Description of Duties			
Oversee global operations for BD's Infusion Set business. BD bought CareFusion in 2015 and my job duties and job location did not change			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

12-3-24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bradley Payne

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-3-2024

Date

Please have this section completed in the presence of a Notary Public.

State of PA ss. County of Philadelphia

I, Bradley Payne, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12-3-2024

Date

Subscribed and Sworn to before me this 3 day of Dec 2024

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 120 Phyllis Drive

City: Croydon State: PA Zip: 19021

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 215-613-3001 Website: www.pci.com

Licensing Company Email: compliance.PCIPharma@gmail.com

Section 2: Personal Information

First: Jeannie Middle: Lynne Last: Metzinger

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Hudson State: MA Zip: [redacted]

Telephone: [redacted] Email: jeannie.metzinger@pci.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Temple University		09/05- 12/07	
Address	**City**	**State**	**Zip**
501 Carnell Hall	Phila	PA	19122
Diploma/Degree obtained, if any			
Masters of Science Regulatory Affairs			
School Name		**From - To (MM/YY – MM/YY)**	
Holy Family University		09/75 - 05/79	
Address	**City**	**State**	**Zip**
9801 Frankford Ave	Phila	PA	19114
Diploma/Degree obtained, if any			
BS in Biology and Chemistry			
School Name		From - To (MM/YY – MM/YY)	
Bishop McDevitt High School		09/71 - 06/75	
Address	City	State	Zip
125 Royal Ave	Wynecote	PA	19095
Diploma/Degree obtained, if any			
HS Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/21 - Present	[redacted]	Hudson	MA	[redacted]
10/97 - 7/21		Dresher	PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive		11/12 - Present	
Business Address	**City**	**State**	**Zip**
120 Phyllis Drive	Croydon	PA	19021
Phone	**Title**		
815-484-8900	Chief Quality and Compliance Officer		
Description of Duties			
Responsible for Quality Control, Quality Assurance, Regulatory Affairs and overall Compliance for PCI - globally.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address N A	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Jeannie L Metzinger
Original Signature (electronic, copies or stamps not accepted)

12-3-2021
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeannie Metzinger

Print Name (First, Last)

Jeannie Metzinger — Dec 3, 2024

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Pa, ss. County of Philadelphia

I, Jeannie Metzinger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jeannie Metzinger — Dec 3, 2024

Original Signature — Date

Subscribed and Sworn to before me this 3 day of Dec 2024

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 120 Phyllis Drive

City: Croydon State: PA Zip: 19021

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 215-613-3001 Website: www.pci.com

Licensing Company Email: compliance.PCIPharma@gmail.com

Section 2: Personal Information

First: Salim Middle: Last: Haffar

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Manchester State: NH Zip: [redacted]

Telephone: [redacted] Email: salim.haffar@pci.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

2017

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address [redacted]	City Manchester	State NH	Zip [redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
PCI Pharma Services dba Packaging Coordinators, LLC - Phyllis Drive			
Business Address	**City**	**State**	**Zip**
120 Phyllis Drive	Croydon	PA	19021
Phone	**Title**		
845-282-2636	CEO		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

12-2-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Salim Haffar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-2-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Pa, ss. County of Philadelphia

I, Salim Haffar, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12-2-2024

Date

Subscribed and Sworn to before me this 2 day of Dec, 2024

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

Packaging Coordinators, Inc.
3001 Red Lion Road
Philadelphia, PA 19114-1123

To whom it may concern,

Attached you will find a full list of employees who are currently employed by Packaging Coordinators, LLC.

Vaughn Ricchini
Quality Compliance Analyst
3001 Red Lion Rd.
Philadelphia, PA 19114
Vaughn.Ricchini@PCI.com
215-613-3600

Full Legal Name
Aaliyah Joiner
Abdniel Francisco De Jesus Diaz
Abel Erazo
ABHISHEK PATEL
Abilio Goncalves
Abner Torruellas
Adam Dabkowski
Adam Santiago
Adelina S Paez Parejo
Adolphus Wesley
Agnes Baldwin
Ahmen Cleveland
Ahmet Gungor
Ahmir Rainford
Aida Vega
Ailla Bishop
Aiman Batool
Airin Choudhury
Ajmal Roshan Puthanpurayil Shamsuddin
Akiera McEachin
Akilah Keesee
Alain Louis
Albert Morris
Aleksandros Alaterezoglu
Alex George
Alex Kraus
Alex Mungo
ALEX ROSSOLOV
Alexander Jefferson
Alexander Morrow
Alexander Pappy
Alexander Perez

Alexander Smith
Alexandria Cintron
Alexandria R. Unchis
Alexandria Ziegler
Alexis Burton
Alexis P. Colomy
Aleyamma Varughese
Ali Zeineddine
Alicia Carranco
Alik Zhurbich
Alim Hussein
Alisha Lee
Allen Navilliat
Alvoree Wallace
Alysha Hayes
Alyssa Renee Hampton
Amanda Diaz
Amanda Lokayi
Amarilys Echevarria
Amaya Cintron
Amber Ellis
Amina Noory
Amisha Patel
Ammar Rangunwala
Amy Ing
Amy Schillig
Amya Miller
Amylie Iglesias
Ana Lora
Ana Milagros Echevarria
Ananka Rojas
Andre M. Mosley
Andre Vaughan

Andrea Davis
Andrea Scott
Andres Reyes
Andrew Alexandrou II
Andrew Brenner
Andrew Colomy-Wright
Andrew Jenkins
Andrew Puchalski Jr.
Andrew Turzanski
Andrey Lapin
Anecita Huber
Angel Arias
Angel Fuentes
Angel Lopez Jr.
Angel Rodriguez
Angela Dam
Angela Dyer
Angela Nicolette Tillman
Angelica Oscal
Angelina Hopkins
Angelique Glenn
Anil Stephen
Anissa Montanez
Anita Bangura
Aniya Burroughs
Anna L. Gray
Anna Torres
Annamaria Berger
Annamma Varghese
Annette Parks
Anthonia Adeyeye
Anthony Anderson
Anthony Green

Anthony Rue
Anthony Watkins
Antoinette Ervin
Antoinette Tyree
Antwoine Hunter
Anup Varghese
Anwar M. Levere
April West
Ariel Jaquez
Arif Chariwala
Arman Rowshan
Arnitha Barnes
ASHAIYAH BANKS
Ashley Colon Rivera
Ashley Ortiz
Asiyah Saud
Audrey Sell
Avery Jackson
Bahija Ahmida
Baltazar Cisneros-Berrios
Barbara lissbet Grullon Rosario
Barbara Sanderlin
Baron Roane
Barry Nash
BASSIROU DIENG
Benjamin Kim
Benjamin Mc Cann
Benjohnson B Louis
Betty Jackson
Bevis Vanterpool
Biju Varghese
Binika Hada
Bonita Morales

Brandy Kugler
Brea Jacobs
Brenda Derolf
Brenden Jackson
Brent Collins
BRETT RADZISZEWSKI
Brian Beers
Brian Kite
Brian Mooney
Brian William Mullin
Briana Rodrigues
Brianna Ali
Brianna jacobs
Brittany Allen
Bruce Craig
Bryan Bolds
Bryan Jones
Bryan K Bradley
Bryan Sims
Bryant Collins
Bryheem Jacobs
Caitlin Monahan
Caitlin Rose Mastropietro
Calvern Smith
Camille Sanchez
Camille Simpson-Pryce
Carisma Fisher
Carl D. Davis
Carl Elysee
Carlianys Oquendo
Carlos Alvarez
Carlos Ceballos
Carlos Deyne jr

Carlos J. Deyne
Carmel Nicolas
Carmelo Rodriguez
Carmen Arce
Carmen Rodriguez
Carmencita Minaya
CAROLYN HENSOR
Casey Koger
Catalina Duque
Catherine Cabrera
Catherine Shipton
Ceirra Williams
Champa Bardhan
Chanda Bhatti
Chandrikaben Brahmbhatt
Chanelle Clark
Chanyia Kirkland
Charlene Darrah
Charles Harris
Chenelle Stokes
Cherisse Russell
Cheryl D Wimberly-Perry
Cheryl Russell
Chester Venable Jr
CHIDINMA MAPP
Choudhury Jamy
Chris Chapluk
Christen Jones-Bryant
Christian Alejandro
CHRISTIAN AMARO
Christian Matos
Christina Giles
Christine Marie Aust

Christopher Adrian Durant
Christopher Borden
Christopher Gourdine
Christopher Harrison
Christopher Jackson
Christopher Kline
Christopher Lentz
CHRISTOPHER SANTIAGO
Christopher Selden
Christopher Steigerwalt
Cindy Figueroa
Claire Crawford
Clarence McCorkle
Claude Clark
Claudette Bernadel
Claudia Jervas
Cleveland Matthews
Cleveland Pickett
Cody Miller
Cody Saez
Colette Destin
Colleen Schmid
Connor Derolf
Constance M. Koerner
Coraly Melendez
Corbin Bradshaw
Corey Dailey
Courtney Burgess
Courtney Cahill
Craig Hughes
Cristopher Santiago Cabrera
Cyesha Burton
Cynthia Evans

Cynthia Lavorgna
Cynthia Trang
Cynthia Wells
Daemon Maguire
Dafna Karikari
Dagnela Meneus
Daiquan Haynesworth
Dalice Amore Carter
Dallas Salley
Damaris De Jesus
Damaris Rivera
Damien Pedrosa
Danessa Lopez
DANIEL RODRIGUEZ
Daniel Smith
Dante Orlando
Daren Burton Jr
Darlene Rodriguez
Darnell Grandy
Darnell Taylor
Darryl Stukes
Davena MCkenzie
Daveshu Patel
David Collacchi
David J. Burger
David Kountz
David Leach
David Miller
David Pabon
David Yeow
Deborah Booker
Deborah Duerstock
Deborah Howell

Deborah St Marie-Nuttall
Debra Sherrick
Deepa Kochukaleeckal Philemon
Delani Rivera
Delilah Lebron
DeLisa Hool
Demetrius Mann
Demetrius Porter
Demetrius Sutton
Denise Brach
Denise Garay
Denise Holmes
Denise Smith
Dennis Cliggett
Dennis Johnson
Dennis Mullen Jr
Denny Alex
Deon A. McKenzie
Derek Edward Still
Desiree Baldwin
Destiny Bell
Destiny Savage
Dewey Wakefield
Dezmand Davis
Diana Vegerano-Rodriguez
Diane Stoner
Dief Remonnette
Dieufait Morisset
Diocko Gandega
Dion Cottingham
Divya Tripathi
Dmitri Murray
Dolly Gladson

Dominiq Bass
Dominique Johnson
Donald Bowers
Donald Cliggett
Donald Rookstool
Donna Connor
Donna McCauley
Donna Sterling
Donnell Jackson
Dontae Dawson
Dontae Wilson
Dorian Douglass
Dorothy Harmon
Dwayne Divers
dwayne forman
Dweep Dey
Eboni Killing
Ebony Byrd
Edalys Maria Duran
Edgardo Albandoz
Ediberto Gonzalez-Portalatin
Edieca Perez
Edward B Rehl
Edward Coffin
Edward Kaye
Edward Szczepankiewicz
Edwige Chery
Edwin A. Bushey
Edwin Nicholas
Edwin Ortiz Mendez
Edwin Rafael Rosario
Efran Junior Maldonado JR Jr.
Efran Maldonado

Egbert Gordon
Eileen Echevarria
Elaine Jewell
Elaine Smith
Elaine Stirling
Eleasim Maisonet
Eleonora Rytsar
Elijah Munoz
Elizabeth Carcano
Elizabeth Colon
Elizabeth Crummy
Elizabeth Suarez
Ellis Gibbs
Elma Chowdhury
Elvira Roci
Elwood Dennis
Emely Santana Diaz
Emilson Mazile
Emmanuel Okendu
Entela Bileri
Erianna Marie Padua
Eric Bass
Eric Boafo
Eric Lilly
Eric Martin
Eric Silver-Folk
Erica Gabel
Erich Pollinger
Ertha Cineus Narcisse
Eseeta Reme Hossain
Esther Olmo
Ethewaldo Cribas Diaz
Eugene Groves

Eva Soto
Faatimah Hayes
Fabiola Bijou
Fakia Leake
Fanny Early
Farah Joseph
Farah Samuel
Farida Aly
Farida Barkas
Farran Haynes
Fatiha Berdaoui
Felicia Bynes
Felicia Kennard
Felix Melendez
Fernando Massillon
Fnu Sanju Sunny
Francis Schleinkofer
Franky Aponte
Freddie Gomez
Freddy Joy Joseph
Fuat Hyseneshi
Gabriel Figueroa
Gabrille Cunningham
Gail Wildonger
Gardy Eliser
Garry Teagle
Gelane Pratts
Genesis Burgos
George Garbrah
George Philip
George Thomas
George V George
Geyonna Jones

Giorgi Tsuladze
Giovanna Barbato
Giovanni Delhomme
Giovanny Mejias
Gloria M Feliciano
Grazyna Krengiel
Gregory Vutera
Guilherme De Faria Eisinger
Gulshan Toirjonova
Gulyara Karimova
Gwendolyn Williams
Haider Khan
Hannibal Collick
Harry Philizaire
Hassan Khan
Hazel Missimer
Hazera Munira
Heinrich Rost
Hendry Dominguez
Henrietta Fraley
Hilda Aviles
Hina Ishaq Khan
Holly Summers
Honesto I Nunez III
Hugo Colin Charles Pochart
Huy Ngo
Iang My
Ida Tender
Ikea Murray
Imran Khan
Irene Matthew
Irene Miriam George
Iris Bautista

Iris Gonzalez
Iris Roman
Isabel Gutenberger
Isabella Giordano
Isiah Golson
Israel Lugo
Isys Alexia Reese
IVAN OTAMAS
Ivan Valentin
Ivette Lopez
Ivette Mandes Gallardo
Ivy Smith
Iysis Holly
Jack Hastings
Jacob Seamon
Jacqueline Cupp
Jacqueline Faulcon - Harris
Jacqueline Reese
Jacqueline Schonewolf
Jahziar Johnson
Jakhi Hilton
Jala Williams
Jalen Graves-Lawimore
Jamaal Ford
Jamal Talukder
JAMAR WASHINGTON
Jamarr Jefferson
Jamel Harvey
James Affleck
James Edessaril
James Hurley
James Jacobs
James Jamison

James Johnson
James M Clark
James Montague
James Mooney
James Nuttall
James Reingruber
James Sanderlin
James Semler
James W. Miller
JAMES WEBB
Jameson Augustin
Jamie Burton
Jamie McGlone
Jamilka Rivera
Jamison Bullock
Janessa Washington
Janine Mayhew
Jaquan James
Jarred Spencer
Jarvis Lynch
Jasen Carroll
Jasmin Vasquez
Jasmine Bryant
Jasmine Williams
Jason Garcia
Jason Kuhns
Jason Lewis
Jason Piccone
Javier Celeste
Javonne Wilkinson
Jayda Mullins
Jayme Hopkins Allison
Jazmin Parrilla

Jean Augustin
Jean Elie Ostagne
Jean Gerald Similien
Jean-Michael Bowler
Jeffrey Charles Noak
Jeffrey Greate
Jeffrey L Schlesinger
Jeffrey Ming Tan
Jeffrey Rein
Jeffrey Wright
Jeiser Rodriguez
Jelani Carter
JENELLE R HOLLOMAN
Jenneh Wawood
Jennifer Aviles
Jennifer Bovack
Jennifer Carrion
Jennifer Celeste
Jennifer Dagnall
Jennifer Do
Jennifer Giacinto
Jennirose Graboskie
Jenny Garcia
Jeremiah Robinson
Jeremy Bennett
Jeremy Norwood
Jermaine Tillman
Jerome Thomas
JERYLL BALLESTEROS
Jesenia Camacho
Jesse Cartagena
Jessica Achecar
Jessica B Wolfenden

Jessica Dejesus
Jessica Khamphoumy
Jessie Pascual
Jettleen Carter
Jinny Samuel Thomas
Jn Francois Yves Nicolas Altag Lapierre
Joann Natchez
Joanna Philemon
Joanna Rosado
Joanne Valentine
Jobin Thomas
Joel Garcia
Joel Hartmann
Joel Mirabal
Joel Sutherlan
Johanna Maysonet-Hernandez
John Bates
John Bracey
John Davila
JOHN DOMINGUEZ
John Helverson
John Parankamoottil Mathew
John Redfain
John Stride
John Viaud
Johna Little
JOHNATHAN GLOVER
Johnathan Nowacki
JOHNNY HUA
Johnny Torres
Jonathan Girard
Jonathan Hill
Jonathan Mayanan

Jonathan Napper
Jordan Dyer
Jordan Lewis
Jordan Mormello
Jordan Stockage
Jorge Ivan Luciano Garcia
Jorge Vicent
Jorge Vicent
Jose K John
Jose Ortiz
Jose Soto
Jose Thomas
Jose Torres
JOSELINE MORALES
Joseph Annan
Joseph Badillo
Joseph Bisirri
Joseph Clark
Joseph Fedorowycz
Joseph Floody
Joseph Hettinger
Joseph Schnell
Joshua Jackson
Joshua Searle
Joshua Simmons
Joshua Subramani
Journn'i Flamer
Joy Browning
Juan Bonilla
Juana Gonzalez
Juanita Berry
Julia Bahamonde
Julian Cora

Juliet Vicent
Julio Ceasar Ferrer Mendez
Justin Michael Kravchuck
Justin Perez
Justin T Pollino
Kaday Mansaray
Kahri Haynesworth
Kaleb Llovet
Kalin Parham
Kalu Azuma
Kamaar Briggs
Kamari Reaves
Kameesha Reid
Kareem Edwards
Karen Hall
Karen Ryan
Kathleen Kafel
Katrena Bethel
Katrina Armstrong
Katrina Campbell
KAVANIA ROBINSON
Kellan Spencer
Kelli Zajdel
Kendal Morris
Kenneth Cave
Kenneth Kenneth Brown Sr.
Kenneth Ray
Kera Cathel
Kerolos Akraz
Kerry Harper
Keshia Richardson
Kevin Buzby
Kevin C. Bryant

Kevin Guerra
Kevin Hagler
Kevin Haxton
Kevin Lawrence
Kevin Mance
Kevin Wallace
Keving Nicolas
Keyra Torres
Keyvon Montague
Khalif Barrett
Khalil Gibson
Khayree Elliot
Kian Kinchloe
Kiana Simone Spratley
Kimball Eng
Kimberly Michele Wiggins
Kimberly Wiggins
Kimetha Reese
Kofi Ampofo
Koshy George
Kristen Paden
KWAMAIR RILEY
Kyle Felix
Kyle Josey
Kyle Prima
Kyshaun Hall
Lan Trinh
Lance Jordon
Lanlie America
Laronda Shanell Jones
Lashawn Hayes
LaTanya Turner
Latascha Seals

Latrese McLeod
Lauren Michelle Robinson
Laurie Cooper
Laverne Summers
Leena Thomas
Lemoryd Holmes
Leonora Garcia Wright
Leroy Hawkins
Leslie P. Langley
Liam Slavin
Libin Mathew Abraham
Libu Varghese
Lileana Cruz
Linda Candelaria
Linda Scull
Lisa Ann Sponheimer
Lisa Harley
Lisa Kiple
Lisa Martin
Lisa Scrimenti
Lisandra Gonzalez
Loretta Ramirez
Lorna Beal
Lorraine Daniels
Lorraine Marrow
Louis Stefanoni
Louise Bailey
Lourdes Deyne
Ludivico Perillo
Luis Bizaldi
Luis Galvan
Luis Rosario
Luke Growney

Luqman Abram
Luz De Jesus
Lynette Roman
Lynette Torres
Lyudmila Shubinsky
Ma teresa Garcia
Madison Maxwell Gummel
Mahbub Suny
Mahmad S Tai
Makir Henry
Malaejah Sample
Maleina Morales
Malik Young
Malika Pryor
Manasa Jaymon
Manisha Mathew
Manisha Morker
Manjula Littu
Marcelo R Romero Curbelo
Marcus C. Turner
Margaret Clark
Margaret Dooley
Margaret Huynh
Margareth Coriolan
Margaretta Carrecter
Maria Alarcon
Maria E Roberts
Maria Nunez
Maribel Cribas
Maribel Torres
Marie Claire Daphnee Casseus
Marie Rosenie Elysee Jeune
Marie Yobouet

Mariely Manan
Mario Victor Parlapiano
Mario Ward
Marion Banks
Marisol Torres
Maritza Lopez
Mark Jackson
Mark Kiple
Mark Ligato
Mark Tilley
Markeeta Price
Marlee Wuchter
Marlene Rijo
Marlisa Thomas
Marlon Bennett
Marquetta Woodlyn
Marquis McGill
Marsela Dosti
Martin Jakos
Marveenlee Pierre
Marvin Parker
Mary Curichiyil
Mary E Hendry
Mary Ortiz
Mary Sol Ramos
Maryam Hamza
Marzuwq Shamsid-Deen
Masiah Hurst
Massiel Cruz
Mastila Dosti
Mathew Kuttielavumkal
MATI ULLAH
Matthew Eroh

Matthew Gavenda
Matthew Glisson
matthew hanson
Matthew McDermott
Matthew Merriweather
Matthew Mullen
Matthew Sweet
Maurice Harmon
Maurice Hockaday
Maurice Miller
Maymary Huynh
md rahman
Md Sadequr Rahman
MD Shohidul Islam
Megan Monahan
Meghan Lacey Gallagher
Mehwish Shadab
Melanie Walker
Melisa Gunawan
Melissa Haynes
Melissa Montanez
Melody Achille
Melody Joiner
Melvin Anthony Maldonado Jr.
Mercy Mathew
Merida Colon
Michael Bradby
Michael Brennan
Michael Cheung
Michael Devanney
Michael Galinsky
Michael Guerrero
Michael H. Anderson

Michael Jacobs
Michael lockwood
Michael Luke
Michael Menaldi
Michael Menaldi
Michael Rubinstein
Michael Santiago
Michael Smith
Michael Thomas Trainor
Michael West
Michael Wood
Michelle Carrington
Michelle Perez
Michelle Pressley
Migdalia Rivera
Miguel A. Burgos
Miguel Rodriguez
Mihaela Tilica
Mikel Kararaj
Minerva Cardona
Mobisha Monachan
Mohamed Bangura
Mohammad Shah Imran
Mohammed Al-Bataineh
Mohammed Ali
Monica Rios
Monique Diane Phelps
Mosky Georges
Moussasrey Christian Bamba
Mr. Binu Thankachan
Mr. Enrique Ricardo Rodriguez
Mr. Marchello Kiheem Hancock
Mr. Rokeysh Jerell Lyde

Mr. Stanford Hill
Ms. Renette Mahotiere
Muggett Rivera
Mugguett Diaz
Muhammed Chariwala
Mukesh Mahida
Myeesha Walker
Myrnaliza Pierce
Mysha Maria
NADEEM IBRAHIM
Nadir Bryant
Nahid Akhtar
Nancy Arabinick
Nancy Dorr
Nancy Gonzalez
Nancy Hoffman
Nancy Sanchez
Naomi Crompton
Nashel Nazario Velez
Nashi Fussell-Smith
Nasir Sutton
Natalie Oberholtzer
Nathan Point-Dujour
Nathaniel McIntyre
Natia Drake
Nayana Patel
Naylenne Marrero
Neda Rahimi
NEIL WALLOP
Nelson Figueroa
Nettie Lawrence
Nevin Jaison
Neycha Davila-Hernandez

Nicholas Falconiero
Nicholas James Matyi
Nicola Hayes
Nicole Felicioni
Nicole Makin
Nicole Rosselli
Nikia Berry
Nikita Ben Patel
Nikunj J. Patel
Nilesh Shah
Nirzari Patel
Nishita Patel
Nithin Lalith
Nitza Lee Robles
Noah Brodecki
Noman Patel
Noorul Aain
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Norma Hernandez
Norma Rodriguez
Nuon Tek
Nyasia Gonzalez
Nyire Dorsey
Nyree Walker
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Osayogie D Osemwegie
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Parker Chen
Patrick Allen Jr
Patrick Heizman
Patrick J. Kelly

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Paul Rodriguez
Pavel Mekhedav
Payal Patel
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Pedro Rodriguez
Penny Burroughs
Peter Cona
Peter Jacuk
Peter Sinesi
Phanosha Sanders
Phara Juste
Philemon Kochukaleeckal
Philip Hughes
Philip Nemirovsky
Phillip O'Driscoll
Pierre Hermann Elysee
Pierre Ossoide Elysee
Pierre Similien
Praise Abraham
Prathish Kurian Abraham
Princemessiah Alexander
Quadir Fleming
Quaron Jainlett
Quincetta Moore
Rachel Zellars
Rafael Arroyo
Rafael Arroyo
Rafael Enrique Vazquez
Rafael L. Arroyo
Rafael Rivera
Rafael Soto
Raheem Holloway

Rahim Diggins
Rajendra Patel
Rajendra Prasad Krishnan
Ramire Jones
Randy Roberts
Ranxie Chen
Raquel Sprual
Rasahn McDuffie
Rashuan Antley
Raul A Velez Jr.
Raul Rodriguez
Raymond Walker
Regina Conly-Klampfer
Rehan Khanzada
Reis Hill
Reji John
Remona Spence
Renee Waters
Rexhina Struga
REXY THOMAS
Ricardo Moise
Ricardo Thomas
Ricci D'Andrea
Richard Canavera
Richard D Sterling
Richard Gowallis
Richard Rossi
RIMON ABOUSEIF
Rina Belaid
Rita Jacuk
Rita Pondexter
Rob Kramer
Robert Bailey

Robert Brown
Robert Bryan Cutler
Robert Costello
Robert Cristinziani
Robert Edelmann
Robert Groves
Robert Henry
Robert Kane
Robert Michael Groves
Robert V. Burger
Robert Viall
Robin Summers
Rock Eben Ezer Laguerre
Rod Coriolan
Rodger Hasty
Rohan Ekambaram
Rollen Malabuyoc
Rollie Palec
Romaire Tisoit
Ronald Daniel
Ronnie Darnell Reed Jr.
Ronnie Rollins
ROSA SILVA
Rosa Teran
Rosamma Sunny
Rosanne Dunn
Rose Franqui
Rose Peters
Rosita Torruella
Roy Thomas
Ruby Quindlen
Ruth Serrano
Ryan Burke

Ryan Kerr
Ryan Luu
Ryan Maguire
Ryan Meehan
Ryan Vogt
Rymone R Auld
Sabria Mason
sadir nobles
Sai Chandana Ventrapragada
Saida Berdaoui
Saige Williams
Sainath Vittal Dadiga
Sam Jones
Sam Laguerre
Samantha Lopez
Samantha Rishel
Samoda Smith
Samone Whittaker
Sampson Snottee Nyawkun
Samuel Mitchell
Samuel Pierre
Sandra Beckler
Sandra Eubanks-Spurgeon
Sandra Gabel
Sandy Burns
Sandy Colon
Santiago Ossa
Santiago Rose
Saquib Siddiq
Saymon Sondi
Schadrack Moise
Scott Griscom
Scott Pleune

Sean Walsh
Sean Whalen
Sebastian Anzalone
Sehar Luqa
Selina Sanderlin
Sena Tahoulan
Serenity Irvin
Shabresha Stover
Shaheed Afzal
Shahiyd Da'ood Tilghman Bullock
Shahzad Masih
Shaji John
Shamira Hurdle
Shamsun Jelly
Shanice Foster-White
Shanik Baxter
Shannon Buckley
Shantel Tomlin
Shaquor Walker
Sha-Rae Seals
Sharee Bentley
Sharon Sweeney
Shatika Jones
Shaun Stephenson
Shawn Webb
Shawneese Douglas
Shayem Shahriar
Sheena Anderson
Sheila Bivens
Shelley Roberson
Shirley A Simpson
Shirley Green
Shiven Patel

Shmill Northan
Siedah Neal
Siju John
Sokha Koy
Sonia I Torres
SONIA LAIFA
Sonia Montanez
Sonia Pascua
Sonia Rosa
Sonja Rhett
Sonya Marie Murray
Sophann Phat
Stacy Cosby
Stanley Sturgis
Stephanie Blackiston
Stephanie Coker
Stephanie M. Burroughs
Stephen John
Stephen Malicek
Stephen Walker
Steven Calhoun
Steven Daniels
Steven Gambrell
Steven Grullon
Steven Nicholson
Stivanson Tailor
Sudha Jose
Sunitha Mary Rays
Sunny Abraham
susan George
Susan Tobin
Susan Yannuzzi
Suzanne Gallagher

Sybil Jacob
Syed Ali
Tai Ong
Taira Saunders
Tajaii Mason
Tamara Leith
Tamia Burton
Tammy Gallinger
Tanajia Johnson
Tania Guerra
Tanimur Chowdhury
Tara Goncalves
Taras Scott
Taryn Jackson
Taslima Akter Rima
Tatyanna Washington
Tavis Wills
Tawanda Ware
Tawanna Clark
Taylor Hammond
Tealia Brown
Tejinder Singh
Terence Jefferys
Terrance Watson
Terrence McBride
Thaely Enid Montijo Rosado
Theresa Bailey
Theresa Barbardo
Thomas Alexander
Thomas Cliggett
Thomas Fasano
Thomas Mathew
Thomas Monefeldt

Tiaesha Randolph
Tiana Cintron
Tieisha Williams
Tiffaney W Quiles
Tiffany Logan
Tiffany Scott
Tigi Thomas
Tijo Parappully
Tim Jaison
Timisha Smith-Rafi
Timothy Martin
Timothy Thagnabouth
Todd O'Neal
Tohura Buyah
Toni Micciolo
Tonya Yao
Travis Cliggett
Tristyn Baumgartner
Trocon Kai
Troy Culver
Trung Trinh
Tucker Rinne
Twanda Jefferson
Twomelay Harding
Tyqua Murray
Tyree Payne
Tyren Booker
Umesh Patel
Urszula Pellegrino
Vadim Balibar
Valerie Ertell
Vanessa Carroll
Vanessa Ravenell

Varghese Littu
Varinder Dhaliwal
Varughese E Thevervelil
Vaughn Ricchini
Vickie Marshall
Victor Fernandez
Victor Manuel Pagan Jr.
Victoria Donadel
Victoria Miller
Victoria Nguyen
Vincent Manochio
Vincent Shaw
Vionnette Cruz
Vital CHATELIER
Vivian White Sardo
Walter Helm
Wayne Cooper
Wendy Dozier
Wilfredo Rivera
William Briggs
William Grogan
WILLIAM JOHNSON
William Joyce
William Kinton
William Prawl
William Proctor
WILLIAM RHIM
Xavier Rivera
Yamisley Colon
Yana Gonzalez
Yesenia Barada
Yi Xing Chen
Yimly Fong Diaz

Yin Leon Chan
Yolanda Hannah Maria Spruill
Yolinda Reyes
Yoly Rodriguez
Yonatan Celeste
Yudy Bernard
Yugkumar Patel
Yvette Rice
Zachary Galloway
Zachary Kane
Zachary M Derolf
Zakia LeVere
ZAKIA TAHIR
Zamear Ashrafali
Zayaini Dennis
Zoila Osorio Navarro
Zuri Parks
Zyhir Chandler

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☑ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☑ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Silver State Medical Supply LLC

Physical Address: 2550 S. Jones

City: Las Vegas State: NV Zip: 89146

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-960-2003 Website: tcmedicore.com

Name of Designated Representative (DR): Minnie Cadray

Licensing Company Email: tcmedicore@gmail.com DR Email: mpcadray@yahoo.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☑ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☑ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/25/25
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: Silver State Medical Supply LLC

Mailing Address: 2550 S. Jones

City: Las Vegas State: NV Zip: 89146

Telephone: 702-960-2003 Email: towbinradiology@gmail.com

Contact Person Name: Rocco Towbin

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. (REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Silver State Medical Supply LLC

Facility Name

Justin Cadray

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/21/25

Date

Board Use Only	Date Received: 3/31/25	Amount: $1000-cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Silver State Medical Supply LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 12/30/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 12/31/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202412315311301
You may verify this certificate online at https://www.nvsilverflume.gov/home

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 2/11/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Skyanne Wilkins
Leavitt Insurance Agency 7881 W. Charleston Blvd. Suite 140 Las Vegas NV 89117	PHONE (A/C, No, Ext): (702) 382-4010 FAX (A/C, No): (702) 947-4010 E-MAIL ADDRESS: skyanne-wilkins@leavitt.com
	INSURER(S) AFFORDING COVERAGE / NAIC #
	INSURER A: ACE Property and Casualty Insurance Con 20699
INSURED	INSURER B:
Silver State Medical Supply LLC DBA: Towbin Caday Medical 2550 S Jones Blvd Las Vegas NV 89146	INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** 2025-2026 Master Cert **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			D02845544/PKG	2/3/2025	2/3/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Other than Products/Comp/OP Agg	$ 1,000,000 $ 1,000,000 $ 5,000 $ 1,000,000 $ 2,000,000 $ Excluded $ 2,000,000
	AUTOMOBILE LIABILITY ANY AUTO ALL OWNED AUTOS SCHEDULED AUTOS HIRED AUTOS NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $ $
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE AGGREGATE	$ $ $
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: Y N/A If yes, describe under DESCRIPTION OF OPERATIONS below			2671816397/WC	2/3/2025	2/3/2026	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Coverage subject to policy terms, conditions, limitations, and exclusions.

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Jordan Leavitt/SKWILK

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IFIC Surety
A Member of IAT Insurance Group

BOND RIDER

To be attached to and form a part of Bond No 0867858

Dated The 17th Day of March 2025 By and Between:

Silver State Medical Supply LLC DBA TC Medicore , as Principal, and

Harco National Insurance Company as Surety, in favor of

Nevada State Board Of Pharmacy , as Obligee.

It is understood and agreed that the bond is changed or revised in the particulars checked below:

☑ Name of Principal changed to:
Silver State Medical Supply LLC DBA TC Medicore

☐ Amount of Bond changed from
to

☑ Other address has been updated:
2550 S Jones Blvd, Las Vegas, NV 89146-5302

Said bond shall be subject to all its terms, conditions and limitations, except as herein expressly modified. This bond Rider shall become effective as of 04/10/2025

IN WITNESS WHEREOF, Harco National Insurance Company has caused its corporate seal to be hereunto affixed this 10th day of April, 20 2 .

Principal: Silver State Medical Supply LLC DBA TC Medicore
By:

Harco National Insurance Company
By: Valerie Aber
Attorney-in-Fact

POWER OF ATTORNEY

Bond # 0867858

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

VALERIE ABER, DANIEL RUGGERI

Litchfield Park, AZ

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2024

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Michael F. Zurcher
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2024, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2029

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, April 10, 2025

A00815

Irene Martins, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0867858

Application/License No. _____

Silver State Medical Supply LLC DBA Towbin Cadey Medical (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 10428 Pacific Sageview Ln, Las Vegas, NV 89144-6564 (Address of Applicant/Principal), as PRINCIPAL, and Harco National Insurance Company (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 702 Oberlin Road Raleigh, NC 27605 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 03/17/2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 17th day of March, 2025.

APPLICANT/PRINCIPAL COMPANY

Rocco Towbin
Authorized Representative Manager

SURETY

Harco National Insurance Company

Valerie Aber
Surety Company's Representative

Valerie Aber, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Silvia Florez
Witness

Tanya Anderson
Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent
Lisa Dawn Stevens, NV License #49803

Scott Kipper, Commissioner of Insurance

Resident Producer

Qualification Effective Dates

Casualty 10/01/2001 Property 10/01/2001

LISA DAWN STEVENS

NPN: 4576705

7881 W CHARELSTON#140

LAS VEGAS, NV 89117

is authorized to transact business as described above

License No: 49803 Issue Date: 10/01/2001 Expiration Date: 02/29/2028

Generated by Sircon 338566379

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

LISA DAWN STEVENS

7881 W CHARELSTON#140

LAS VEGAS, NV 89117

LICENSE NUMBER: 49803 NPN: 4576705

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Resident Producer

Casualty, Property

Issue Date: 10/01/2001 Expiration Date: 02/29/2028

Generated by Sircon 338566379

POWER OF ATTORNEY

Bond # 0867858

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

VALERIE ABER, DANIEL RUGGERI

Litchfield Park, AZ

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"RESOLVED, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-In-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2024

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1984 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Michael F. Zurcher
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2024, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2029

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, March 17, 2025

A00815

Irene Martins, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Silver State Medical Supply LLC MDEG License # (if applicable) _____

Physical Address 2550 S. Jones

City Las Vegas State NV Zip 89146

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-960-2003 Website frmedicore.com

Licensing Company Email fawbincachy medical@gmail.com

Section 2: Personal Information

First MINNIE Middle MURAY Last CADAY

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City LAS VEGAS State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE PHILIPPINES COLLEGE OF NURSING			06/85 – 03/89	
Address	City	State	Zip	
PADRE FAURA ST	MANILA	PHILIPPINES	1000	
Diploma/Degree obtained, if any				
BS NURSING				

School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE PHILIPPINES INTEGRATED SCHOOL			06/79 – 03/83	
Address	City	State	Zip	
RATIPUNAN ROAD	QUEZON CITY	PHILIPPINES	1101	
Diploma/Degree obtained, if any				
HIGH SCHOOL				

School Name			From - To (MM/YY – MM/YY)	
N/A				
Address	City	State	Zip	
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
N/A				
Address	City	State	Zip	
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
N/A				
Address	City	State	Zip	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012 – PRESENT	[redacted]	LAS VEGAS	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
SUNRISE HOSPITAL			3/4/96 – PRESENT	
Business Address	**City**		**State**	**Zip**
3186 MARYLAND PARKWAY	LAS VEGAS		NV	89109
Phone	**Title**		**Number of Employed Hours**	
(702) 961 - 7040	RN		36 / WEEK	

Description of Duties: AS A REGISTERED NURSE I RECEIVE AND ACKNOWLEDGE ORDERS WRITTEN BY PRESCRIBING PHYSICIAN. AFTER VERIFICATION BY PHARMACY, I SECURE AND ADMINISTER MEDICATIONS, IV FLUIDS, OXYGEN AS ORDERED

Business Name			From - To (MM/YY – MM/YY)	
SILVER STATE MEDICAL SUPPLY, LLC			4/3/25 –	
Business Address	**City**		**State**	**Zip**
2550 S. JONES BLVD.	LAS VEGAS		NV	89146
Phone	**Title**		**Number of Employed Hours**	
(702) 960 - 2003	MDEG ADMINISTRATOR		24 / WEEK	

Description of Duties: I WILL IDENTIFY, RECEIVE AND DISPENSE MEDICAL SUPPLIES OF THE COMPANY AS ORDERED. I WILL INSPECT FOR DAMAGES, EXPIRATION AND OVERALL CONDITION OF SUPPLIES. I WILL ENSURE APPROPRIATE STORAGE CONDITIONS PER GUIDELINES.

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties:

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties:

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties:

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/27/25
Date

I, MINNIE PURAY CADAY, **certify that as the MDEG Administrator for**

SILVER STATE MEDICAL SUPPLY LLC,

that I (initial that you have read and meet the following requirements):

1. MC Have a high school diploma or its equivalent;
2. MC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MINNIE CADAY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/21/25

Date

Board Use Only	Date Received: 3/31/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Silver State Medical Supply LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2550 S. Jones

City Las Vegas State NV Zip 89146

Mailing Address (if different from physical address) _____

City Las Vegas State NV Zip 89146

Telephone 702-960-2003 Website fcmedicare.com

Licensing Company Email fowbin caday medical @gmail.com

Section 2: Personal Information

First MINNIE Middle PURAY Last CADAY

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City LAS VEGAS State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE PHILIPPINES COLLEGE OF NURSING		1985 – 1989	
Address: PADRE FAURA ST. MANILA, PHILIPPINES	City: MANILA	State: PHILIPPINES	Zip: 1000
Diploma/Degree obtained, if any: BS NURSING			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE PHILIPPINES INTEGRATED SCHOOL		1979 – 1983	
Address: DILIMAN, KATIPUNAN ROAD	City: QUEZON CITY	State: PHILIPPINES	Zip: 1101
Diploma/Degree obtained, if any: HIGH SCHOOL			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012 – PRESENT	5361 MISTY ACRES CT.	LAS VEGAS	NV	89148
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: SUNRISE HOSPITAL			From - To (MM/YY – MM/YY): 3/4/96 – PRESENT
Business Address: 3186 MARYLAND PARKWAY	City: LAS VEGAS	State: NV	Zip: 89109
Phone: (702) 961-7000	Title: RN		Number of Employed Hours: 36 / WEEK
Description of Duties: AS A REGISTERED NURSE I RECEIVE AND ACKNOWLEDGE ORDERS WRITTEN BY PRESCRIBING PHYSICIAN. AFTER VERIFICATION BY PHARMACY, I SECURE AND ADMINISTER MEDICATIONS, IV FLUIDS, OXYGEN AS ORDERED.			
Business Name: SILVER STATE MEDICAL SUPPLY, LLC			From - To (MM/YY – MM/YY): 4/3/25 –
Business Address: 2550 S. JONES BLVD	City: LAS VEGAS	State: NV	Zip: 89146
Phone: (702) 960-2003	Title: DESIGNATED REPRESENTATIVE		Number of Employed Hours: 24 / WEEK
Description of Duties: I WILL IDENTIFY, RECEIVE AND DISPENSE MEDICAL SUPPLIES OF THE COMPANY, AS ORDERED. I WILL INSPECT FOR DAMAGES, EXPIRATION AND OVERALL CONDITION OF SUPPLIES. I WILL ENSURE APPROPRIATE STORAGE CONDITIONS ACCORDING TO GUIDELINES.			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name N/A		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

3-25-2025

Original Signature (electronic, copies or stamps not accepted) Date

I, MINNIE P CADAY, **certify that as the designated representative for** SILVER STATE MEDICAL SUPPLY LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MC I am at least 21 years of age;
3. MC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

MINNIE CADAY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-25-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MINNIE CADAY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/25/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, MINNIE MURAY CADAY, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/25/25

Date

Subscribed and Sworn to before me this 25th day of March.

Notary Public Signature

AMANDA LEIGH HANEY
Notary Public, State of Nevada
Appointment No. 18-4387-1
My Appt. Expires Nov 22, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Silver State Medical Supply LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 7550 S. Jones

City Las Vegas State NV Zip 89146

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-960-2003 Website 7cmedicore.com

Licensing Company Email fountincadymedical@gmail.com

Section 2: Personal Information

First JUSTIN Middle JOLO Last Cady

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email fountincadymedical@gmail.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
Durango High School	08/16 - 05/20

Address	City	State	Zip
7100 W Dewey Dr, Las Vegas, NV	Las Vegas	NV	89113

Diploma/Degree obtained, if any: College and Career Ready Diploma

School Name	From - To (MM/YY – MM/YY)
University of Nevada, Las Vegas	08/20 - 03/25

Address	City	State	Zip
4505 S. Maryland Pkwy	Las Vegas	NV	89154

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)
N/A	

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)
N/A	

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)
N/A	

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/12 - 12/24	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/25/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin, Cadby

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/25/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Justin Jolo Cadby, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/25/25

Date

Subscribed and Sworn to before me this 25th day of March.

Notary Public Signature

AMANDA LEIGH HANEY
Notary Public, State of Nevada
Appointment No. 18-4387-1
My Appt. Expires Nov 22, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site SILVER STATE MEDICAL SUPPLY LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 2550 S. Jones

City las Vegas State NV Zip 89146

Mailing Address (if different from physical address) X

City X State X Zip X

Telephone 702-960-2003 Website TC medicore.com

Licensing Company Email TOWBIN CADAYMEDICAL@gmail.com

Section 2: Personal Information

First ROCCO Middle NMN Last TOWBIN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 2550 S Jones

City las vegas State NV Zip 89146

Telephone [redacted] Email Rocco@TCmedicore.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (if "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
Durango HIGH SCHOOL	7100 w Dewey Dr	Las Vegas	NV	89113	8/16 – 5/18	n/a
Palo Verde High School	333 Pavilion Center dr	Las Vegas	NV	89144	8/18 - 5/19	n/a
n/a						
n/a						
n/a						

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/13 - 08/16	[redacted]	Las Vegas	NV	[redacted]
08/16 - 10/19		Las Vegas	NV	
10/19 - 5/22		Las Vegas	NV	
05/22 - 03/25		Las Vegas	NV	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Towbin FIAT ALFA ROMEO			From - To (MM/YY – MM/YY): 6/18 - 1/20	
Business Address: 2550 S Jones	City: Las Vegas		State: NV	Zip: 89146
Phone: 702-900-3428	Title: Service Advisor			
Description of Duties: Scheduling and dispatching service for vehicles				

Business Name: Towbin Dodge Ram			From - To (MM/YY – MM/YY): 6/20 - 12/24	
Business Address: 275 AUTO MALL DR	City: Las Vegas		State: NV	Zip: 89014
Phone: 702-957-1740	Title: USED CAR MANAGER			
Description of Duties: Overseeing all operations related to used car sales				

Business Name: n/a			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name: n/a			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name: n/a			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Business Name n/a			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name n/a			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name n/a			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name n/a			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name n/a			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	n/a	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
n/a				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ROCCO TOWBIN
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-25-2025
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, ROCCO TOWBIN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3-25-2025
Date

Subscribed and Sworn to before me this 25th day of March.

Notary Public Signature

AMANDA LEIGH HANEY
Notary Public, State of Nevada
Appointment No. 18-4387-1
My Appt. Expires Nov 22, 2026

(Seal)

- List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.
    - Rocco Towbin (employee)
    - Justin Caday (employee)
    - Minnie Caday (employee)
    - Jonatan Hailemariam (employee)

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☒ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH existing MW00016	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Stat-Med, Inc

Physical Address: 537 E Brooks Ave #407

City: North Las Vegas State: NV Zip: 89030

Mailing Address (if different from physical address): 23606 N 19th Ave, Suite 2

City: Phoenix State: AZ Zip: 85085

Telephone: 623-434-4895 Website: www.stat-med.net

Name of Designated Representative (DR): Resty Dumag

Licensing Company Email: statmedaz@gmail.com DR Email: statmedaz@gmail.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: SNF's, Nursing Homes		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - Stat-Med does nto distrbute pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): N/A

Corporation/Organization Name: Stat-Med, Inc

Mailing Address: 23606 N 19th Ave, Suite 2

City: Phoenix State: AZ Zip: 85085

Telephone: 623-434-4895 Email: jeff.b@stat-med.net

Contact Person Name: Robert J Black

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Stat-Med, Inc

Facility Name

Robert J Black

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/2/25

Date

Board Use Only	Date Received: 5/27/25	Amount: waived - MARK

STAT MED
Specialty beds and equipment with service!

23606 N. 19th Avenue, Suite 2, Phoenix, AZ 85085
Phoenix 623-434-4895 · Las Vegas 702-838-2656
Toll free 866-STAT-MED (866-782-8633)
Fax 623-594-3270

Name	Title	Percent Ownership
Scott Trammell	President	70%
Robert Black	CEO	30%
Mandy Black	Treasurer	0%

Signed: _____ Title: CEO Date: 5-2-25

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **STAT-MED, INC.** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/25/2002, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 04/10/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202504105616553
You may verify this certificate online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

STAT-MED, INC.

Nevada Business Identification # NV20021266324
Expiration Date: 03/31/2026

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 03/31/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202503315581380
You may verify this certificate online at https://www.nvsilverflume.gov/home

BUSINESS LICENSE

City of North Las Vegas
2250 Las Vegas Blvd. North, Suite 110
North Las Vegas, NV 89030

Mailing Address:

STAT-MED
23606 N 19TH AVE #2
PHOENIX, AZ 85085

In conformity with and subject to the provisions of the Ordinances of the City of North Las Vegas and the laws of the State of Nevada, license is hereby granted to operate the business described hereon:

License Number: **BL70987** Expiration Date: **07/31/2025**

Type of License: **GROSS SALES**

Classification: **MISCELLANEOUS GROSS**

Business Location: **STAT-MED**
537 E BROOKS AVE STE. 407
NORTH LAS VEGAS, NV 89030

Owner/Principal(s): **STAT-MED, INC.**

CITY OF
NORTH LAS VEGAS

Alfredo Melesio
Director of Land Development & Community Services

This license is not transferable
POST IN A CONSPICUOUS PLACE

CLARK COUNTY BUSINESS LICENSE

LICENSE NUMBER: 1001510-346

LICENSE PERIOD: 02/01/2025 - 07/31/2025

POST IN A CONSPICUOUS PLACE AT THE BUSINESS LOCATION

ISSUED TO:
Stat-Med LLC
23606 N 19th Ave Ste 2
Phoenix, AZ 85085

BUSINESS LOCATION ADDRESS:

537 E Brooks Ave Ste #407
North Las Vegas, NV 89030

TYPE OF LICENSE: Equipment Sales/Service

All signage must conform to standards set forth in Clark County Codes 30.72 and 30.48. Business owners are responsible to keep business property free of trash and graffiti, conform to all zoning codes requirements and, if applicable, all conditions set forth in a Notice of Final Action issued by Comprehensive Planning.

Current Planning Comments:
APPROVED FOR EQUIPMENT SERVICE/SALES.

DISCLAIMER

ISSUANCE OF A BUSINESS LICENSE IS NOT AN ENDORSEMENT OF THE BUSINESS PRACTICE OF THE LICENSEE.

PLEASE SEE REVERSE SIDE FOR ADDITIONAL INFORMATION

Vincent V. Queano

VINCENT V. QUEANO
DIRECTOR OF BUSINESS LICENSE

DEPARTMENT OF BUSINESS LICENSE
500 S GRAND CENTRAL PARKWAY
BOX 551810
LAS VEGAS NV 89155-1810
PHONE: (702) 455-4340

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 5/20/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER: VGM Insurance Services, Inc. 1111 Van Miller Way Waterloo IA 50701	CONTACT NAME: Becca Mullenbach PHONE (A/C, No, Ext): (319) 274-8622 FAX (A/C, No): E-MAIL ADDRESS: Becca.Mullenbach@vgm.com
INSURED: Stat-Med Inc 537 E Brooks Ave Ste 407 North Las Vegas NV 89030	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A: BENCHMARK INSURANCE COMPANY 41394 INSURER B: TECHNOLOGY INSURANCE COMPANY, I 42376 INSURER C: BENCHMARK INSURANCE COMPANY 41394 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			D1024 G1557-22	05/26/2025	05/26/2026	EACH OCCURRENCE	$ 5,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Professional Liability						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 5,000,000
	POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$ 5,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			TWC4540425	01/19/2025	01/19/2026	X PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
C	Cyber Liability			D1024 G1557-22	05/26/2025	05/26/2026	Aggregate	100,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

537 E Brooks Ave, Ste 407, North Las Vegas NV 89030

CERTIFICATE HOLDER

State of Nevada Dept. of Employment, Training, & Rehab
500 East Third Street
Carson City NV 89713

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 5/20/2025

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IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER: VGM Insurance Services, Inc. 1111 Van Miller Way Waterloo IA 50701	CONTACT NAME: Becca Mullenbach PHONE (A/C, No, Ext): (319) 274-8622 FAX (A/C, No): E-MAIL ADDRESS: Becca.Mullenbach@vgm.com
INSURED: Stat-Med Inc 537 E Brooks Ave Ste 407 North Las Vegas NV 89030	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A: BENCHMARK INSURANCE COMPANY 41394 INSURER B: TECHNOLOGY INSURANCE COMPANY, I 42376 INSURER C: BENCHMARK INSURANCE COMPANY 41394 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY	X		D1024 G1557-22	05/26/2025	05/26/2026	EACH OCCURRENCE	$ 5,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Professional Liability						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 5,000,000
	POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$ 5,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB / OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB / CLAIMS-MADE						AGGREGATE	$
	DED / RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			TWC4540425	01/19/2025	01/19/2026	X PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
C	Cyber Liability			D1024 G1557-22	05/26/2025	05/26/2026	Aggregate	100,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Location: 537 East Brooks Ave, Suite D407, North Las Vegas, NV 89030

Schnitzer Trident, LLC, Schnitzer Properties Management, LLC, and all affiliates are Additional Insureds as required by written contract.

CERTIFICATE HOLDER

Schnitzer Trident, LLC, and all affiliates
3111 S Valley View Blvd Ste K101
Las Vegas NV 89102

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 5/20/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER: VGM Insurance Services, Inc. 1111 Van Miller Way Waterloo IA 50701	CONTACT NAME: Becca Mullenbach PHONE (A/C, No, Ext): (319) 274-8622 FAX (A/C, No): E-MAIL ADDRESS: Becca.Mullenbach@vgm.com
INSURED: Stat-Med Inc 537 E Brooks Ave Ste 407 North Las Vegas NV 89030	INSURER A: BENCHMARK INSURANCE COMPANY 41394 INSURER B: TECHNOLOGY INSURANCE COMPANY, I 42376 INSURER C: BENCHMARK INSURANCE COMPANY 41394 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY	X		D1024 G1557-22	05/26/2025	05/26/2026	EACH OCCURRENCE	$ 5,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Professional Liability						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 5,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 5,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			TWC4540425	01/19/2025	01/19/2026	X PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
C	Cyber Liability			D1024 G1557-22	05/26/2025	05/26/2026	Aggregate	100,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Certificate holder is named as additional insured as required by written contract.

CERTIFICATE HOLDER

Harsch Investment Corp and All Affiliates
3111 S Valley View, Ste. K-101
Las Vegas NV 89102

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 5/20/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER: VGM Insurance Services, Inc. 1111 Van Miller Way Waterloo IA 50701	CONTACT NAME: Becca Mullenbach PHONE (A/C, No, Ext): (319) 274-8622 FAX (A/C, No): E-MAIL ADDRESS: Becca.Mullenbach@vgm.com
INSURED: Stat-Med Inc 537 E Brooks Ave Ste 407 North Las Vegas NV 89030	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A: BENCHMARK INSURANCE COMPANY 41394 INSURER B: TECHNOLOGY INSURANCE COMPANY, I 42376 INSURER C: BENCHMARK INSURANCE COMPANY 41394 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			D1024 G1557-22	05/26/2025	05/26/2026	EACH OCCURRENCE	$ 5,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Professional Liability						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 5,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 5,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			TWC4540425	01/19/2025	01/19/2026	X PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
C	Cyber Liability			D1024 G1557-22	05/26/2025	05/26/2026	Aggregate	100,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Covers locations at; 23606 N 19th Ave, Ste 2, Phoenix AZ 85085; 537 E Brooks Ave, Ste 407, North Las Vegas NV 89030; 1655 West Grant Rd, Tucson AZ 85745

CERTIFICATE HOLDER

EVIDENCE OF INSURANCE

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. EACX3005210

Application/License No. _____

Stat-Medical, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
537 E Brooks Ave Ste 407 N Las Vegas NV 89030-3973, as
(Address of Applicant/Principal)
PRINCIPAL, and Endurance Assurance Corporation, a
(Surety Company)
corporation organized under the laws of the state of Delaware
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
4 Manhattanville Road Purchase NY 10577 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 05/23/2025.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23 day of May, 2025.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Brandi Miller

Surety Company's Representative

Brandi Miller, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Becca Mullenbach

Witness

Becca Mullenbach

Witness

Countersigned by:

Nevada Resident Agent

SOMPO INTERNATIONAL
INSURANCE

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that **Endurance Assurance Corporation**, a Delaware corporation ("EAC"), **Endurance American Insurance Company**, a Delaware corporation ("EAIC"), **Lexon Insurance Company**, a Texas corporation ("LIC"), and/or **Bond Safeguard Insurance Company**, a South Dakota corporation ("BSIC"), each, a "Company" and collectively, **"Sompo International"** do hereby constitute and appoint: Brandi Miller
as true and lawful Attorney(s)-In-Fact to make, execute, seal, and deliver for, and on its behalf as surety or co-surety; bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking so made, executed and delivered shall obligate the Company for any portion of the penal sum thereof in excess of the sum of $ 100,000.00

Such bonds and undertakings for said purposes, when duly executed by said attorney(s)-in-fact, shall be binding upon the Company as fully and to the same extent a if signed by the President of the Company under its corporate seal attested by its Corporate Secretary.

This appointment is made under and by authority of certain resolutions adopted by the board of directors of each Company by unanimous written consent effective the 30th day of March, 2023 for BSIC and LIC and the 17th day of May, 2023 for EAC and EAIC, a copy of which appears below under the heading entitled "Certificate".

This Power of Attorney is signed and sealed by facsimile under and by authority of the following resolution adopted by the board of directors of each Company by unanimous written consent effective the 30th day of March, 2023 for BSIC and LIC and the 17th day of May, 2023 for EAC and EAIC and said resolution has not since been revoked, amended or repealed:

RESOLVED, that the signature of an individual named above and the seal of the Company may be affixed to any such power of attorney or any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signature or seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN WITNESS WHEREOF, each Company has caused this instrument to be signed by the following officers, and its corporate seal to be affixed this 25th day of May, 2023.

Endurance Assurance Corporation
By: Richard M Appel
Richard Appel; SVP & Senior Counsel

Endurance American Insurance Company
By: Richard M Appel
Richard Appel; SVP & Senior Counsel

Lexon Insurance Company
By: Richard M Appel
Richard Appel; SVP & Senior Counsel

Bond Safeguard Insurance Company
By: Richard M Appel
Richard Appel; SVP & Senior Counsel

ACKNOWLEDGEMENT

On this 25th day of May, 2023, before me, personally came the above signatories known to me, who being duly sworn, did depose and say that he/they is an officer of each of the Companies; and that he executed said instrument on behalf of each Company by authority of his office under the by-laws of each Company.

By: Amy Taylor
Amy Taylor, Notary Public – My Commission Expires 3/9/27

CERTIFICATE

I, the undersigned Officer of each Company, DO HEREBY CERTIFY that:

1. That the original power of attorney of which the foregoing is a copy was duly executed on behalf of each Company and has not since been revoked, amended or modified; that the undersigned has compared the foregoing copy thereof with the original power of attorney, and that the same is a true and correct copy of the original power of attorney and of the whole thereof;
2. The following are resolutions which were adopted by the board of directors of each Company by unanimous written consent effective 30th day of March, 2023 for BSIC and LIC and the 17th day of May, 2023 for EAC and EAIC and said resolutions have not since been revoked, amended or modified:
   "RESOLVED, that each of the individuals named below is authorized to make, execute, seal and deliver for and on behalf of the Company any and all bonds, undertakings or obligations in surety or co-surety with others: RICHARD M. APPEL, MATTHEW E. CURRAN, MARGARET HYLAND, SHARON L. SIMS, CHRISTOPHER L. SPARRO,
   and be it further
   RESOLVED, that each of the individuals named above is authorized to appoint attorneys-in-fact for the purpose of making, executing, sealing and delivering bonds undertakings or obligations in surety or co-surety for and on behalf of the Company."
3. The undersigned further certifies that the above resolutions are true and correct copies of the resolutions as so recorded and of the whole thereof.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the corporate seal this 23rd day of May, 2025.

By: Daniel S. Lurie, Secretary

NOTICE: U. S. TREASURY DEPARTMENT'S OFFICE OF FOREIGN ASSETS CONTROL (OFAC)

No coverage is provided by this Notice nor can it be construed to replace any provisions of any surety bond or other surety coverage provided. This Notice provides information concerning possible impact on your surety coverage due to directives issued by OFAC. **Please read this Notice carefully.**
The Office of Foreign Assets Control (OFAC) administers and enforces sanctions policy, based on Presidential declarations of "national emergency". OFAC has identified and listed numerous foreign agents, front organizations, terrorists, terrorist organizations, and narcotics traffickers as "Specially Designated Nationals and Blocked Persons". This list can be located on the United States Treasury's website – https://www.treasury.gov/resource-center/sanctions/SDN-List
In accordance with OFAC regulations, if it is determined that you or any other person or entity claiming the benefits of any coverage has violated U.S. sanctions law is a Specially Designated National and Blocked Person, as identified by OFAC, any coverage will be considered a blocked or frozen contract and all provisions of any coverage provided are immediately subject to OFAC. When a surety bond or other form of surety coverage is considered to be such a blocked or frozen contrac no payments nor premium refunds may be made without authorization from OFAC. Other limitations on the premiums and payments may also apply.

Nevada State Board Of Pharmacy

(Firm mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 10/22/2024
Amount: $ 525.00
Permit #: MW00016

STAT-MED
537 E BROOKS AVE #407
NORTH LAS VEGAS NV 89030

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Permit #
MW00016
Active

Medical Devices Equipment Gas
Effective Date:11/01/2024
Expires:10/31/2026

STAT-MED
537 E BROOKS AVE #407
NORTH LAS VEGAS NV 89030

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Medical Devices Equipment Gas

Permit Type: Medical Devices Equipment Gas
Permit #: MW00016
Effective Date: 11/01/2024

Expires: 10/31/2026
STATUS: Active

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENCED

STAT-MED
537 E BROOKS AVE #407
NORTH LAS VEGAS NV 89030

NONTRANSFERABLE
POST THIS PERMIT PROMINENTLY IN A CONSPICUOUS PLACE

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: STAT-MED, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MW00016

Physical Address: 537 E. Brooks Avenue, Suite 407

City: North Las Vegas State: NV Zip: 89030

Mailing Address (if different from physical address): 23606 N. 19th Avenue, Suite 2

City: Phoenix State: AZ Zip: 85085

Telephone: (623) 434-4895 Website: www.stat-med.net

Licensing Company Email: statmedaz@gmail.com

Section 2: Personal Information

First: Scott Middle: Steven Last: Trammell

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Phoenix State: AZ Zip: [redacted]

Telephone: (623) 434-4895 Email: scott.t@stat-med.net

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Iowa		09/83-05/86	
Address	**City**	**State**	**Zip**
2900 University Capitol Center, 201 S. Clinton St.	Iowa City	IA	52242
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Iowa City High School		09/80-05/83	
Address	**City**	**State**	**Zip**
1900 Morningside Drive	Iowa City	IA	52245
Diploma/Degree obtained, if any			
Diploma issued upon graduation.			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/17-present	[redacted]	Paradise Valley	AZ	[redacted]
02/16-05/17		Phoenix	AZ	
04/14-02/16		Scottsdale	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
STAT-MED, Inc.			03-96- present
Business Address	**City**	**State**	**Zip**
23606 N. 19th Avenue, Suite 2	Phoenix	AZ	85085
Phone	**Title**		
(623) 434-4895	President		
Description of Duties			
Sales			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY -- MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	✔	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

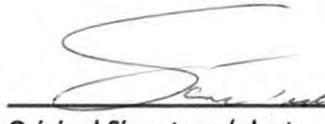
Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/02/2002	04/08/2002	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
02F02132X		Las Vegas Justice Court		
Reason/Charge				
Possession of Drug Not to be Introduced Into Commerce (NRS 454.351)				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Scott Trammell				
Name of Business/Industry/Entity				

Provide explanation below:

I was arrested on February 2, 2002, for possession of a schedule II controlled substance. I was out with a group of friends and acquaintances and was given some by a member of the group. I pleaded guilty to a misdemeanor charge of Possession of a Drug Not to be Introduced Into Commerce on April 8, 2002 and was sentenced at that time to 50 hours of community service, completion of required counseling, and fines totaling $500.00. I completed all Court requirements and the matter was closed on October 4, 2002.



Original Signature (electronic, copies or stamps not accepted)

4/30/2025

Date

REGISTER OF ACTIONS
CASE NO. 02F02132X

State of Nevada vs Trammell, Scott S

Case Type: **Felony**
Date Filed: **02/26/2002**
Location: **JC Department 2**

PARTY INFORMATION

Defendant **Trammell, Scott S**
Other Agency Numbers
1696474 Justice Court Scope ID Subject Identifier

Lead Attorneys
William S. Skupa, ESQ
Retained
702-385-2558(W)

State of Nevada **State of Nevada**

CHARGE INFORMATION

Charges: Trammell, Scott S	Statute	Level	Date
1. POSSESSION DRUG NOT INTRODUCE INTO COMMERCE	454.351	Misdemeanor	02/02/2002

EVENTS & ORDERS OF THE COURT

DISPOSITIONS

04/08/2002 **Disposition** (Judicial Officer: Tobiasson, Melanie A.)
1. POSSESSION DRUG NOT INTRODUCE INTO COMMERCE
PLED TO LESSER INCLUDED MISDEMEANOR

04/08/2002 **Plea** (Judicial Officer: Tobiasson, Melanie A.)
1. POSSESSION DRUG NOT INTRODUCE INTO COMMERCE
Guilty

04/08/2002 **Conversion Sentence Event Type** (Judicial Officer: Tobiasson, Melanie A.)
1. POSSESSION DRUG NOT INTRODUCE INTO COMMERCE
Condition - Adult:
1. COUNSELING, 04/08/2002, Active 04/08/2002
Comment (US JUSTICE ASSOCIATES COUNSELING;MAY DO 50 HRS COMM SVC)
Comment (DATE: 04/08/2002 JC FINE: 0400 AA FINE: 100 JC TOTAL: 0500 JC EXCUSED:)

OTHER EVENTS AND HEARINGS

02/03/2002 **JAIL RELEASED**
JAIL RELEASED
02/05/2002 **RETURNING FOR FURTHER INVESTIGATION**
RETURNING FOR FURTHER INVESTIGATION
02/26/2002 **TRANSFERRED TO JC**
TRANSFERRED TO JC
02/26/2002 **CTRACK Track Assignment JC02**
02/27/2002 **RECEIVED FROM DA**
RECEIVED FROM DA
02/27/2002 **COMPLAINT FILED**
COMPLAINT FILED
03/04/2002 **P/H DATE SET** (Judicial Officer: Smith, Douglas E.)
FELONY ARRGN
03/04/2002 **Arraignment** (8:00 AM) (Judicial Officer Smith, Douglas E.)
Result: COMPLETED
04/08/2002 **SEE CHARGE/DISPOSITION/SENT RECORDS** (Judicial Officer: Toblasson, Melanie A.)
PRELIM HEARING
04/08/2002 **COURTESY NOTICE OF DISPOSITION GENERATED**
MinuteCode1: COURTESY NOTICE OF DISPOSITION GENERATED MinuteCode3: COURTESY NOTICE OF DISPOSITION GENERATED
04/08/2002 **Preliminary Hearing** (8:00 AM) (Judicial Officer Tobiasson, Melanie A.)
Result: GUILTY/SENT
09/24/2002 **JCON Accounting Detail**
Rcpt #: 05325184 Deft Name: TRAMMELL, SCOTT Payer Name: TRAMMELL, SCOTT Deft ID: 01696474 Fund: 502 Payment Type: CHK Location: LTR Case #: 02F02132X
10/04/2002 **REQUIREMENTS COMPLETED** (Judicial Officer: Smith, Douglas E.)
OTHER
10/04/2002 **OTHER** (8:00 AM) (Judicial Officer Smith, Douglas E.)
Result: COMPLETED

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott Trammell

Print ~~Name (First, Last)~~

Original Signature (electronic, copies or stamps not accepted)

4/30/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Scott Trammell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/30/2025

Date

Subscribed and Sworn to before me this 30th day of April 2025

Notary Public Signature

KARIN VAZQUEZ
Notary Public - Arizona
Maricopa County
Commission # 647817
My Commission Expires April 30, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site STAT-MED, Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) MW00016

Physical Address 537 E Brooks Ave #407

City North Las Vegas State NV Zip 89030

Mailing Address (if different from physical address) 23606 N 19th Avenue Suite #2

City Phoenix State AZ Zip 85085

Telephone (623) 434-4895 Website www.stat-med.net

Licensing Company Email statmedaz@gmail.com

Section 2: Personal Information

First Robert Middle Jeffray Last Black

Alias(es, nicknames, name changes, etc.) Jeff

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Lewisville State NC Zip [redacted]

Telephone [redacted] Email jeffb@stat-med.net

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Hinkley High School		09/75-05/77	
Address	**City**	**State**	**Zip**
1250 Chambers Rd	Aurora	CO	80011
Diploma/Degree obtained, if any			
Yes			

School Name		From - To (MM/YY – MM/YY)	
University of Northern Colorado		09/77-05/78	
Address	**City**	**State**	**Zip**
501 20th Street	Greeley	CO	80639
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/14-06/21	[redacted]	Phoenix	AZ	[redacted]
06/21-05/25	[redacted]	Lewisville	NC	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
STAT-MED, Inc			01/02-05/25	
Business Address		**City**	**State**	**Zip**
23606 N 19th Avenue Suite #2		Phoenix	AZ	85085
Phone	**Title**			
(623) 434-4895	CEO / owner			
Description of Duties				
Oversee all aspects of business on a daily basis.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Jeffrey Black

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-9-25

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Forsyth

I, Robert J Black, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5-9-25

Date

Subscribed and Sworn to before me this 09 day of MAY.

Notary Public Signature

JESSE E. MARTINEZ
Notary Public
Forsyth Co., North Carolina
My Commission Expires June 24, 2029
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

y

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Stat-Med, Inc — MDEG License # (if applicable): MW00016

Physical Address: 537 E Brooks Ave #407

City: North Las Vegas — State: NV — Zip: 89030

Mailing Address (if different from physical address):

City: — State: — Zip:

Telephone: 623-434-4895 — Website: www.stat-med.net

Licensing Company Email: statmedaz@gmail.com

Section 2: Personal Information

First: Restituto — Middle: Rindon — Last: Dumag

Alias(es, nicknames, name changes, etc.): Resty

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas — State: NV — Zip: [redacted]

Telephone: [redacted] — Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Delano High School		03/84 - 06/89	
Address	**City**	**State**	**Zip**
1331 Cecil Avenue	Delano High School	CA	93215
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Santa Barbara Business College		01/91 - 07/92	
Address	**City**	**State**	**Zip**
5300 California Ave	Bakersfield	CA	93309
Diploma/Degree obtained, if any			
Diploma in Accounting Clerk			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2010 - Present	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Stat-Med, Inc			01/06 - Present	
Business Address		**City**	**State**	**Zip**
537 E Brooks Ave #407		North Las Vegas	NV	89030
Phone	**Title**		**Number of Employed Hours**	
623-434-4895	Medical Equipment Service Technician		In Excess of 40,000	
Description of Duties				
Drive Box Truck, Deliver, Set-Up, Service, Pickup, Document, Clean & QC Medical Equipment, On-Call Every Other Week for Same. Provide Great Customer Service to Approximately 25 Medical Facilities				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/29/2008	10/01/2008	NV	North Las Vegas	Clark

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CR008963-08	

Reason/Charge
Battery Domestic Violence No Priors

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
City of North Las Vegas	NA

Name of Business/Industry/Entity
NA

Provide explanation below:

Please read attached court papers.

RD

Original Signature (electronic, copies or stamps not accepted)

5/6/25

Date

NORTH LAS VEGAS
MUNICIPAL COURT
FILED

MUNICIPAL COURT

2008 SEP 11 P 2:32

NORTH LAS VEGAS, NEVADA

CITY OF NORTH LAS VEGAS, NEVADA,

Plaintiff,

vs.

RESTITUTO R DUMAG JR,

Defendant.

CASE NO. : CR008963-08

COMPLAINT
COERCION
NRS 207.190.2B
NLVCC 2.150

KIMBERLY PHILLIPS, Deputy City Attorney, on this September 5, 2008, in the City of North Las Vegas, County of Clark, State of Nevada, makes the following declarations subject to the penalty for perjury and says

That within **her** knowledge, information and belief, on **08/29/2008** or thereabout, and before the filing of this complaint and within the City of North Las Vegas, County of Clark, State of Nevada, at approximately **11:53 p.m.,** a misdemeanor was committed by such defendant who did wilfully and unlawfully, without the use of force or violence caused or compelled or restrained another to-wit: **LAURIE LATTA** from doing that which she had a right to do to-wit: **grabbing the phone away from her and disconnecting the line and/or would not give her the phone when she attempted to call the police,** which occurred at **6551 MCCARRAN #1051,**

all of which is contrary to the form, force and effect of NRS 207.190 in such case made and provided against the North Las Vegas City Charter 2.150 and against the peace and dignity of the people of the City of North Las Vegas. Said complainant makes this declaration subject to the penalty according to law.

KIMBERLY PHILLIPS Complainant
Deputy City Attorney

CA003866-08 PAD

IN THE MUNICIPAL COURT OF THE CITY OF

NORTH LAS VEGAS

COUNTY OF CLARK - STATE OF NEVADA

JUDGMENT OF SENTENCE

DEFENDANT: RESTITUTO R DUMAG JR **COURT:** CR008963-08

SSNO: [redacted] **DATE OF BIRTH:** [redacted]

DATE OF ARREST/VIOLATION : 08/29/2008

VIOLATION OF ORDINANCE (S): BATTERY DOMESTIC VIOLENCE NO PRIORS
COERCION

DATE OF DISPOSITION 10/01/2008 **IN OPEN COURT**

FINAL CHARGE (S)	CONVICTION	DISPOSITION OF SENT.
BATTERY DOMESTIC VIOLENCE NO PRIORS	PLED NO CONTEST AT ARRAIGNMENT/SENTENCING – FOUND GUILTY	FINED $1000 6 MONTHS DOMESTIC VIOLENCE COUNSELING SENTENCE SERVED 2 DAYS IN CUSTODY 48 HRS COMMUNITY SERVICE 180 DAY SUSPENDED SENTENCE STAY OUT OF TROUBLE ORDER
COERCION	DISMISSED BEFORE TRIAL AT ARRAIGNMENT/SENTENCING	
		CASE CLOSED 10/14/2009

COURT CLERK

CERTIFIED COPY
The document to which this certificate is attached is a full, true and correct copy of the original on file and of record in my office.
DATE 4/4/12
Municipal Court Administrator of the City of North Las Vegas, State of Nevada.

MUNICIPAL JUDGE

NLVMCPG-028/7-1-11

I, RESTITUTO DUMAG, **certify that as the MDEG Administrator for**

_____,

that I (initial that you have read and meet the following requirements):

1. RD Have a high school diploma or its equivalent;
2. RD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RESTITUTO DUMAG

Print Name (First, Last)

RD

Original Signature (electronic, copies or stamps not accepted)

5/6/25

Date

Board Use Only	Date Received: 5/27/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Stat-Med, Inc

Pharmacy/Wholesaler License # (if applicable): MW00016

Physical Address: 537 E Brooks Ave #407

City: North Las Vegas State: NV Zip: 89030

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 623-434-4895 Website: www.stat-med.net

Licensing Company Email: statmedaz@gmail.com

Section 2: Personal Information

First: Restituto Middle: Rindon Last: Dumag

Alias(es, nicknames, name changes, etc.): Resty

Date of Birt: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Delano High School		03/84 - 06/89	
Address	**City**	**State**	**Zip**
1331 Cecil Avenue	Delano	CA	93215
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Santa Barbara Business College		01/91 - 07/92	
Address	**City**	**State**	**Zip**
5300 California Ave	Bakersfield	CA	93309
Diploma/Degree obtained, if any			
Diploma in Accounting Clerk			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2010-Present	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for [redacted] hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing a[redacted]tion of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of em[redacted]yment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Stat-Med, Inc			01/06 - Present
Business Address	**City**	**State**	**Zip**
537 E Brooks Ave #407	North Las Vegas	NV	89030
Phone	**Title**	**Number of Employed Hours**	
623-434-4895	Medical Equipment Service Technician	In Excess of 40,000	
Description of Duties			
Drive Box Truck, Deliver, Set-Up, Service, Pickup, Document, Clean & QC Medical Equipment, On-Call Every Other Week for Same. Provide Great Customer Service to Approximately 25 Medical Facilities			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/29/2008	10/01/2008	NV	North Las Vegas	Clark County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CR008963-08	North Las Vegas Municipal Court

Reason/Charge
Battery - Domestic Violence - No Priors

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
City of North Las Vegas	NA

Name of Business/Industry/Entity
NA

Provide explanation below:

Please read attached court papers.

RD

Original Signature (electronic, copies or stamps not accepted)

5/6/25

Date

NORTH LAS VEGAS
MUNICIPAL COURT
FILED

MUNICIPAL COURT

2008 SEP 11 P 2:32

NORTH LAS VEGAS, NEVADA

CITY OF NORTH LAS VEGAS, NEVADA,

Plaintiff,

vs.

RESTITUTO R DUMAG JR,

Defendant.

CASE NO. : CR008963-08

COMPLAINT
COERCION
NRS 207.190.2B
NLVCC 2.150

KIMBERLY PHILLIPS, Deputy City Attorney, on this September 5, 2008, in the City of North Las Vegas, County of Clark, State of Nevada, makes the following declarations subject to the penalty for perjury and says

That within **her** knowledge, information and belief, on **08/29/2008** or thereabout, and before the filing of this complaint and within the City of North Las Vegas, County of Clark, State of Nevada, at approximately **11:53 p.m.,** a misdemeanor was committed by such defendant who did wilfully and unlawfully, without the use of force or violence caused or compelled or restrained another to-wit: **LAURIE LATTA** from doing that which she had a right to do to-wit: **grabbing the phone away from her and disconnecting the line and/or would not give her the phone when she attempted to call the police,** which occurred at **6551 MCCARRAN #1051,**

all of which is contrary to the form, force and effect of NRS 207.190 in such case made and provided against the North Las Vegas City Charter 2.150 and against the peace and dignity of the people of the City of North Las Vegas. Said complainant makes this declaration subject to the penalty according to law.

KIMBERLY PHILLIPS Complainant
Deputy City Attorney

CA003866-08 PAD

IN THE MUNICIPAL COURT OF THE CITY OF

NORTH LAS VEGAS

COUNTY OF CLARK - STATE OF NEVADA

JUDGMENT OF SENTENCE

DEFENDANT: RESTITUTO R DUMAG JR **COURT:** CR008963-08

SSNO: [redacted] **DATE OF BIRTH:** [redacted]

DATE OF ARREST/VIOLATION : 08/29/2008

VIOLATION OF ORDINANCE (S): BATTERY DOMESTIC VIOLENCE NO PRIORS
COERCION

DATE OF DISPOSITION 10/01/2008 **IN OPEN COURT**

FINAL CHARGE (S)	CONVICTION	DISPOSITION OF SENT.
BATTERY DOMESTIC VIOLENCE NO PRIORS	PLED NO CONTEST AT ARRAIGNMENT/SENTENCING – FOUND GUILTY	FINED $1000 6 MONTHS DOMESTIC VIOLENCE COUNSELING SENTENCE SERVED 2 DAYS IN CUSTODY 48 HRS COMMUNITY SERVICE 180 DAY SUSPENDED SENTENCE STAY OUT OF TROUBLE ORDER
COERCION	DISMISSED BEFORE TRIAL AT ARRAIGNMENT/SENTENCING	
		CASE CLOSED 10/14/2009

COURT CLERK

CERTIFIED COPY
The document to which this certificate is attached is a full, true and correct copy of the original on file and of record in my office.
DATE 4/4/13
Municipal Court Administrator of the City of North Las Vegas, State of Nevada.

Sean Hoeftger
MUNICIPAL JUDGE

NLVMCFO-023/7-1-11

I, RESTITUTO DUMAG, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RD I am at least 21 years of age;
3. RD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

RESTITUTO DUMAG

Print Name (First, Last)

RD

Original Signature (electronic, copies or stamps not accepted)

5/6/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RESTITUTO DUMAG

Print Name (First, Last)

RD

Original Signature (electronic, copies or stamps not accepted)

5/4/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Restituto R. Dumag Jr., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

RD

Original Signature

5/6/25

Date

Subscribed and Sworn to before me this 6 day of May 2025.

Notary Public Signature

CHELSEA SMITH
Notary Public - State of Nevada
Appointment No. 23-8688-01
My Appointment Expires 02/27/2027
(Seal)

Stat-Med Organization Chart

Scott Trammell (Owner)

Jeff Black (CEO, Owner)

Mandy Black (CFO)

Randy Clark	Alex Johnson
Operations Manager	Billing Manager
Kristian Greenberg	Chelsea Jackson
Senior Repair Tech	Assistant Billing Manager
Scott Stokes	Administration
(Tech-Liaison-Trainer)	Rebecca Clore
	Krstal Maddox

Service Teams

Phoenix	
Kyle Herndon	(Tech)
Jimbob Lewis	(Tech)
Collin Morgan	(Tech)
Matthew Ciolek	(Cleaner)
William Townsell	(Tech)
William Phillips	(Tech)
Austin Sturgeon	(Tech)
Derek Cable	(Tech)
Tucson	
Jorge Navarro	(Tech)
Benjamin Altamirano	(Tech)
Jorge A. Navarro	(Cleaner)
Shane Granlee	(Tech-PT)
Las Vegas	
Resty Dumag	(Tech)
Cody Charles	(Tech)

v.4.9.25

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: EDF Holdings LLC, dba TENS Pros

Physical Address: 1131 N Warson Rd

City: St. Louis State: MO Zip: 63132

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-724-1121 Website: https://www.tenspros.com/

Name of Designated Representative (DR): Gary Kapustin

Licensing Company Email: manager@tenspros.com DR Email: gary.tenspros@gmail.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
▣ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: DME Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Compass Health
Address: 6753 Engle Rd City: Middleburg Heights State: OH Zip: 44130

Name: Bauerfeind USA
Address: 75 14th Street NE, Suite 2350 City: Atlanta State: GA Zip: 30309

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: William Patterson
Business Name: EDF Holdings LLC
Business Address: 1131 N Warson Rd
City: St. Louis State: MO Zip: 63132
Telephone: 314-749-3242 Email: bpatterson@usmedrehab.com

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

EDF Holdings LLC, dba TENS Pros

Facility Name

William Patterson

Print Name of Authorized Person Submitting Application

William Patterson

Original signature of Authorized Person (copies or stamps not accepted)

4/7/2025

Date

Board Use Only	Date Received: _____	Amount: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

STATE OF MISSOURI

Denny Hoskins
Secretary of State

CORPORATION DIVISION
CERTIFICATE OF GOOD STANDING

I, DENNY HOSKINS, Secretary of State of the STATE OF MISSOURI, do hereby certify that the records in my office and in my care and custody reveal that

EDF Holdings, LLC
LC1720406

was created under the laws of this State on the 28th day of July, 2020, and is active, having fully complied with all requirements of this office.

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, this 25th day of April, 2025.

Denny Hoskins
Secretary of State

Certification Number: CERT-04252025-0054

City of Creve Coeur
300 N. New Ballas Rd.
Creve Coeur, MO 63141
(314) 432-6000

2025 Business License Certificate

Business Name:	EDF Holdings, LLC	**License Number:**	20001770
DBA:	Active Living, Allvation, LSI International, TENS Pros, US MdRehab	**License Type:**	Business
Business Location:	1131 N Warson Rd Creve Coeur, MO 63132	**Business Type:**	Retail
Issued Date:	1/7/2025	**Fees Paid:**	$630.00
Expiration Date:	12/31/2025		

Lori Obermoeller

Signature

TO BE POSTED IN A CONSPICUOUS PLACE

CHUBB®

SMALL COMMERCIAL UMBRELLA POLICY DECLARATIONS

Policy Number: D02796107	Previous Policy Number: New

COVERAGE IS PROVIDED IN THE COMPANY SHOWN BELOW

Bankers Standard Insurance Company
436 Walnut Street
Philadelphia, PA 19106
215-640-1000

Named Insured and Address:	Producer Name and Address:
EDF HOLDINGS LLC 1131 N Warson Rd Saint Louis, MO, 63132-1803	BANK OF SPRINGFIELD - CISA 3400 WABASH AVE SPRINGFIELD, IL, 62711-0000
	Producer Code 0037716-00104

Policy Period: From 12-30-2024 To 12-30-2025 12:01 A.M. Standard Time at the Address of the Named Insured as stated herein

Limits of Insurance

$1,000,000	Each Occurrence	$0	Self-Insured Retention
$1,000,000	General Aggregate		
$Excluded	Products Completed-Operations Aggregate		

Policy Period Premium

$ 1,227 Premium $ 58 Terrorism Premium included in Annual Premium

$ 0.00 State Surcharge

$ 1,227.00 Premium, including all Surcharges and Assessments

Schedule of Underlying Insurance

Underlying Policy Type: Businessowners Company	Policy Number: LSIMOD027916633N Limits of Insurance	Limit Amount
ACE Property And Casualty Insurance Company	Other Than Products-Completed Operations Aggregate	$2,000,000
Policy Period 12-30-2024 to 12-30-2025	Products-Completed Operations Aggregate	$0
☒ Including Hired and Non Owned Only Auto Liability (within GL)	Liability and Medical Expenses Per Occurrence	$1,000,000
☐ Employee Benefits Liability		

Includes copyrighted material of Insurance Services Office, with its permission.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. GM246620

Application/License No. _____

EDF Holdings LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1131 N WARSON RD., ST. LOUIS, MO 63132 (Address of Applicant/Principal), as PRINCIPAL, and Great Midwest Insurance Company (Surety Company), a corporation organized under the laws of the state of Texas (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 800 Gessner, Suite 600, Houston, TX 77024 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 04/15/2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23rd day of April, 20 25.

APPLICANT/PRINCIPAL

COMPANY
EDF Holdings LLC

William Patterson
Authorized Representative

SURETY
Great Midwest Insurance Company

Surety Company's Representative

Jeremy J. Crawford, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Hannah Jamski
Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Great Midwest Insurance Company

KNOW ALL MEN BY THESE PRESENTS, that **GREAT MIDWEST INSURANCE COMPANY**, a Texas Corporation, with its principal office in Houston, TX, does hereby constitute and appoint: Amanda M. Quigley, Andrea J. Michael Haight, Bradford J. Quiri, Ethan M. Baker, Jeremy J. Crawford, Michael D. Williams, Michael E. Konzen, Sydney R. Epema, Victoria L. Spohnholtz, William V. Gerber

its true and lawful Attorney(s)-In-Fact to make, execute, seal and deliver for, and on its behalf as surety, any and all bonds, undertakings or other writings obligatory in nature of a bond.

This authority is made under and by the authority of a resolution which was passed by the Board of Directors of **GREAT MIDWEST INSURANCE COMPANY**, on the 1st day of April, 2025 as follows:

Resolved, that the President, or any officer, be and hereby is, authorized to appoint and empower any representative of the Company or other person or persons as Attorney-In-Fact to execute on behalf of the Company any bonds, undertakings, policies, contracts of indemnity or other writings obligatory in nature of a bond not to exceed One-Hundred Million dollars ($100,000,000.00), which the Company might execute through its duly elected officers, and affix the seal of the Company thereto. Any said execution of such documents by an Attorney-In-Fact shall be as binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company. Any Attorney-In-Fact, so appointed, may be removed in the Company's sole discretion and the authority so granted may be revoked as specified in the Power of Attorney.

Resolved, that the signature of the President and the seal of the Company may be affixed by electronic mail on any power of attorney granted, and the signature of the Secretary, and the seal of the Company may be affixed by electronic mail to any certificate of any such power and any such power or certificate bearing such electronic signature and seal shall be valid and binding on the Company. Any such power so executed and sealed and certificate so executed and sealed shall, with respect to any bond of undertaking to which it is attached, continue to be valid and binding on the Company.

IN WITNESS THEREOF, **GREAT MIDWEST INSURANCE COMPANY**, has caused this instrument to be signed by its President, and its Corporate Seal to be affixed this 8th day of April, 2025.

GREAT MIDWEST INSURANCE COMPANY – CORPORATE SEAL – TEXAS CORPORATION

GREAT MIDWEST INSURANCE COMPANY

BY Mark W. Haushill

Mark W. Haushill
President

ACKNOWLEDGEMENT

On this 8th day of April 2025, before me, personally came Mark W. Haushill to me known, who being duly sworn, did depose and say that he is the President of **GREAT MIDWEST INSURANCE COMPANY**, the corporation described in and which executed the above instrument; that he executed said instrument on behalf of the corporation by authority of his office under the By-laws of said corporation.

NOTARY PUBLIC – STATE OF TEXAS
CHRISTINA BISHOP
My Notary ID # 131090488
Expires April 14, 2029

BY Christina Bishop

Christina Bishop
Notary Public

CERTIFICATE

I, the undersigned, Secretary of **GREAT MIDWEST INSURANCE COMPANY**, A Texas Insurance Company, DO HEREBY CERTIFY that the original Power of Attorney of which the foregoing is a true and correct copy, is in full force and effect and has not been revoked and the resolutions as set forth are now in force.

Signed and Sealed at Houston, TX this 23rd Day of April 2025.

GREAT MIDWEST INSURANCE COMPANY – CORPORATE SEAL – TEXAS CORPORATION

BY Patricia Ryan

Patricia Ryan
Secretary

"WARNING: Any person who knowingly and with intent to defraud any insurance company or other person, files and application for insurance of claim containing any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

Acknowledgment of Surety

State of Minnesota
County of Hennepin

On this 23rd day of April, 2025 before me personally appeared **Jeremy J. Crawford** who acknowledged that he or she is the attorney in fact who is authorized to sign on behalf of **Great Midwest Insurance Company** (surety company), the foregoing instrument, and he thereupon duly acknowledged to me that he executed the same.

Madison Santjer
Notary Public

MADISON KELLY SANTJER
Notary Public-Minnesota
My Commission Expires Jan. 31, 2029

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG EDF HOLDINGS LLC, DBA TENS PROS MDEG License # (if applicable) _____

Physical Address 1131 NORTH WARSON ROAD

City SAINT LOUIS State MO Zip 63132

Mailing Address (if different from physical address) 1131 NORTH WARSON ROAD

City SAINT LOUIS State MO Zip 63132

Telephone 888-724-1121 Website tenspros.com

Licensing Company Email manager@tenspros.com

Section 2: Personal Information

First EMILY Middle NICOLE Last CROWCROFT

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City SAINT LOUIS State MO Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
EDF HOLDINGS LLC DBA TENS PROS			07/22 - PRESENT	
Business Address		City	State	Zip
1131 NORTH WARSON ROAD		SAINT LOUIS	MO	63132
Phone	Title		Number of Employed Hours	
888-724-1121	MEDICAL DIRECTOR		5,720	
Description of Duties				
DIRECTS CLINICAL STRATEGIES AND PROVIDES CLINICAL SUPPORT TO CLIENTS AND CUSTOMERS.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
NEW BERLIN HIGH SCHOOL		08/08 - 05/12	
Address	City	State	Zip
300 W ELLIS STREET	NEW BERLIN	IL	62670
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
SOUTHERN ILLINOIS UNIVERSITY EDWARDSVILLE		08/12 - 05/17	
Address	City	State	Zip
1 HAIRPIN DRIVE	EDWARDSVILLE	IL	62026
Diploma/Degree obtained, if any			
BACHELOR'S DEGREE - EXERCISE SCIENCE ; MINOR - EXERCISE AND SPORT PSYCHOLOGY			

School Name		From - To (MM/YY – MM/YY)	
LOGAN UNIVERSITY		01/19 - 04/22	
Address	City	State	Zip
1851 SCHOETTLER ROAD	CHESTERFIELD	MO	63017
Diploma/Degree obtained, if any			
DOCTORATE OF CHIROPRACTIC			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/21 - PRESENT	[redacted]	SAINT LOUIS	MO	[redacted]
5/20 - 12/21		CHESTERFIELD	MO	
6/19 - 5/20		CHESTERFIELD	MO	
7/18 - 6/19		EDWARDSVILLE	IL	
3/17 - 3/18		SAINT LOUIS	MO	
6/16 - 3/17		EDWARDSVILLE	IL	
6/15 - 6/16		EDWARDSVILLE	IL	
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, EMILY CROWCROFT, **certify that as the MDEG Administrator for**

EDF HOLDINGS LLC, DBA TENS PROS,

that I (initial that you have read and meet the following requirements):

1. EC Have a high school diploma or its equivalent;
2. EC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. EC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. EC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

EMILY CROWCROFT
Print Name (First, Last)

Emily Crowcroft
Original Signature (electronic, copies or stamps not accepted)

4/3/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler TENS Pros

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1131 N Warson Rd

City St. Louis State MO Zip 63132

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-724-1121 Website www.tenspros.com

Licensing Company Email thetenspros@gmail.com

Section 2: Personal Information

First Gary Middle Joseph Last Kapustin

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City St. Louis State MO Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. Louis University		08/09 - 05/13	
Address	**City**	**State**	**Zip**
1 N Grand Blvd	St. Louis	MO	63103
Diploma/Degree obtained, if any			
B.S. Marketing			

School Name		From - To (MM/YY – MM/YY)	
Parkway North High School		08/05 - 05/09	
Address	**City**	**State**	**Zip**
12860 Fee Fee Rd	St. Louis	MO	63141
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/00 - PRESENT	[redacted]	St. Louis	MO	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
TENS Pros			09/14 - PRESENT	
Business Address		**City**	**State**	**Zip**
1131 N Warson Rd		St. Louis	MO	63132
Phone	**Title**		**Number of Employed Hours**	
888-724-1121	VP, Sales		22,000	
Description of Duties				
Management of e-commerce sales and marketing				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Gary Kapustin, **certify that as the designated representative for**

TENS Pros,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. GK I am at least 21 years of age;
3. GK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. GK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. GK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. GK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. GK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Gary Kapustin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/2/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gary Kapustin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of St. Louis

I, ~~Hailey Goedeke~~ Gary Kapustin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/4/2025

Date

Subscribed and Sworn to before me this 4th day of April 2025

Hailey Goedeke

Notary Public Signature

HAILEY S GOEDEKE
Notary Public - Notary Seal
St Louis County - State of Missouri
Commission Number 21917359
My Commission Expires Jul 22, 2025

(Seal)

EDF Holdings LLC Employees

William Patterson	Owner & CEO
Jon Magnuson	SVP Sales & Ops
Ray Becker	Controller
Donna Jennings-Byrd	Staff Accountant
Gary Kapustin	VP Sales
Andrew Johnson	VP Sales
Kevin Lipson	VP Sales
Dr. Emily Crowcroft	Medical Director
Aaron Bunce	VP Operations
Jim McGowan	Operations Lead
Vlad Buhlak	Technician
Caden Magnuson	Customer Service
Mike Tetrault	Lead Shipper
Ben Rodgers	Shipper

Lender

St. Louis Bank	SBA Loan Holder

Holder of Indebtedness

Sean Alsup	Former Owner and Seller Note Holder
Danielle Abramovich	Former Owner and Seller Note Holder
Leon Abramovich	Former Owner and Seller Note Holder
Ryan Moore	Former Owner and Seller Note Holder

William S. Patterson
NSP 4/25/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site EDF Holdings LLC, dba TENS Pros

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1131 N Warson Rd

City St. Louis State MO Zip 63132

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-724-1121 Website www.tenspros.com

Licensing Company Email manager@tenspros.com

Section 2: Personal Information

First William Middle Stewart Last Patterson

Alias(es, nicknames, name changes, etc.) Bill

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City St. Louis State MO Zip [redacted]

Telephone [redacted] Email bpatterson@usmedrehab.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. Louis University		2004-2006	
Address	**City**	**State**	**Zip**
1 N Grand Blvd	St. Louis	MO	63103
Diploma/Degree obtained, if any			
Masters of Business Administration (MBA)			

School Name		From - To (MM/YY – MM/YY)	
University of Missouri		1996-2000	
Address	**City**	**State**	**Zip**
105 Jesse Hall	Columbia	MO	65211
Diploma/Degree obtained, if any			
Bachelor of Science, Finance and Banking			

School Name		From - To (MM/YY – MM/YY)	
DeSmet Jesuit High School		1992-1996	
Address	**City**	**State**	**Zip**
233 N New Ballas Rd	St. Louis	MO	63141
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2015 - Current	[redacted]	St. Louis	MO	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2004 - 2015		St. Louis	MO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
EDF Holdings LLC, dba TENS Pros			12/2024 - Present
Business Address	**City**	**State**	**Zip**
1131 N Warson Road	St. Louis	MO	63132
Phone	**Title**		
888-724-1121	Owner and CEO		

Description of Duties
Owner and CEO of EDF Holdings, dba TENS Pros, directing the strategic direction of the Company.

Business Name			From - To (MM/YY – MM/YY)
Equifax Worforce Solutions			7/2024 - 12/2024
Business Address	**City**	**State**	**Zip**
11432 Lackland Rd	St. Louis	MO	63146
Phone	**Title**		
877-664-8778	Sr. Director, Product Management		

Description of Duties
Led the development of and ongoing lifecycle management for the Company's I-9, Federal-State-Local New Hire Forms, and Work Opportunity Credit (WOTC) solutions.

Business Name			From - To (MM/YY – MM/YY)
Evernorth Health Services			7/2021 - 12/2023
Business Address	**City**	**State**	**Zip**
One Express Way	St. Louis	MO	63121
Phone	**Title**		
800-282-2881	Managing Director, Solutions Enablement		

Description of Duties
Led Solutions Enablement within the Growth Office leading a team of 17 configured around a logical progression of the product lifecycle, beginning with the translation of enterprise strategy into an informed product roadmap, through product portfolio prioritization and approval activities and ending with the product launch process.

Business Name			From - To (MM/YY – MM/YY)
Express Scripts			5/2017 - 7/2021
Business Address	**City**	**State**	**Zip**
One Express Way	St. Louis	MO	63121
Phone	**Title**		
800-282-2881	Sr. Director, Benefit & New Solutions		

Description of Duties
Led Innovation, delivering industry leading digital healthcare technologies to the Evernorth/Express Scripts Care Solutions and Supply Chain product suites, and the Benefit Solutions portfolio, which drive top line revenue through solutions that address the member experience and optimal use of the pharmacy benefit.

Business Name			From - To (MM/YY – MM/YY)
Express Scripts			1/2016 - 5/2017
Business Address	**City**	**State**	**Zip**
One Express Way	St. Louis	MO	63121
Phone	**Title**		
800-282-2881	Sr. Director, Benefit Solutions		

Description of Duties
Developed, deployed and managed the lifecycle of products and capabilities that impacted the member experience and optimal use of the pharmacy benefit, including Consumer-Directed Healthcare, Value-Based Incentive Design, Pricing Transparency, Pharmacy Benefit Design Strategy, Open Enrollment, and Refill Too Soon.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Express Scripts			3/2014 - 12/2015	
Business Address		City	State	Zip
One Express Way		St. Louis	MO	63121
Phone	Title			
800-282-2881	Director, Benefit Solutions			
Description of Duties				
Led product strategy and development for Consumer-Directed Healthcare (CDH), Value-Based Insurance Design (VBID), and Refill Too Soon (RTS) solutions.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Patterson

Print Name (First, Last)

William Patterson

Original Signature (electronic, copies or stamps not accepted)

3/31/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of St Louis

I, WILLIAM PATTERSON, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

William Patterson

Original Signature

4/7/2025

Date

Subscribed and Sworn to before me this 7th day of April 2025

Stacy Butler

Notary Public Signature

STACY BUTLER
NOTARY PUBLIC - NOTARY SEAL
STATE OF MISSOURI
MY COMMISSION EXPIRES JUNE 26, 2026
ST. CHARLES COUNTY
COMMISSION #14450912

(Seal)

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Y

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FA8904218
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☒ Other: Mail Order	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH PH04153		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Alto Pharmacy

Physical Address: 600 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119-9011

Mailing Address (if different from physical address): 600 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119-9011

Telephone: (800) 874-5881 Toll Free # (NAC 639.708, NRS 639.23286): (800) 874-5881

Fax: (415) 484-7058 Contact Email: pharmacycompliance@alto.com

Website: www.alto.com

Nevada Business License # (if applicable) NV20212001945

Supervising/Managing Pharmacist Name (NRS 639.220): Bernadette S. Stanton

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19962

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Bernadette S. Stanton	NV Pharmacist Registration #: 19962
Name: Chinwe Okonkwo	NV Pharmacist Registration #: 20351
Name: Jaymie Padero	NV Pharmacist Registration #: 23846
Name: Kenneth Kunke	NV Pharmacist Registration #: 16042
Name: Shistata Bhurtel	NV Pharmacist Registration #: 19542
Name: Vivian Ho	NV Pharmacist Registration #: 20251
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A-Not Applicable

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Alto Pharmacy Investments, LLC

Corporation/Organization Name: Alto Pharmacy LLC

Mailing Address: 645 Harrison Street, Suite 200

City: San Francisco State: CA Zip: 94107

Telephone: (800) 874-5881 Email: pharmacycompliance@alto.com

Contact Person Name: Lisa M. Jurinka

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A-Not Applicable

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A-Not Applicable

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Secretary (title) for Alto Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Lisa M. Jurinka

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

5/24/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Lisa M. Jurinka hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary (title) for Alto Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 24th day of May, 2025

Notary Public

OFFICIAL STAMP
TYLER DYE
NOTARY PUBLIC - OREGON
COMMISSION NO. 1055222
MY COMMISSION EXPIRES JANUARY 21, 2029

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Bernadette S. Stanton Pharmacist Registration #: 19962

Pharmacy Name: Alto Pharmacy

Initial each statement below to indicate you have read and agree with the following:

BS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

BS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

BS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

BS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

BS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

6/4/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lisa M. Jurinka, Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

5/24/25
Date

Board Use Only	Date Received: 6/18/25	Amount: $500-cc

Section 3: History of Company

Please be advised, the information provided relates to the Applicant's affiliate pharmacies located in San Francisco and Los Angeles, CA.

As the Applicant and affiliate locations operate under the same legal name and ownership, we are providing this information with transparency in mind, to ensure are aware of these matters.

Further be advised, the Applicant has not had a license investigated, disciplined nor are any investigations or disciplinary actions pending.

By:
Name: Lisa M. Jurinka
Title: Secretary

Date: 05/09/2025

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - San Francisco (Harrison Street), California				
		FACILITY	09/26/2024	Texas Board of Pharmacy (Case #: 2024-01512) On July 19, 2024, the Texas Board of Pharmacy ("Board of Pharmacy") issued an Agreed Board Order ("ABO") in which the Board of Pharmacy alleges, from about September 28, 2023, through on or about November 29, 2023, Alto Pharmacy, located at 645 Harrison Street, Suite 200, San Francisco, CA 94107, Texas Non-Resident Pharmacy Permit #: 34204, operated without a Texas licensed pharmacist named on the Texas Non-Resident Pharmacy Permit. Alto Pharmacy acknowledges operating without the required Texas licensed pharmacist, Alto Pharmacy further acknowledges contact, and correspondence was made with the Board of Pharmacy, requesting guidance and direction on operating without a Texas licensed pharmacist. The Board of Pharmacy and Alto Pharmacy finalized the ABO on November 5, 2024, and a fine of $1,000 was paid. Alto Pharmacy's Texas Non-Resident Pharmacy Permit remains active, in good standing and unrestricted. The Board of Pharmacy considered the matter closed and took no further action.

TEXAS STATE BOARD OF PHARMACY

November 7, 2024

ALTO PHARMACY
C/O TSAI LING JIANG
PHARMACIST-IN-CHARGE
645 HARRISON ST STE 200
SAN FRANCISCO, CALIFORNIA 94107

RE: In the Matter of Alto Pharmacy

Dear Tsai Ling Jiang:

Enclosed is a copy of Agreed Board Order (ABO) #2024-01512 that was entered by the Texas State Board of Pharmacy (Board) concerning the above-referenced matter. The Board entered this Order on November 5, 2024. The requirements and conditions of the enclosed Order and matters relating to the Order are discussed below.

ADMINISTRATIVE PENALTY (FINE)

Under the terms of this Order, Alto Pharmacy (pharmacy license #34204) must pay an administrative penalty (fine) of $1,000. **This fine is due on or before March 5, 2025.** Please make your cashier's check or money order payable to the "Texas State Board of Pharmacy" and submit to the Board's office by the due date. Please include your ABO number (#2024-01512) on the cashier's check or money order. **Note:** The Board will **not** accept partial payments. You must submit payment for the full amount by the due date.

LICENSE RENEWAL APPLICATIONS

Prior to the next expiration date of pharmacy license #34204, the pharmacy will complete a license renewal application for the Texas State Board of Pharmacy. This application will require a pharmacy representative to answer the question:

> "Has the pharmacy, the pharmacy's owner or any officer or partner (if the pharmacy is owned by a corporation or partnership) been the subject of any professional disciplinary action or are any such actions pending against you by a regulatory authority within the last 36 months?..."

As a result of the entry of ABO #2024-01512, Alto Pharmacy must answer "yes" to this question for 36 months from the date of the termination of all sanctions. Consequently, an Alto Pharmacy representative must answer "yes" to this question on any renewal applications submitted beginning November 5, 2024 and ending 36 months following the termination of all sanctions.

If you have any questions about this Order, please contact Knijiah Samuel, Monitoring Specialist, at (512) 305-8054 or via monitoring@pharmacy.texas.gov.

Sincerely,

Robert Rivera
Enforcement Manager

RR:ks

Enclosure: Agreed Board Order #2024-01512

c: Lisa Jurinka
Managing Officer, Alto Pharmacy LLC
On behalf of Alto Pharmacy
pharmacycompliance@alto.com

Kianna L. Sitarski
Legal Counsel for Alto Pharmacy
Brown & Fortunato, P.C.
7557 Rambler Road, Suite 510
Dallas, Texas 75231
ksitarski@bf-law.com

AGREED BOARD ORDER #2024-01512

RE: IN THE MATTER OF
ALTO PHARMACY
(PHARMACY LICENSE #34204)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 34204 issued to Alto Pharmacy (Respondent), 645 Harrison Street, Suite 200, San Francisco, California 94107.

By letter dated July 19, 2024, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 562.101(f); and 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2023); and

Section 291.103 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2023); in that allegedly:

COUNT

From on or about September 28, 2023, through on or about November 29, 2023, Alto Pharmacy, 645 Harrison Street, Suite 200, San Francisco, California 94107, was engaged in the operation of a non-resident pharmacy in violation of Texas State Board of Pharmacy Rules, in that the pharmacy was not under the supervision of a pharmacist-in-charge licensed as a pharmacist in Texas.

By letter dated July 19, 2024, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Lisa Jurinka, Managing Officer, Alto Pharmacy LLC, on behalf of Respondent, and Kianna L. Sitarski, Legal Counsel for Respondent, neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to an informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(3) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2023), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2024).

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 5th day of November, 2024.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Daniel Carroll, Pharm.D.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Lisa Jurinka, Managing Officer, Alto Pharmacy LLC
On behalf of Alto Pharmacy

Kianna L. Sitarski, Legal Counsel for Alto Pharmacy
Brown & Fortunato, P.C.
7557 Rambler Road, Suite 510
Dallas, Texas 75231

APPROVED AS TO FORM:

Megan G. Holloway, General Counsel
Texas State Board of Pharmacy

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - San Francisco, California				
		FACILITY	03/22/2023	California Board of Pharmacy (Case #: CI2022 96563) On March 22, 2023, the California Board of Pharmacy ("Board of Pharmacy")issued a Modified Citation and Fine ("Citation"), in which the Board of Pharmacy alleges, on or about July 2, 2022, the Licensee dispensed and delivered prescription drugs to a wrong address. On or about July 6, 2022, the prescription drugs were returned to the Licensee and afterwards placed into the Licensee's inventory. Further, Board of Pharmacy alleges the Licensee failed to quarantine and prepare the returned prescription drugs for destruction pursuant to Board of Pharmacy rules and regulations. Licensee acknowledges the returned prescription drugs were placed into inventory, not quarantined and prepared for destruction as required by Board of Pharmacy rules and regulations. Licensee agreed to pay the Board of Pharmacy's fine of $1,000 as indicated in the attached Citation. To ensure correct practices are followed, the Licensee's Compliance and Pharmacy Operations Departments have reviewed their Policies and Procedures, which address the handling of returned prescription drugs, with the staff at the pharmacy location. Staff has acknowledged the review, training and the proper procedures to follow when previously dispensed prescription drugs are returned to the pharmacy location. The Licensee's California Pharmacy Permit remains active, in good standing and unrestricted. Upon receipt of the fine, the Board of Pharmacy considered the matter closed and took no further action.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 22, 2023

CERTIFIED MAIL

ALTO PHARMACY
ATTN: MATTIEU GAMACHE-ASSELIN, CEO
1400 TENNESSEE ST UNIT 2
SAN FRANCISCO, CA 94107

Natalia Mazina
100 Pine St Ste 1250
San Francisco, cA 94111-5235

RE: CI 2022 96563
ALTO PHARMACY
PHY 54523

As a result of the explanation and information you provided at the office conference, the amount of the fines assessed in Citation and Fine, CI 2022 98558 have been reduced.

The modified Citation is attached and is hereby issued pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (d).

If you desire a hearing to appeal the attached Citation, you must submit a written request for a hearing to the Board of Pharmacy ("Board") within 30 days of the date this Citation was issued. (See Bus. Prof. Code sec. 125.9, subd. (b)(4), and C.C.R., title 16, sec. 1775.4, subd. (d).). Unless the Board receives a written request within the 30 days, you will be deemed to have waived your right to a hearing in this matter and the Citation shall become the final order of the Board. If a hearing is not requested, the timely payment of the imposed fine(s) shall not constitute an admission of the violation(s) charged in the Citation.

Failure to pay any imposed fine(s) within 30 days of the date the Citation was issued may result in disciplinary action being taken.

If any fine(s) are not timely paid, then the full amount of the unpaid fine(s) shall be added to the fee for the renewal of your license. Your license shall not then be renewed without full payment of the renewal fee and the assessed fine(s).

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

Attachments

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check | | I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: ALTO PHARMACY PHY 54523 Respondent	Citation Case No : CI 2022 96563 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED

(Respondent)

Mailing Address of Respondent:

_____

(Street Address)

(City (State) (Zip) ( ) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

(Attorney's Name

_____

(Street Address)

(City (State) (Zip) ( ) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: ALTO PHARMACY, PHY 54523
Citation and Fine CI 2022 96563

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On March 22, 2023, I served the attached:

Cover Letter, Citation, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: MATTIEU GAMACHE-ASSELIN, CEO 1400 TENNESSEE ST UNIT 2 SAN FRANCISCO, CA 94107	7020 2450 0000 3084 4580
Natalia Mazina 100 Pine St Ste 1250 San Francisco, CA 94111-5235	7020 2450 0000 3084 4573

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 22, 2023, at Sacramento, California.

DECLARANT

Suelynn Yee
Citation and Fine Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2022 96563	ALTO PHARMACY, PHY 54523

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4342 subd. (a)/Health & Safety Code § 111295	**Prevent sale of drugs lacking quality/It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated**	**$1,000.00**

CONDUCT:

Actions by the Board to prevent sales of preparations or Drugs lacking quality of strength; Penalties for knowing or willful violation of Regulations governing those sales: Business and Professions Code (BPC) 4342(a), states in pertinent part: (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code), as it relates to Health and Safety Code (HSC) 111295, which states, It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. Specifically, Alto Pharmacy, PHY54523, located at 1400 Tennessee St., Unit 2, San Francisco, CA 94107, on or around 7/2/2022, dispensed and delivered prescription numbers: 883850002 and 883850003, to an unknown person and location and held at an unknown tempterature, the chain of custody was broken. The prescriptions showed up at the reception desk of the correct address around 7/6/2022 and were then handed to the correct patient. They were subsequently retrieved by Alto Pharmacy. Alto Pharmacy was in violation when they determined the drugs once returned, would be returned to stock, meaning they would be held and offered for sale/re-dispensed to another patient. Those drugs are considered adulterated and should have been quarantined and then sent for destrucation as they were out of Alto Pharmacy's control between dates: 7/2/2022 and 7/6/2022. It was unknown how they were stored and if they had been tampered with in any way. Holding or offering for sale, prescription drugs which where out of Alto Pharmacy's control between dates 7/2/2022 to 7/6/2022, which should be considered adulterated, was a violation according to BPC 4342(a) as it relates to HSC 111295.

CITATION ISSUED ON: March 22, 2023 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: April 21, 2023

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

COPY

Citation Number	Name, License No
CI 2022 96563	ALTO PHARMACY, PHY 54523

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4342 subd. (a)/Health & Safety Code § 111295	Prevent sale of drugs lacking quality/It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	$1,000.00

CONDUCT:

Actions by the Board to prevent sales of preparations or Drugs lacking quality of strength; Penalties for knowing or willful violation of Regulations governing those sales: Business and Professions Code (BPC) 4342(a), states in pertinent part: (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code), as it relates to Health and Safety Code (HSC) 111295, which states, It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. Specifically, Alto Pharmacy, PHY54523, located at 1400 Tennessee St., Unit 2, San Francisco, CA 94107, on or around 7/2/2022, dispensed and delivered prescription numbers: 883850002 and 883850003, to an unknown person and location and held at an unknown tempterature, the chain of custody was broken. The prescriptions showed up at the reception desk of the correct address around 7/6/2022 and were then handed to the correct patient. They were subsequently retrieved by Alto Pharmacy. Alto Pharmacy was in violation when they determined the drugs once returned, would be returned to stock, meaning they would be held and offered for sale/re-dispensed to another patient. Those drugs are considered adulterated and should have been quarantined and then sent for destrucation as they were out of Alto Pharmacy's control between dates: 7/2/2022 and 7/6/2022. It was unknown how they were stored and if they had been tampered with in any way. Holding or offering for sale, prescription drugs which where out of Alto Pharmacy's control between dates 7/2/2022 to 7/6/2022, which should be considered adulterated, was a violation according to BPC 4342(a) as it relates to HSC 111295.

CITATION ISSUED ON: March 22, 2023

TOTAL AMOUNT OF FINE(S): $1,000.00

PAYMENT OF FINE(S) DUE BY: April 21, 2023

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - Los Angeles, California				
		FACILITY	07/14/2023	California Board of Pharmacy (Case #: CI 2021 95943) On December 28, 2023, the California Board of Pharmacy ("Board of Pharmacy") issued a dismissal of the Citation and Fine, in which the Board of Pharmacy alleged, on or about July 14, 2023, the Licensee failed to update their pharmacy systems and inventory indicating a certain prescription drug was not available for dispensing to a patient requesting the medication, thus delaying the receipt of the prescription medication for the patient. Alto Pharmacy's California Resident Pharmacy Permit remains active, in good standing and unrestricted.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

December 28, 2023

CERTIFIED MAIL

ALTO PHARMACY
ATTN: ALICIA DAVIS, CEO
5916 BOWCROFT ST
LOS ANGELES, CA 90016

Sweta Patel
1255 Treat Blvd., Suite 300
Walnut Creek, CA 94597

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

After thorough and careful consideration of the explanation and information you provided at the office conference, it was decided to dismiss Citation and Fine. CI 2021 95943 as originally issued. Effective immediately the fines assessed in Citation CI 2021 95943, have been dismissed.

This decision is the final administrative order regarding the Citation.

Please contact Associate Enforcement Analyst Suelynn Yee at (916) 518-3013, if you have any questions.

Sincerely

Julia G. Ansel
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY FIRST CLASS CERTIFIED MAIL

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and no party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suit 100, Sacramento, California 95833.

On December 28, 2023, I served the attached:

in said cause, by placing a true copy thereof enclosed in two separate sealed envelopes w postage thereon fully prepaid by Certified Mail and First Class Mail, in the United States m at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: ALICIA DAVIS, CEO 5916 BOWCROFT ST LOS ANGELES, CA 90016	7017 0530 0000 3305 3269
Sweta Patel 1255 Treat Blvd., Suite 300 Walnut Creek, CA 94597	7017 0530 0000 3305 3252

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 28, 2023, at Sacramento, California.

DECLARANT
Sueiynn Yee
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 14, 2023

DATED MATERIAL ENCLOSED

ALTO PHARMACY
ATTN: ALICIA DAVIS, CEO
5916 BOWCROFT ST
LOS ANGELES, CA 90016

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- August 13, 2023: Unless the Citation is contested payment of fine(s) must be received by the Board.
- July 28, 2023: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- August 13, 2023: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By:

Suelynn Yee
Citation and Fine Analyst

Attachments

Alto Pharmacy LLC

Owners and Officers

Name and Title	Work Address, Telephone and Email	Home Address and Telephone	Date of Birth	SSN or FEIN	Ownership %
Alto Pharmacy Investments, LLC Parent / Sole Member	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 pharmacycompliance@alto.com	[redacted]			100%
Alicia Boler Davis President and CEO	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 alicia.bolerdavis@alto.com	[redacted]			0%
Jamie E. Cohen CFO and Treasurer	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 jamie.cohen@alto.com	[redacted]			0%
Lisa M. Jurinka Secretary	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 lisa.jurinka@alto.com	[redacted]			0%

Managers

Name and Tile	Work Address, Telephone and Email	Home Address and Telephone	Date of Birth	SSN	Ownership %
Alicia Boler Davis Manager	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 alicia.bolerdavis@alto.com	[redacted]			0%

November 1, 2023

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALTO PHARMACY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





5763030 8300

SR# 20250175196

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202724830

Date: 01-17-25

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Alto Pharmacy LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 01/28/2021, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 06/11/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202506115802781
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Alto Pharmacy

Pharmacy/Wholesaler License # (if applicable): PH04153

Physical Address: 600 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119-9011

Mailing Address (if different from physical address): 600 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119-9011

Telephone: (800) 874-5881 Website: www.alto.com

Licensing Company Email: erik.heikkenen@adeiaservices.com

Section 2: Personal Information

First: Bernadette Middle: S. Last: Stanton

Alias(es, nicknames, name changes, etc.): Bernadette Konigsberg

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Addres[redacted]

City [redacted] State: NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		09/15-05/18	
Address	City	State	Zip
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Nevada State University		09/12-05/14	
Address	City	State	Zip
1300 Nevada State DR	Henderson	NV	89002
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Silverado High School		08/96-05/00	
Address	City	State	Zip
1650 Silver Hawk Ave	Las Vegas	NV	89123
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
2008-present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Alto Pharmacy			02/25-Present	
Business Address		**City**	**State**	**Zip**
600 Pilot Road, Suite A		Las Vegas	NV	89119-9011
Phone	**Title**		**Number of Employed Hours**	
(800) 874-5881	Pharmacy Manager		800	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			03/22-12/24	
Business Address		**City**	**State**	**Zip**
		Las Vegas	NV	
Phone	**Title**		**Number of Employed Hours**	
	Pharmacy Manager		6,240	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			08/18-03/22	
Business Address		**City**	**State**	**Zip**
		Las Vegas	NV	
Phone	**Title**		**Number of Employed Hours**	
	Pharmacist		8,320	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Bernadette S. Stanton, **certify that as the designated representative for**

Alto Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BS I am at least 21 years of age;
3. BS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Bernadette S. Stanton
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/16/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bernadette S. Stanton

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/16/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Bernadette S. Stanton, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/16/2025

Date

Subscribed and Sworn to before me this 16 day of JUNE 2025

Notary Public Signature

ANTHONY J. MOJICA
Notary Public, State of Nevada
No: 23-9471-01
My Appt. Exp. Aug. 10, 2027

Nevada State Board of Pharmacy

For licensing inquires please send an email to, pharmacylicensing@pharmacy.nv.gov (mailto:pharmacylicensing@pharmacy.nv.gov).

For current information on **disciplinary actions taken against licensees**, please send an email to teambc@pharmacy.nv.gov (mailto:teambc@pharmacy.nv.gov).

VERIFY LICENSE

Last Name	First Name	License#	License Status	License Expiration Date	City	State	Discipline	Action
STANTON	BERNADETTE	19962	Active	10/31/2025	LAS VEGAS	NV	N	

License Number : 19962
Name : STANTON, BERNADETTE
License Type : Pharmacist
License Status : Active
License Date : 08/15/2018
Discipline : None
Expiration Date : 10/31/2025



Drop file(s) here to upload or click here to browse and select file(s) to upload. ()

Complete Upload Reset

Document Type	Upload Date	Name	Other Name	Is Public?	Status	Uploaded By	Link	Actions

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Personal History Record Application

N/A - Not Applicable. Applicant Alto Pharmacy LLC dba Alto Pharmacy is a 100% wholly owned subsidiary of Alto Pharmacy Investments, LLC. There are no individual owners.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA8904218	06-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-20-2022

ALTO PHARMACY
600 PILOT RD STE A
LAS VEGAS, NV 891199011

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
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ALTO PHARMACY
600 PILOT RD STE A
LAS VEGAS, NV 891199011

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Form DEA-223 (9/2016)

NABP ACCREDITED

DIGITAL PHARMACY

Alto Pharmacy LLC

with headquarters located at

1400 Tennessee Street, Unit 2, San Francisco, CA 97107

This business has met all the digital pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accredited locations may also be verified by visiting the digital pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

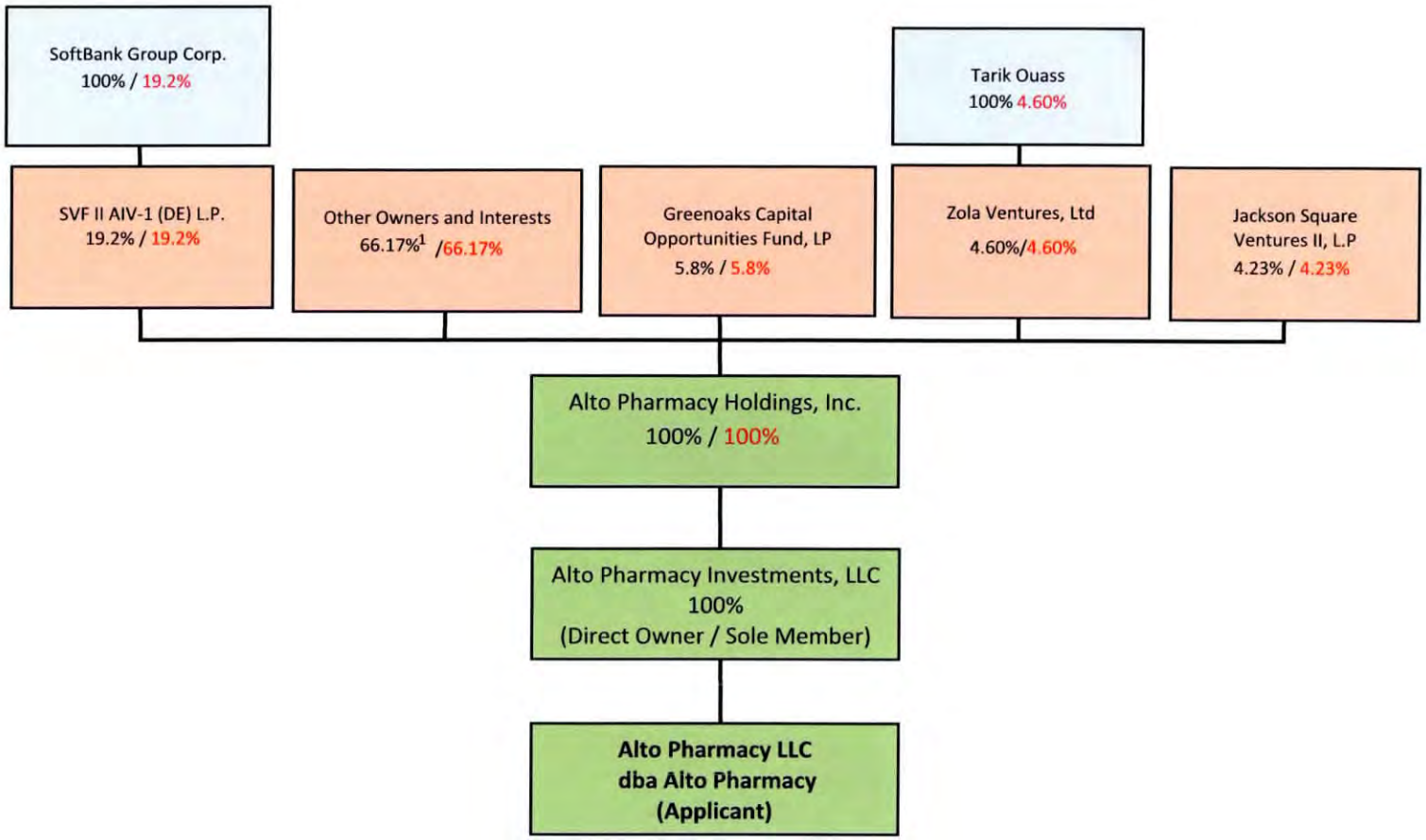
04/25/2024 - 04/24/2027
Period of Accreditation

List of 1 NABP-Accredited Digital Pharmacies

Accreditation is valid for 3 years

Business Name Pharmacy Name	Website	End Date Membership Type
Alto Pharmacy 1400 Tennessee Street San Francisco, CA 97107 [-] 15 Stores	https://alto.com	04/24/27 Open to all
Alto Specialty Pharmacy	4175 Freidrich Lane, Suite 202 Austin, TX 78744	
Alto Pharmacy	4950 Terminal St , Suite 200 Bellaire, TX 77401-6013	
Alto Pharmacy	13010 NE 20th Street, Suite 200 Bellevue, WA 98005	
Alto Pharmacy	929 N Broadway Denver, CO 80203	
Alto Pharmacy	20 Fairbanks, Suite 187 Irvine, CA 92618	
Alto Pharmacy	600 Pilot Road, Suite A Las Vegas, NV 98119	
Alto Pharmacy	475 State Highway 121 Bypass, Suite 150 Lewisville, TX 75067	
Alto Pharmacy	5916 Bowcroft Street Los Angeles, CA 90016	
Alto Pharmacy	100 Park Ave, Front E New York, NY 10017	
Alto Pharmacy	245 Newtown Road, Suite 300 Plainview, NY 11803	
Alto Pharmacy	6201 W. Plano Parkway, Suite 400 Plano, TX 75093	
Alto Pharmacy	4240 Kearny Mesa Rd, Suite 107 San Diego, CA 92111	
Alto Pharmacy	1400 Tennessee St San Francisco, CA 94107	
Alto Pharmacy	645 Harrison St San Francisco, CA 97107	
Alto Pharmacy	2360 Qume Dr, Suite A San Jose, CA 95131-1838	

Alto Pharmacy, LLC dba Alto Pharmacy
Pre-Close Organizational Chart

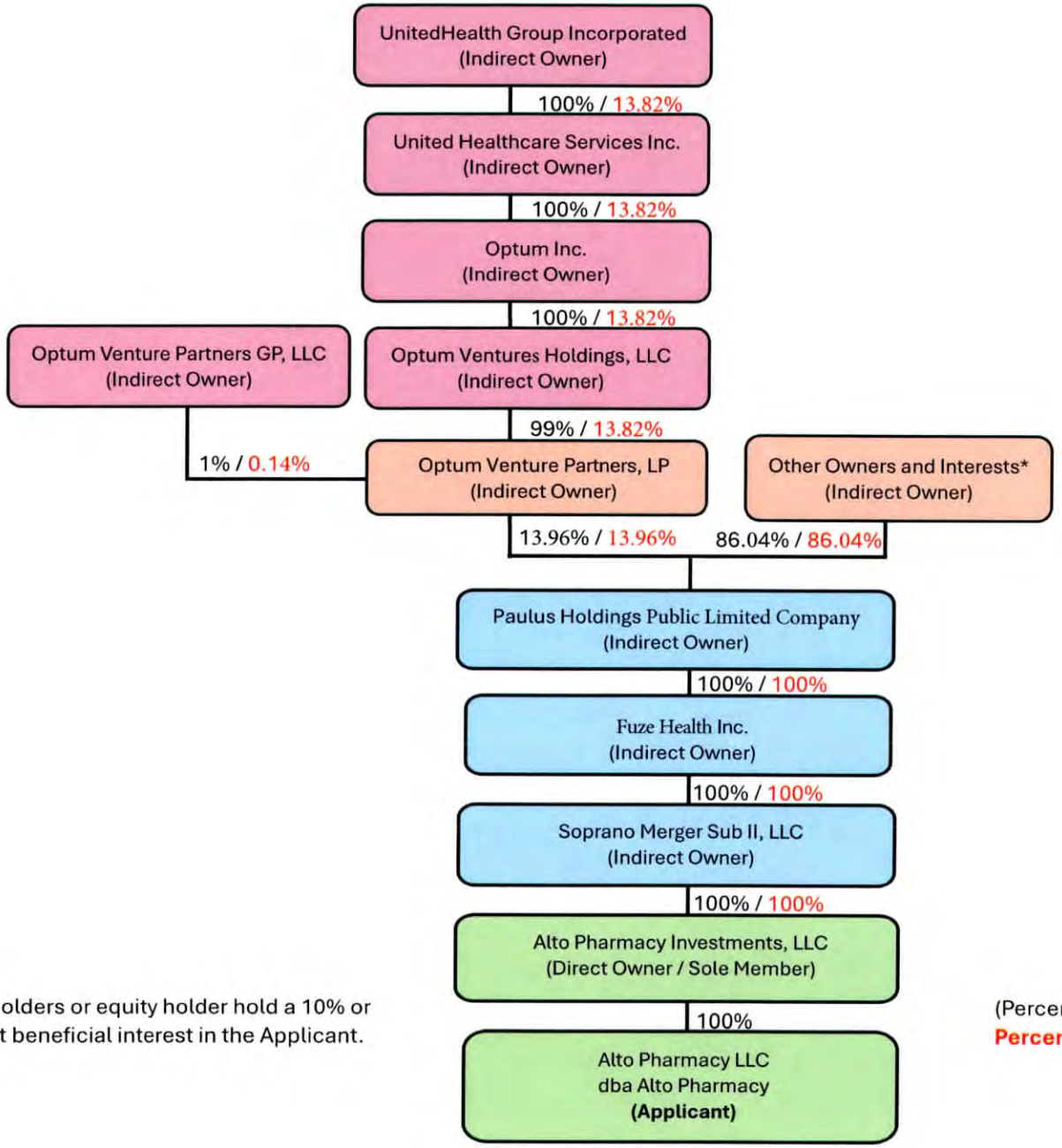


(Percentage is Direct Ownership in Owned Entity /
Percentage is Indirect Ownership of Applicant)

[1]Approximately 900+ Individual owners or interests.
No individual or interest holding 5% or more direct or indirect ownership

May 20, 2025

Alto Pharmacy, LLC dba Alto Pharmacy
Post-Close Organizational Chart



*No individual shareholders or equity holder hold a 10% or more direct or indirect beneficial interest in the Applicant.

(Percentage is Direct Ownership in Owned Entity / **Percentage is Indirect Ownership of Applicant)**

May 20, 2025

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: TBD
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Community Health Alliace Neil Road Pharmacy

Physical Address: 3915 Neil Road

City: Reno State: NV Zip: 89502

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (775)870-4302 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: (775)870-4602 Contact Email: kmaxim@chanevada.org

Website: www.chanevada.org

Nevada Business License # (if applicable) B202506035780052

Supervising/Managing Pharmacist Name (NRS 639.220): Kelsey Maxim

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 18749

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kelsey Maxim	NV Pharmacist Registration #: 18749
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: Community Health Alliance

Mailing Address: 680 South Rock Blvd

City: Reno State: NV Zip: 89502

Telephone: (775)329-6300 Email: jwheeler@chanevada.org

Contact Person Name: Jennifer Wheeler

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

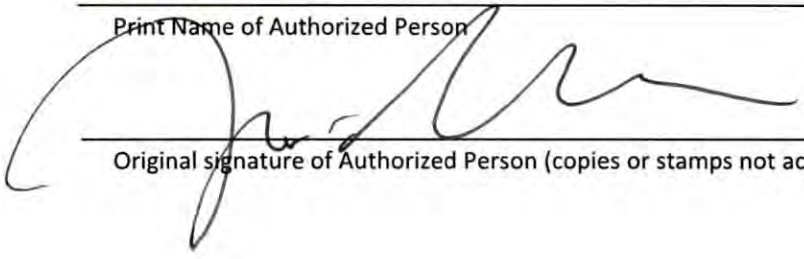
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Operating Officer (title) for Community Health Alliance Neil Road Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Jennifer Wheeler

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

07/01/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Jennifer Wheeler hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Operating Officer (title) for Community Health Alliance Neil Road Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 1st day of July, 2025

Notary Public

BONNIE DAUGHERTY
Notary Public - State of Nevada
Appointment Recorded in Washoe County
No: 16-2110-2 - Expires April 4, 2026

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Kelsey Maxim Pharmacist Registration #: 18749

Pharmacy Name: Community Health Alliance Neil Road Pharmacy

Initial each statement below to indicate you have read and agree with the following:

KM I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

KM I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

KM I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

KM I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

KM I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KMaxim 07/01/2025

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kelsey Maxim

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

K Maxim

Original signature of Authorized Person (copies or stamps not accepted)

07/01/2025

Date

Board Use Only	Date Received: 7/2/25	Amount: $500-CC

2025 Community Health Alliance Board Members

1. Alexsis Adams
2. Bayo Curry-Winchill
3. Daniel Spogen
4. Laura Martinez
5. Mathew Thornton
6. Mathew Work
7. Nathan DuPree
8. Noemi Gomez
9. Osvaldo Jimenez
10. Paul Parent

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **COMMUNITY HEALTH ALLIANCE** as a DOMESTIC NONPROFIT CORPORATION (82) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/31/1992, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 06/03/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202506035780052
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Community Health Alliance - Neil Road Pharmacy
Pharmacy/Wholesaler License # (if applicable):
Physical Address: 3915 Neil Road
City: Reno State: NV Zip: 89502
Mailing Address (if different from physical address):
City: State: Zip:
Telephone: 775-870-4302 Website: www.chanevada.org
Licensing Company Email:

Section 2: Personal Information

First: Kelsey Middle: Anne Heslington Last: Maxim
Alias(es, nicknames, name changes, etc.): Kelsey Anne Heslington
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ■ F ☐ X
Mailing Address: [redacted]
City: Sparks State: NV Zip: [redacted]
Telephone: [redacted] Email: [redacted]
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Utah, College of Pharmacy		08/2010-05/2014	
Address	**City**	**State**	**Zip**
201 Presidents Circle	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Doctor of Pharmacy, PharmD			
School Name		**From - To (MM/YY – MM/YY)**	
University of Nevada		08/2005-05/2009	
Address	**City**	**State**	**Zip**
1664 N Virginia St	Reno	NV	89557
Diploma/Degree obtained, if any			
Bachelors of Science - Biochemistry			
School Name		**From - To (MM/YY – MM/YY)**	
Edward C. Reed High School		08/2001-06/2005	
Address	**City**	**State**	**Zip**
1350 Baring Blvd	Sparks	NV	89434
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2020-current	[redacted]			
08/2009-11/2020				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Community Health Alliance			03/2016-current	
Business Address		**City**	**State**	**Zip**
680 S. Rock Blvd		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
775-336-3035	Director of Retail Pharmacy		> 18,000 hours	
Description of Duties				
Have worked since 2016 first as a per diem pharmacist, then a staff pharmacist, then the Director of Pharmacy for three different pharmacy locations. Address listed is the corporate address.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Kelsey Maxim, **certify that as the designated representative for**

Community Health Alliance - Neil Road Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KM I am at least 21 years of age;
3. KM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kelsey Maxim

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 16, 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kelsey Maxim

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 16, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Kelsey Maxim, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

July 17, 2025

Date

Subscribed and Sworn to before me this 17th day of July 2025.

Notary Public Signature

BONNIE DAUGHERTY
Notary Public - State of Nevada
Appointment Recorded in Washoe County
No: 16-2110-2 - Expires April 4, 2026

4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: FREE STANDING EMERGENCY ROOM	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☑ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☑ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☑ Holidays	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ER at North Valleys, an Extension of Northern Nevada Medical Center

Physical Address: 7515 Sky Vista Parkway

City: Reno State: NV Zip: 89506

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: sieu.long@uhsinc.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Sieu Long

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 16340

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Duro, Raymond	NV Pharmacist Registration #: 17133
Name: Fracker, Lori	NV Pharmacist Registration #: 11082
Name: Kelly, Melanie	NV Pharmacist Registration #: 16028
Name: Marshall, Keith	NV Pharmacist Registration #: 11473
Name: Harlass, Steven	NV Pharmacist Registration #: 17002
Name: Kemper, Ruth	NV Pharmacist Registration #: 09551
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.012S, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Sparks Family Hospital, Inc.

Business Name: Northern Nevada Medical Center

Business Address: 2375 E. Prater Way

City: Sparks State: NV Zip: 89434

Telephone: 775 356-4070 Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Pharmacist (title) for ER at North Valleys, an Extension of Northern Nevada Medical Center (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Sieu Long

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/1/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Sieu Long hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Pharmacist (title) for ER at North Valleys, an Extension of Northern Nevada Medical Center (Name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 7 day of July, 2025

Notary Public

CORY POWELL
Notary Public, State of Nevada
Appointment No. 24-8281-02
My Appt. Expires Jan 19, 2028

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Sieu Long Pharmacist Registration #: 16340

Pharmacy Name: ER at North Valleys, an Extension of Northern Nevada Medical Center

Initial each statement below to indicate you have read and agree with the following:

x	I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.
x	I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.
x	I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.
x	I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).
x	I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	✔	

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
Disciplinary	Nevada	12/5/2012	12-050-RPH-N

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

7/1/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sieu Long

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7/1/2025

Date

Board Use Only	Date Received: 7/8/25	Amount: $500-cc

Sieu Long
Northern Nevada Medical Center
2375 E. Prater Way
Sparks, NV. 89434
(775) 356-4070
Sieu.long@uhsinc.com

July 1, 2025

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206.
Reno, NV. 89521
(775) 850-1440

To whom this may concern,

I, Sieu Long, a Nevada pharmacist license #16340 was disciplined by the Nevada State Board of Pharmacy on December 5, 2012 for a mislabeled prescription, please see attached Notice of Intended Action and Accusation and Stipulation and Agreement for further explanations. Thank you.

Sincerely,

Sieu Long

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

SIEU LONG, R.PH.
Certificate of Registration No. 16340

SCOLARI'S PHARMACY #26
Certificate of Registration No. PH01081

Respondents.

NOTICE OF INTENDED ACTION AND ACCUSATION

Case No. 12-050-R.PH.-N

Case No. 12-050-PH-N

COMES NOW Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, and makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy has jurisdiction over this matter and these Respondents because Respondent Sieu Long (Certificate Number 16340) is a registered pharmacist with the Board and Respondent Scolari's Pharmacy (Scolari's #26) is a pharmacy licensed by the Board, located at 1300 Disc Drive, Sparks, Nevada.

II.

On or about June 26, 2012, Robert Cecchini was seen by his Advanced Nurse Practitioner (APN) who prescribed a quantity of fourteen levofloxacin 500 mg. tablets with instructions to take one tablet by mouth daily for the treatment of a sinus infection. The prescription was electronically prescribed and transmitted to Scolari's Pharmacy #26, filled and picked up by Mr. Cecchini's wife the same day. Pharmacist Long counseled Mr. Cecchini's wife at the time of purchase.

III.

Per the instructions on the prescription label, Mr. Cecchini ingested two levofloxacin tablets per day for the next seven days. During his follow-up appointment on July 2, 2012, the APN discovered that the dispensed prescription was filled with

fourteen levofloxacin 500 mg. tablets and mislabeled with directions to take one tablet by mouth twice daily rather than one tablet by mouth once daily. She instructed Mr. Cecchini to discontinue the medication. Mr. Cecchini had ingested thirteen of the fourteen tablets by then and was suffering from diarrhea. On or about July 5, 2012, Mr. Cecchini allegedly experienced chest pain and was transported by ambulance to a hospital where he was kept overnight for observation.

IV.

During the investigation of this matter, a review of the Scolari's Transaction Report and biometric inputs detailing the production sequence indicated that the original prescription was input into the pharmacy computer system by an intern pharmacist. A pharmaceutical technician completed the processing of the prescription prior to staging it for pharmacist Long's verification. During verification, pharmacist Long failed to heed a high dosage alert on the DUR Conflict Description window and also failed to identify the dosing error on the prescription label. Pharmacist Long believes that when she was verifying the prescription, she was comparing the data on the prescription label and not with the actual electronic prescription. Pharmacist Long also failed to identify the incorrect dosing instructions when counseling Ms. Cecchini.

V.

A new pharmacy computer system at Scolari's #26 was installed in April of 2012. The only functions of the filling sequence captured in the Transaction Detail Report for Mr. Cecchini's prescription were insurance adjudication and label printing. Scanning and initial data entries were not listed as separate functions nor were they captured biometrically or otherwise. The identity of the employee responsible for the transcription error could therefore not be determined. Counseling was not indicated on the Transaction Detail Report and was not recorded biometrically which appears to be a training issue related to unfamiliarity with the new computer system. Pharmacist Long did affix and initial a counseling sticker in the hard copy log but failed to indicate counseling was completed with a biometric scan at the counseling screen.

FIRST CAUSE OF ACTION

VI.

In failing to strictly follow the directions of Robert Cecchini's APN by mislabeling his prescription for levofloxacin 500 mg. tablets with incorrect dosing instructions, namely "take two tablets by mouth daily" rather than take one tablet by mouth daily, Ms. Long violated Nevada Revised Statutes (NRS) 639.210(4) and/or Nevada Administrative Code (NAC) 639.945(1)(d) and/or (i).

SECOND CAUSE OF ACTION

VII.

By not being able to identify the employee responsible for the transcription error on the Transaction Detail Report because the scanning and initial data entries were not listed as separate functions nor were they captured biometrically for Mr. Cecchini's prescription for levofloxacin 500 mg. tablets, Scolari's #26 violated NRS 639.210(4) and/or NAC 639.945(1)(i) and/or (2).

THIRD CAUSE OF ACTION

VIII.

In owning and operating the pharmacy in which Ms. Long committed the above violations, Scolari's #26 violated NRS 639.210(4) and/or NAC and/or 639.945(1)(d) and/or (i) and (2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent.

Signed this 9th day of October, 2012.

Larry L. Pinson, Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.**	**STIPULATION AND AGREEMENT**
SIEU LONG, R.Ph., **Certificate of Registration #16340,**	**Case No. 12-050-RPH-N**
SCOLARI'S PHARMACY #26 **Certificate of Registration No. PH01081** **Respondents.**	**Case No. 12-050-PH-N**

Carolyn J. Cramer, General Counsel for the Nevada State Board of Pharmacy, and Sieu Long, R.Ph. representing herself and David Chan, R. Ph. Director of Pharmacy for Scolari's, stipulate and agree as follows:

1 Respondent Long admits the factual allegations made in the First Cause of Action.

2. Respondent Scolari's admits the factual allegations made in the Second and Third Causes of Action.

3. The Board Staff concluded after investigation that Respondent Long's inattention and inadequate counseling lead to the errors in this case. The Scolari system for filling prescriptions, while in compliance with Nevada Pharmacy Law, did raise areas of concern that needed to be addressed with regard to the Rapid-Fill System Data Entry Policy. The Policy was amended, implemented by Scolari's after review and acceptance by Board Staff, requiring all data entry staff, whether a pharmacist or a pharmacy technician, to be responsible for all tasks completed with his or her biometric identity.

4. Ms. Long fully recognizes the errors that were made and has taken corrective action to avoid such errors in the future. Mr. Chan has recognized the need to amend the Scolari's pharmacy policies and procedures to strengthen the data entry process.

5. The parties shall present this Stipulation and Agreement to the Board at its meeting on December 5, 2012. The parties agree that the Board may ask questions of the parties, may discuss and deliberate regarding the presentations, and shall enter an Order that may impose discipline as recommended by the parties.

6.. Board Staff and the Respondent Long will recommend that her certificate of registration #16340 be placed on probation for one year subject to the following terms and conditions:

a. Within 10 days of acceptance of the stipulation Ms. Long shall contact the Your Success Rx consultant to enroll in its pharmacist remediation program (hereinafter "the program") according to the terms and conditions imposed by the program and the following terms and conditions.

1. Ms. Long shall cooperate fully and genuinely with the needs, demands, and requirements of the program.

2. Ms. Long shall inform and assure that her employing pharmacy is made aware of her participation in the program and that her employing pharmacy accommodates the program's needs regarding Ms. Long's time needed to participate in the program and the program's potential need to be present in the employing pharmacy.

3. Ms. Long shall pay the entire cost of her participation in the program.

4. When Ms. Long has completed the program; the program shall submit to Board Staff a final report regarding Ms. Long's participation in the program. Board Staff will set a meeting with Ms. Long and the Your Success Rx program administrator to discuss the report.

b. Ms. Long will have no further violations of state or federal law, statute or regulation related to the practice of pharmacy. The failure by Ms. Long to comply with

any term in this stipulation and order shall result in the immediate suspension of her license and will also result in further discipline, up to and including revocation of her license.

c. Ms. Long will pay a fine of $250 by cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this order.

7. Board Staff and Respondent Scolari's #26 will recommend that the Board impose discipline on Scolari's # 26 for the Second Cause of Action in the amount of $250 and for the Third Cause of Action in the amount of $250 for a total fine of $500 to be paid by cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this order.

8. Board Staff and the Respondent Scolari's will recommend that the Board accept and recognize the corrections and actions taken by Scolari's #26 be accepted and no additional discipline or corrective action taken accept the payment of the fine as stated in paragraph 6.

9. If the Board rejects any part or all of this stipulation, the parties agree that a full hearing on the merits of this matter may be heard by the Board and that the Board would hear this matter at its meeting on March 6, 2013. The terms and admissions in this stipulation may not be used or referred to in the full hearing on the merits of this matter.

10. The Board shall release Ms. Long and Scolari's #26 from all claims, whether known or unknown, that might otherwise have existed on or before the effective date of the Board's order in this matter. Ms. Long and Scolari's #26 shall release the Board from all claims, whether known or unknown, that might otherwise have existed on or

before the effective date of the order in this matter. Said releases shall be effective upon the Board's acceptance of this stipulation and order.

Signed this 5th day of November, 2012.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Pharmacy

Carolyn J. Cramer, General Counsel

David Chan, R.Ph.
Director of Pharmacy

Sieu Long, R.Ph.

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision and hereby orders that the foregoing Stipulation be made effective. This decision and order shall be effective on the 5th day of December, 2012.

12/5/12
DATED

Beth Foster, President
Nevada State Board of Pharmacy

FILED

JUN 16 2025

WASHOE COUNTY CLERK
BY _____ DEPUTY

CORPORATION, LLC, BUSINESS TRUST & LEGAL ENTITIES
CERTIFICATE OF BUSINESS: FICTITIOUS FIRM NAME
* * **THIS CERTIFICATE EXPIRES:* 06/16/2030 * * *
(OFFICE USE ONLY)

○ Renewal ◉ New Filing *Contact Number:* (610) 382-3395 *Email:* uhscorpfilings@uhsinc.com

THE UNDERSIGNED does hereby certify that IT IS conducting a free standing emergency department business at 7515 Sky Vista Parkway (Physical street address), Reno (City), NV (State) 89506 (Zip code) under the fictitious firm name of: ER at North Valleys, an Extension of Northern Nevada Medical Center and that said firm is composed of the following *legal entity* (or entities)* whose mailing address, signing officer's name, and title are as follows:

Legal Entity Name: Sparks Family Hospital, Inc.
(Legal entity must state name exactly as it is on file in State of Nevada)

Entity Physical Address: 2375 E. Prater Way (Physical street address), Sparks (City), NV (State), 89434 (Zip code)

Signing Officer Name: Steve Filton

Signing Officer Title: Vice President

FOR ADDITIONAL OWNERS, PLEASE USE ADDITIONAL PAGES

Alternate Mailing Address: 367 S Gulph Rd (P.O. Box or Physical street address other than listed above), King of Prussia (City), PA (State), 19406 (Zip code)

Prior Related DBA Filing (if applicable): _____

WITNESS my hand this 6th day of June, 20 25.

The undersigned hereby swears under penalty of perjury that he/she has authority to sign on behalf of and to bind the above-named legal entity to a contract.

X _____
Signature of authorized officer

STATE OF Pennsylvania
COUNTY OF Montgomery } ss.

On this 6th day of June, 20 25 personally appeared before me, a Notary Public,

Steve Filton
(Name of individual whose signature is being notarized)

who acknowledged that he/she executed the above instrument.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official stamp at my office in the County of Montgomery the day and year in this certificate first above written.

_____
Signature of Notary Public

For office use only

IF SUBMITTING A NOTARIZED DOCUMENT, PLEASE PROVIDE AN ORIGINAL AND 3 COPIES, A SELF-ADDRESSED STAMPED ENVELOPE AND $25.00 FILING FEE TO:
WASHOE COUNTY CLERK
1001 E. Ninth St., Bldg. A
RENO, NV 89512

Commonwealth of Pennsylvania - Notary Seal
DOUGLAS ROSS TEWKSBURY - Notary Public
Montgomery County
My Commission Expires October 25, 2028
Commission Number 1301489

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **SPARKS FAMILY HOSPITAL, INC.** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 04/06/1979, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/07/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507075873127
You may verify this certificate online at https://www.nvsilverflume.gov/home

4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FB5538458
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 03433		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Meta Pharmacy Services

Physical Address: 8352 W Warm Springs RD, #120

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): 8352 W Warm Springs RD, #120

City: Las Vegas State: NV Zip: 89113

Telephone: 702-754-0172 Toll Free # (NAC 639.708, NRS 639.23286): 844-334-1010

Fax: 702-754-6996 Contact Email: admin@metapharmacyservices.com

Website: www.metapharmacyservices.com

Nevada Business License # (if applicable) NV20243252567

Supervising/Managing Pharmacist Name (NRS 639.220): Bruce M. Thielke

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 14061

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name:	Tommy Dinh	NV Pharmacist Registration #:	20256
Name:	Jenner Sinang	NV Pharmacist Registration #:	18954
Name:	Maile Olah	NV Pharmacist Registration #:	19841
Name:	Jaymie Padero	NV Pharmacist Registration #:	23846
Name:	Bruce M. Thielke	NV Pharmacist Registration #:	14061
Name:	Christopher Goodman	NV Pharmacist Registration #:	16422
Name:	Dino Dzanic	NV Pharmacist Registration #:	20718
Name:		NV Pharmacist Registration #:	
Name:		NV Pharmacist Registration #:	
Name:		NV Pharmacist Registration #:	

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	N/A	Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): OGB Meta III, LLC

Corporation/Organization Name: Meta Pharmacy Services, LLC

Mailing Address: 1015 Atlantic Blvd, STE 433

City: Atlantic Beach State: FL Zip: 32233

Telephone: (917) 288-7585 Email: derek@jbncp.com

Contact Person Name: Derek O'Leary

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President and Treasurer (title) for Meta Pharmacy Services (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Derek O'Leary

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/30/25

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Bruce M. Thielke Pharmacist Registration #: 14061

Pharmacy Name: Meta Pharmacy Services

Initial each statement below to indicate you have read and agree with the following:

BT I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

BT I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

BT I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

BT *I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are* reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

BT I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BT

Original signature of Managing Pharmacist (copies or stamps not accepted)

7-31-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Derek O'Leary, President and Treasurer

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 7/30/25

Board Use Only	Date Received: 8/1/25	Amount: $500.00

Meta Pharmacy Services, LLC - Owners and Officers

Name and Title	Business Address and Telephone	Home Address and Telephone	Date of Birth	SSN or FEIN	Ownership %
OGB Meta III, LLC Parent / Sole Member	1015 Atlantic Blvd, Suite 433 Atlantic Beach, FL 32233 (917) 288-7585 derek@jbncp.com	[redacted]	[redacted]	[redacted]	100%
Derek O'Leary President and Treasurer	1015 Atlantic Blvd, Suite 433 Atlantic Beach, FL 32233 (917) 288-7585 derek@jbncp.com	[redacted]	[redacted]	[redacted]	0%

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Meta Pharmacy Services, LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 12/10/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/24/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507245934553
You may verify this certificate online at https://www.nvsilverflume.gov/home

State of Florida
Department of State

I certify from the records of this office that META PHARMACY SERVICES, LLC is a limited liability company organized under the laws of the State of Florida, filed on November 22, 2024.

The document number of this limited liability company is L24000492499.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on April 25, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourteenth day of May, 2025



Secretary of State

Tracking Number: 5155361491CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NABP ACCREDITED
COMPOUNDING PHARMACY

Meta Pharmacy Services

located at

8352 W Warm Springs Rd, Ste 120, Las Vegas, NV 89113

This business has met all the compounding pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the compounding pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/compounding

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/25/2024 - 04/24/2027
Period of Accreditation

2281

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Meta Pharmacy Services

Pharmacy/Wholesaler License # (if applicable): PH03433

Physical Address: 8352 West Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): 8352 West Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113

Telephone: (702) 754-0172 Website: www.metapharmacyservices.com

Licensing Company Email: admin@metapharmacyservices.com

Section 2: Personal Information

First: Bruce Middle: M. Last: Thielke

Alias(es, nicknames, name changes, etc.): N/A-Not Applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Midwestern University			09/94-05/98	
Address	City	State	Zip	
555 31st Street	Downers Grove	IL	60515	
Diploma/Degree obtained, if any				
PharmD				

School Name			From - To (MM/YY – MM/YY)	
University of Wisconsin			09/90-05/94	
Address	City	State	Zip	
500 Lincoln Dr.	Madison	WI	53706	
Diploma/Degree obtained, if any				
Pre-Pharmacy Studies				

School Name			From - To (MM/YY – MM/YY)	
Whitefish Bay High School			09/88-05/90	
Address	City	State	Zip	
1200 East Fairmount Ave	Milwaukee	WI	53217	
Diploma/Degree obtained, if any				
Diploma				

School Name			From - To (MM/YY – MM/YY)	
N/A-Not Applicable				
Address	City	State	Zip	
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/13-Present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Meta Pharmacy Services			06/25-Present
Business Address	**City**	**State**	**Zip**
8352 West Warm Springs Road, Suite 120	Las Vegas	NV	89113-3629
Phone	**Title**		**Number of Employed Hours**
(702) 754-0172	Pharmacist-in-Charge		Approximately 400
Description of Duties	Manage and oversee the practice of pharmacy in compliance with all Federal, state, local laws and regulations as well as company policies.		

Business Name			From - To (MM/YY – MM/YY)
HealthTrust Performance Group			04/22-06/25
Business Address	**City**	**State**	**Zip**
1100 Dr. Martin L. King Jr. Blvd, Suite 1100	Nashville	TN	37203
Phone	**Title**		**Number of Employed Hours**
(615) 344-3000	Division Director, Pharmacy Operations		Approximately 7,800
Description of Duties	Overaw pharmacy operations across multiple facilities within a specific geographical areas. Developed and managed pharmacy budgets, analyzing financial trends, and implementing strategies to improve financial performance. Ensured compliance with regulatory requirements and accreditation standards.		

Business Name			From - To (MM/YY – MM/YY)
Southern Hills Hospital and Medical Center			03/18-04/22
Business Address	**City**	**State**	**Zip**
9300 West Sunset Road	Las Vegas	NV	89148
Phone	**Title**		**Number of Employed Hours**
(702) 916-5000	Director, Pharmacy Services		Approximately 8,320
Description of Duties	Developed and implemented operational strategies to optimize efficiency, cost-effectiveness, and overall pharmacy performance. Ensured adherence to all relevant local, state, and federal laws, regulations and accreditation standards		

Business Name			From - To (MM/YY – MM/YY)
Southern Hills Hospital and Medical Center			04/11-03/18
Business Address	**City**	**State**	**Zip**
9300 West Sunset Road	Las Vegas	NV	89148
Phone	**Title**		**Number of Employed Hours**
(702) 916-5000	Manager, Pharmacy Operations		Approximately 14,560
Description of Duties	Manage and oversee the practice of pharmacy in compliance with all Federal, state, local laws and regulations as well as company policies.		

Business Name			From - To (MM/YY – MM/YY)
N/A-Not Applicable			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Bruce M. Thielke, **certify that as the designated representative for** Meta Pharmacy Services,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BMT I am at least 21 years of age;
3. BMT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BMT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BMT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BMT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BMT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Bruce M. Thielke

Print Name (First, Last)

BMT

Original Signature (electronic, copies or stamps not accepted)

7-31-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bruce M. Thielke

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-31-25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Bruce Thielke, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-31-25

Date

Subscribed and Sworn to before me this 31 day of July 2025

Misty Richardson

Notary Public Signature

MISTY DAWN RICHARDSON
Notary Public, State of Nevada
Appointment No. 24-1238-01
My Appt. Expires Mar 14, 2028

(Seal)

Meta Pharmacy Services
8352 W. Warm Springs Rd Suite 120
Las Vegas, NV 89113

Personal History Record Application

N/A - Not Applicable. Applicant Meta Pharmacy Services, LLC dba Meta Pharmacy Services is a 100% wholly owned subsidiary of OGB Meta III, LLC. There are no individual owners.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Meta Pharmacy Services

NV Pharmacy or Outsourcing facility license # (if applicable): PH03433

Physical Address: 8352 W Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): 8352 W Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113

Telephone: 844-334-1010 Toll Free # (NAC 639.708, NRS 639.23286): 844-334-1010

Fax: 702-754-6996 Contact Email: admin@metapharmacyservices.com

Website: www.metapharmacyservices.com

Nevada Business License # (if applicable) NV20243252567

Supervising/Managing Pharmacist Name (NRS 639.220): Bruce M. Thielke

Supervising/Managing Pharmacist NV Pharmacist Registration #: 14061

Name of Designated Person(s) as defined by revised USP-797 guidelines: Bruce M. Thielke

Email of Designated Person(s): bthielke@metapharmacyservices.com

Telephone of Designated Person(s): (844) 334-1010

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ■ Category 1 ■ Category 2 ☐ Category 3

   If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☑ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 05/22/2025

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☑ Yes ☐ No

follow-up to occurr at the next annual inspection in October 2025

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☑ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Biannually

10. Will you be performing sterile hazardous drug compounding? ☑ Yes ☐ No

    If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

please see attached

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway, Suite 546

City: Oklahoma City State: OK Zip: 73104

Telephone: (800) 393-1595

13. What is your procedure for visual inspection of compounded sterile products?

Compounded sterile products will be inspected, before dispensing, by supervising pharmacists through a double-check system. (1.) Inspection of CSPs includes: (a.) Visual inspection for particulates and/or cloudiness. The CSP will be examined against a lighted white or black background, or both.; (b.) Verification of prescription orders with the written work order / compounding record (preparation; records). (c.) Verification of ingredients used, including correct amounts and concentrations (d.) Verification of final fill amounts (e.) Verification of aseptic manipulations and sterilization (f.) Package integrity, any leakage observed (g.) Visual inspection of syringes and additive containers used (h.) Correct and complete label: i. Name of patient; ii. Patient location; iii. Correct names, amounts and concentrations of the ingredients; iv. Total volume ; v. Preparation date; vi. Beyond-use date; vii. Route of administration; viii. Storage requirements; ix. Infusion rate when applicable; x. The initials of the final Pharmacist check (i.) Labels for CSPs must be clear, consistent, legible and in compliance with state and federal regulations. (2.) CSPs with visual defects will be immediately discarded. (3.) When the identity and concentrations of ingredients cannot be verified, samples of the CSPs will be assayed. (4.) CSPs that are not immediately dispensed will be stored according to procedure. a. CSPs that are stored, will again be inspected before the CSPs are dispensed.

14. How often do you perform glove fingertip and medial fill testing?

Biannually

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Aseptic technique training will be ongoing; personnel must pass a media-fill test every 6 months. Compounding personnel who fail media-fill test would be re-evaluated. All compounding personnel must successfully complete 3 (three) initial Gloved Fingertip sampling prior to compounding CSPs for human use. Ongoing GFS to be performed with the preparation of media fill units which is required initially (before compounding CSPs for human use) and every 6 months for compounding staff of pharmacies performing Category 2 compounding. Personnel who have direct oversight of compounding personnel, but do not compound, must complete training initially and every 12 months. Pharmacy Department shall demonstrate, assess, maintain and improve staff competence on an ongoing basis. Personnel must have didactic and practical training. Staff will receive guided instruction in the theory and practice of compounded sterile preparations, in addition to hands-on training before assuming compounding responsibilities.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see attached policy: 3.020 Cleaning and Maintenance of Non-Sterile Compounding Area

17. Who performs the sterile compounding process at your facility?

Licensed staff members who have documented completion of appropriate competencies.

18. Who is responsible and accountable for the sterile compounding process at your facility?

Bruce M. Thielke, Pharmacist-in-Charge

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Please see attached policy: 1.090 Delivery of Compounded Preparations

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Laminar Flow Hood, Powder Hood, Biological Safety Cabinet		
2. Are you complying with all USP 800 guidelines?	☑ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	☑ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	☑ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☑ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☑ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☑ Yes	☐ No
9. If yes, list the name of the device: Chemo-clave		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

The Applicant provides education to patients upon admission and on an on-going basis while patients are actively on service.
(a.) Patients are to receive an admission packet, including information explaining how to contact the pharmacy for any concerns or questions.
(b.) Patients are to receive individual consultation as well as ongoing communication with the pharmacists.
(c.) Patients have access to the website, which allows them access to patient specific information.
(d.) Patients have access to pharmacists for any concerns or questions about their medications.
(e.) Patients review and sign a consent form explaining the therapy and medications involved (indication for IT drug(s), side effects, and when to call the pharmacy or physician).
(f.) Patients will be given patient drug information leaflets, that are available, the first time a medication is dispensed or when there is serious risk.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

(1.) On-the-job experiential training from experienced compounding personnel.
(2.) Staff will receive guided instruction in the theory and practice of compounded sterile preparations, in addition to hands-on training before assuming compounding responsibilities. A PATT for the appropriate risk level of CSPs, and a 3-part initial Glove Fingertip Test must be passed before assuming compounding responsibilities.
(3.) Staff will participate in training and assessment (web-based continuing education for USP 797 compliance) upon hire and annually thereafter.
(4.) Staff will have access to the ASHP Sterile Compounding Library in order to complete a 3- course program with interactive lessons and follow-up testing. This program is completed annually and will include: a. Hand hygiene; b. Garbing procedure for ISO classified environments; c. Cleaning and disinfection of the Ante-area, Cleanroom, and PECs; d. Aseptic technique
(5.) Pharmacy Competency Skills Checklist performed annually
(6.) Bi-annual Aseptic Personnel Assessment Form
(7.) Bi-annual PATT requirement
(8.) Bi-annual Glove Fingertip Sampling
(9.) Instruction on safety procedures
(10.) Instruction on CSPs to include: a. Identification; b. Accurate measuring, weighing, dilution and mixing of ingredients; c. Purification, sterilization; d. Packaging; e. Labeling; f. Storage; g. Dispensing; h. Transport; i. Documentation of the compounding process; j. Sterilization for high-risk CSPs
(11.) Proper use and maintenance of all equipment, including an understanding of HEPA Filtered air flow in ISO classified environments
(12.) Transport of materials to and from the Cleanroom
(13.) Only those individuals who are qualified through license, experience and training to assess sterile compounding skills will conduct competency assessments.
(14.) When improvement activities (written test and media-fill tests) lead to a determination that a person with performance problems is unable or unwilling to improve, the staff member's work assignment may be revised. Further education and training will be required or other corrective action(s) may be taken.
(15.) The staff member will not return to compounding duties until performance problems are resolved.
(16.) The competence assessment program is continuous and ongoing, with reports of competency outcomes available to the Pharmacist-in-Charge.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
N/A-Not Applicable

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?
N/A-Not Applicable

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☐ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?
N/A-Not Applicable

5. What is the frequency for completing surface sampling? N/A-Not Applicable	
6. What is the frequency for using sporicidal agents? N/A-Not Applicable	
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	☐ Yes ☐ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	☐ Yes ☐ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bruce M. Thielke

Name of Person who Completed the Form

Pharmacist-in-Charge

Title



Signature (copies or stamps not accepted)

7-31-25

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Attachment: List of Sterile Compounded Products

Drug Description
ALPHA LIPOIC ACID 25 MG/ML INJECTION
BCAA ISOLEUCINE/LEUCINE/VALINE 15/10/40 MG/ML INJ SOLUTION
BIOTIN 10MG/ML INJECTABLE SOLUTION
CARNITINE 50% INJECTABLE SOLUTION
DEXPANTHENOL 250 MG/ML INJECTABLE SOLUTION
GLUTATHIONE 20% INJECTION
HYDROXOCOBALAMIN (B12) 10 MG/ML INJ
LIPO C 15MG/50MG/50MG/25MG/15MG/5MG (Carnitine, Choline, Inositol, Methionine, Thiamine, Dexpanthenol)
LIPO INJECTION (MIC) (Methionine, Inositol, Choline)
LIPO-B (MIC-B12) STERILE SOLUTION (Methionine, Inositol, Choline, and Methylcobalamin)
METHYLCOBALAMIN 12.5MG/ML INJ
MYERS COCKTAIL IV ADMIXTURE
NAD+ 1,000MG/50ML VIAL INJECTION
NANDROLONE DECANOATE 200 MG/ML GRAPESEED OIL
PYRIDOXINE 100 MG/ML INJECTABLE SOLUTION
QUADMIX STANDARD INJECTION (Atropine, Alprostadil, Papaverine, Phentolamine)
SEMAGLUTIDE/L-CARNITINE 2.5/100MG/ML
SERMORELIN 3MG/3ML SOLUTION INJECTION
STANOZOLOL 50 MG/ML 'IM' INJECTION
SUPER TRIMIX INJ (Alprostadil, Papaverine, Phentolamine)
TAURINE 50 MG/ML INJECTABLE SOLUTION
TIRZEPATIDE/L-CARNITINE 16.7/100MG PER ML
TRIMIX #1 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #3 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #4 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #5 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #6 INJ (Alprostadil, Papaverine, Phentolamine)
TRT CYPIONATE-ZINC SULFATE 200-1 MG/ML IN GRAPESEED OIL
VITAMIN B COMPLEX INJECTION
VITAMIN C 50% FOR INJECTION (Sodium Ascorbate)
VITAMIN D3 50000 UNITS/ML 'IM' INJ
TOBRAMYCIN 1.5% (15 MG/ML) EYE DROP
VANCOMYCIN 2.5% (25 MG/ML) EYE DROPS

TITLE: CLEANING & MAINTENANCE OF NON-STERILE COMPOUNDING AREA	
SOP NUMBER: 3.020	**VERSION NUMBER: 1.0**
Authorized By: Meta Pharmacy Services	Date: 02/01/2022
Prepared By: Pharmacist-In-Charge	Date:
Reviewed By: Pharmacy Compliance Officer	Date:
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for the cleaning and maintenance of the non-sterile compounding area.

2.0 SCOPE

2.1 This procedure applies to the Meta Pharmacy Services non-sterile compounding area under conditions that meet or exceed state and federal guidelines.

2.2 This procedure must be followed to reduce the amount of particulate matter and airborne contamination and to prevent cross-contamination of chemicals.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-Charge, or a pharmacist designee, shall supervise this procedure and document that all non-sterile compounding personnel will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 SOP 1.050 "General Compounding Technique"

4.3 SOP 4.010 "Compounding Equipment"

4.4 SOP 4.020 "Use, Calibration and Maintenance of the Drug Product Refrigerator and Freezer"

4.5 SOP 8.020 "Good Documentation Practices (GDP)"

4.6 SOP 8.100 "Required Garb for Non-Sterile Compounding Area"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Daily (when non-sterile compounding activities are planned)

6.1.1 Clean all horizontal surfaces.

6.1.2 Sweep floors.

6.1.3 Clean all in-use powder hoods.

6.1.4 Wipe down all in-use equipment.

6.1.5 Record room temperature and humidity.

6.1.6 Record temperature of drug product refrigerator/freezer.

6.1.7 Clean all utensils after use.

6.1.8 Remove and discard trash.

6.2 Weekly

6.2.1 Perform daily requirements listed in section 6.1.

6.2.2 Order supplies as necessary.

6.2.3 Mop floors with dry mop followed by a sponge mop and cleaning solution.

6.3 Monthly

6.3.1 Perform daily requirements listed in section 6.1.

6.3.2 Perform weekly requirements listed in section 6.2.

6.3.3 Clean and sanitize the drug product refrigerator/freezer.

6.3.4 Clean and sanitize shelving.

6.3.5 Clean cabinet exteriors.

7.0 EQUIPMENT & SUPPLIES

7.1 Proper gowning protocol placards

7.2 Mop with disposable cleaning pads labeled for use on floors of non-sterile compounding area

7.3 Paper towels

7.4 Bleach concentrate or appropriate cleanser (Acidified Bleach Disinfectant Solution)

7.5 70% isopropyl alcohol (IPA)

7.6 Waste container liners

7.7 Step stool

7.8 Room thermometer

7.9 Room hygrometer (If applicable)

7.10 Equipment manuals (if applicable)

TITLE: CLEANING & MAINTENANCE OF NON-STERILE COMPOUNDING AREA	
SOP NUMBER: 3.020	**VERSION NUMBER: 1.0**
Authorized By: Meta Pharmacy Services	Date: 02/01/2022
Prepared By: Pharmacist-In-Charge	Date:
Reviewed By: Pharmacy Compliance Officer	Date:
Date Effective:	

8.0 GENERAL INFORMATION

8.1 Cleaning Solutions

8.1.1 Non-sterile 70% IPA – for use in areas with equipment that may be damaged by the use of bleach.

9.0 PROCEDURE

9.1 Personnel must gown appropriately for the areas to be cleaned following the appropriate gowning procedure.

9.2 Cleaning solutions shall be prepared as needed.

9.2.1 Do not combine disinfectants or use them in concentrations other than those outlined in the SOPs.

9.2.2 Disinfectants with no expiration date should be assigned an expiration date of 30 days after opening.

9.3 Except for sanitization of the workbenches, utensils or equipment, cleaning of the non-sterile compounding area is prohibited during compounding operations.

9.3.1 Ensure all compounded preparations are completed.

9.3.2 The operator must clean and sanitize the exposed work surfaces before and after each batch preparation and immediately should a spill occur.

9.4 The order of cleaning within the non-sterile compounding area is as follows:

9.4.1 Hoods (powder hood)

9.4.2 Non-sterile compounding area: counters, shelves, equipment

9.4.3 Warehouse storage room

9.5 Daily Requirements (when non-sterile compounding has occurred)

9.5.1 At the beginning of the day:

9.5.1.1 Check supplies and straighten up the non-sterile compounding area (if necessary).

9.5.1.2 Calibrate balances.

9.5.1.3 Turn on all necessary equipment and computers.

9.5.1.3.1 Power on all equipment at least 30 minutes prior to compounding.

9.5.1.4 Prepare shipping materials for the day.

9.5.2 Temperature and humidity readings shall be taken in the non-sterile compounding area at the beginning and end of each day and more frequently if needed.

9.5.2.1 The temperature and humidity in the non-sterile compounding area shall be monitored electronically.

9.5.2.2 The humidity should be maintained in the range of 30%–50%.

9.5.2.3 The temperature shall be maintained between 67°F–77°F.

9.5.2.4 Document results on the Temperature and Humidity Monitoring of the Non-Sterile Compounding Area form (Attachment 2).

9.5.3 Record drug product in refrigerator/freezer temperature on Attachment 3 of SOP 4.020, "Use, Calibration and Maintenance of the Drug Product Refrigerator and Freezer."

9.5.4 Clean and sanitize countertops/sinks.

9.5.5 Clean and sanitize equipment as needed. Document equipment cleaning on appropriate cleaning log as per SOP 4.010, "Compounding Equipment."

9.5.6 Allow all rooms and equipment to air dry before non-sterile compounding resumes.

9.5.7 At the end of the day:

9.5.7.1 Turn off all equipment and computers as required.

9.5.7.2 Sweep the floor.

9.5.7.3 Empty all waste receptacles by removing the filled plastic bag.

9.5.8 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area form (Attachment 1). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.6 Weekly Requirements

9.6.1 Includes all requirements listed in section 8.5.

9.6.2 Mop floors

9.6.3 Order supplies as necessary.

9.6.4 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area form (Attachment 1). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.7 Monthly Requirements

9.7.1 Includes all requirements listed in section 8.5 an 8.6.

9.7.2 Clean and sanitize the drug product refrigerator/freezer.

9.7.3 Remove all supplies from shelving in the non-sterile compounding area and clean and sanitize the shelves.

9.7.4 Clean and sanitize cabinet exteriors.

9.7.5 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area form (Attachment 1). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.8 Cleaning can be performed as often as needed, but the minimum requirement will be at the end of the day after compounding.

9.9 The Pharmacist-in-Charge, or a pharmacist designee, shall ensure the completion of tasks on a daily basis and shall review and sign/date Attachment 1 at the end of each month. The form shall be retained in a cleaning/maintenance binder.

10.0 ATTACHMENTS

10.1 Attachment 1 – Cleaning and Maintenance of the Non-Sterile Compounding Area

10.2 Attachment 2 – Refrigerator Temperature and Humidity Monitoring of the Non-Sterile Compounding Area

10.3 Attachment 3 – PCCA Formula 11186 Acidified Bleach Solution

10.4 Attachment 4 – Daily Cleaning Log

10.5 Attachment 5 – Weekly Cleaning Log

10.6 Attachment 6 – Monthly Cleaning Log

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request

TITLE: CLEANING & MAINTENANCE OF NON-STERILE COMPOUNDING AREA	
SOP NUMBER: 3.020	**VERSION NUMBER: 1.0**
Authorized By: Meta Pharmacy Services	Date: 02/01/2022
Prepared By: Pharmacist-In-Charge	Date:
Reviewed By: Pharmacy Compliance Officer	Date:
Date Effective:	

			Number
1.0		New SOP	

This policy will be reviewed and updated annually by the Pharmacist-in-Charge and the Pharmacy Compliance Officer.

All pharmacy staff shall comply with this policy. Violations of this policy could result in disciplinary action based on the seriousness of the offense or other factors. Disciplinary action may include written warning, suspension, or termination.

Remainder of this page intentionally left blank.

CLEANING AND MAINTENANCE OF NON-STERILE COMPOUNDING AREA (META PHARMACY SERVICES)

Month/Year: _____ **Cleaning Solution:** _____

Day	Daily							Weekly		Monthly			
	Countertops Cleaned	Floors swept	Hood(s) Cleaned	Equipment Wiped Down	Utensils Cleaned	Trash Discarded	Tacky Mat Refreshed	Supplies Ordered	Floors Mopped	Shelves Cleaned/Sanitized	Drug Product Refrigerator Cleaned/Sanitized	Drug Product Freezer Cleaned/Sanitized	Cabinet Exteriors Cleaned/Sanitized
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
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30													
31													

Reviewed By: _____ **Date:** _____

REFRIGERATOR TEMPERATURE AND HUMIDITY MONITORING OF THE NON-STERILE COMPOUNDING AREA (META PHARMACY SERVICES)

MONTH/YEAR: _____ Appropriate Refrigerator Temperature: 35°F to 60°F Appropriate Lab Humidity %: 30-50%

Day	Time				Fridge Temp (°F)				Thermostat 1				Thermostat 2			
									Temp (°F)		Humidity (%)		Temp (°F)		Humidity (%)	
	AM	Initial	PM	Initial	AM	Initials	PM	Initial	AM	Initial	PM	Initial	AM	Initials	PM	Initial
1																
2																
3																
4																
5																
6																
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2303

Acidified Bleach Disinfectant Solution

SUGGESTED FORMULA FOR
Acidified Bleach Disinfectant Solution
Version: 1.0
3238.3 mL

Sodium Hypochlorite 8.25% Solution	98 ml
White Vinegar	140 ml
Liquid Dish Soap	0.3 ml
Purified Water, USP	3,000 ml

SUGGESTED COMPOUNDING PROCEDURE

Note: It is recommended that you follow USP <795> recommendations for potency testing which states "... each preparation shall contain not less than 90.0% and not more than 110.0% of the theoretically calculated and labeled quantity of active ingredient ...". In order to provide some guidance in this area, please contact Eagle Analytical Services regarding the use of Skip Lot testing.

Note: Sodium Hypochlorite 8.25% Solution - Pharmacy Stock. Source: Commercial Unscented Laundry Bleach.

Note: White Vinegar - Pharmacy Stock.

Note: Liquid Dish Soap - Pharmacy Stock. Source: Grocery Store.

Note: Use syringe which delivers 20 Drops/mL.

1. In an appropriate size container, add Purified Water. Use an amount of Purified Water that is approximately one-third of the specified amount. For example, if the specified amount is 3000 mL, use 1000 mL of Purified Water.
2. Add Sodium Hypochlorite 8.25% Solution to Step 1 with mixing.
3. Add White Vinegar to Step 2 with mixing. Use an amount of White Vinegar that is approximately 90% of the specified volume. For example, if the specified volume is 140 mL, use 126 mL of White Vinegar.
4. Add Purified Water to Step 3 with mixing. Use an amount of Purified Water that is approximately one-third of the specified amount. For example, if the specified amount is 3000 mL, use 1000 mL of Purified Water.
5. Add Liquid Dish Soap to Step 3 with mixing.
6. Add Purified Water to Step 5 with mixing. Use an amount of Purified Water that is approximately one-third of the specified amount. For example, if the specified amount is 3000 mL, use 1000 mL of Purified Water.
7. Check the pH of Step 6 with a pH meter. If necessary, adjust the pH to 6 (5.8 - 6.2) by adding White Vinegar in small increments with mixing. Check pH after each addition.

Note: The final preparation should contain approximately 2375 ppm of available chlorine.

Note: NOT FOR HUMAN USE!

Note: No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Note: Beyond Use Dates of preparations are conservative estimates by the formulator using reference books, peer reviewed literature, intended duration of therapy, formulation from commercially available products, organoleptic stability observations and current USP guidelines. Compounders may have stability tests performed by a reputable laboratory if they wish to extend the Beyond Use Date.

Note: Beyond Use Date after compounding is estimated to be 5 days.

11186
Revised: Sun Oct 05, 2014

DAILY CLEANING LOG
META PHARMACY SERVICES

Daily cleaning duties are performed and recorded each day at the end of each shift. These duties include; Cleaning and wiping down all compounding surfaces and equipment with 70% isopropyl alcohol. Visually inspecting and cleaning bulk chemical containers. Sweeping and vacuuming the compounding area. Replacing and restocking compounding supplies. Calibrating scales and initial cleaning at the beginning of each shift and cleaning after each compounded order.

Month: _____

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

WEEKLY CLEANING LOG
(META PHARMACY SERVICES)

MONTH	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5
January					
February					
March					
April					
May					
June					
July					
August					
September					
October					
November					
December					

MONTHLY CLEANING LOG
META PHARMACY SERVICES

Monthly cleaning activities include the daily and weekly cleaning responsibilities as well as cleaning and sanitize the drug products in refrigerator/freezer, cleaning shelving, and cabinet exteriors.

YEAR: _____

MONTH	COMPLETED BY
JAN	
FEB	
MAR	
APR	
MAY	
JUN	
JULY	
AUG	
SEP	
OCT	
NOV	
DEC	

TITLE: DELIVERY OF COMPOUNDED PREPARATIONS	
SOP NUMBER: 1.090	**VERSION NUMBER: 1.0**
Authorized By: Meta Pharmacy Services	Date: 02/01/2022
Prepared By: Pharmacist-In-Charge	Date:
Reviewed By: Pharmacy Compliance Officer	*Date:*
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to ensure that compounded preparations are delivered to the patient or health care facility in a manner such that the product integrity, quality, safety and efficacy are not compromised.

2.0 SCOPE

2.1 This procedure applies to all shipping personnel at Meta Pharmacy Services.

3.0 RESPONSIBILITY

3.1 The Pharmacist-In-Charge, or a pharmacist designee, shall supervise this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 This procedure shall be followed for each compounded preparation that is to be shipped to a patient's home or to another facility.

7.0 EQUIPMENT & SUPPLIES

7.1 Compounded preparation(s) and appropriate equipment/devices if necessary
7.2 Appropriate shipping container
7.3 Affiliated shipping company: i.e. FedEx, USPS (United States Postal Service)
7.4 Detailed shipping instructions

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 All pharmacy staff working in Meta Pharmacy Services, shall assure that the compounded preparation is properly shipped to the patient or health care facility without compromising the product integrity, quality, safety and efficacy, which will be verified by the Pharmacist-In-Charge and/or designee.

9.2 All compounded preparations shall be shipped in appropriate containers that will protect the preparation from wide variations in temperatures, structural damage or unapproved light sources.

9.2.1 Handling and shipping of refrigerated products shall follow USP<795 > guidelines

9.2.2 Refrigerated items are shipped in insulated containers with adequate ice packs to ensure product stability.

9.2.3 Refrigerated items are shipped through FedEx.

9.3 Items that are controlled substances or have a value greater than $1,000.00 will be shipped requiring a signature upon delivery (signature required). Once the patient receives the item the signature is documented in the shipping company's system.

9.4 In the case of a shipping error, pharmacy staff will immediately notify the patient and provide a return shipping label via FEDEX, UPS or USPS. The correct item will be resent to the patient without a fee. In addition, in such an error, the Pharmacist-In-Charge or designee will prepare a report and submit same to the Pharmacy Compliance Officer.

9.5 In the case of a lost shipment, Meta Pharmacy Services staff will attempt to track the lost shipment and file a claim with the appropriate shipping company. Pharmacy staff will verify the address with the patient and resend a new product to the patient. The Pharmacist-In-Charge and/or designee will prepare a written report and submit same to the Pharmacy Compliance Officer.

9.5.1 A Tracking Number for each shipment is stored in the system and can be given to patients upon request.

9.6 Instructions for proper inspection of the preparation will be transmitted to the patient or caregiver prior to shipment of the package.

9.7 A material safety data sheet (MSDS) for each product used in the compounded preparation shall be available in Meta Pharmacy Services in case a spill or accident occurs during transit.

9.8 Storage instructions shall be provided to the patient or caregiver to ensure that the product is stored appropriately at the patient's home or at the health care facility.

9.9 Instructions shall be provided to the patient or caregiver on how to contact the pharmacist for patient counseling.

9.10 The patient should be instructed to sign and return the Acknowledgment of Privacy Practice and Shipment Form (Attachment #1)

10.0 ATTACHMENTS

10.1 Attachment 1 – Acknowledgment of Privacy Practice and Shipment Form

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0		New SOP	

This policy will be reviewed and updated annually by the Pharmacist-in-Charge and the Pharmacy Compliance Officer.

All pharmacy staff shall comply with this policy. Violations of this policy could result in disciplinary action based on the seriousness of the offense or other factors. Disciplinary action may include written warning, suspension, or termination.

TITLE: DELIVERY OF COMPOUNDED PREPARATIONS	
SOP NUMBER: 1.090	**VERSION NUMBER: 1.0**
Authorized By: Meta Pharmacy Services	Date: 02/01/2022
Prepared By: Pharmacist-In-Charge	Date:
Reviewed By: Pharmacy Compliance Officer	Date:
Date Effective:	

Remainder of this page intentionally left blank.

Acknowledgement of Notice of Privacy Practices

The purpose of the form below is to verify that you received the Notice of Privacy Practices. You are not required to sign or return this form; however, we are requesting that you do sign and return, so that we may maintain a record of your receipt of the prescription and privacy notice which will be maintained in your pharmacy records. Your pharmacy services will continue even if you do not return this form.

If you choose to return this form, please complete the information below and mail this page of the notice to the following address:

Meta Pharmacy Services

11717 NE Glisan Street

Portland, OR 97220-2141

All Members of your family who are on your prescription benefits plan may also sign this form acknowledging that they read the notice. Please share this notice with your family members.

Print Name: _____ Date: _____

Signature: _____

In addition, your doctor may have indicated a course of therapy that will require prescription refills. For your convenience we offer an automatic-refill service on certain prescriptions and therapies. Please indicate your interest by placing an "X" in the appropriate box, sign and return to the pharmacy.

☐ Yes, I would like to enroll in your auto-refill service.

☐ No thank you, please call me.

Print Name: _____ Date: _____

Signature: _____

Certificate of Compliance

Awarded to:

META PHARMACY

Meta Pharmacy Services

TSS certifies that:

Gowning Room, located at META PHARMACY 8352 W Warm Springs Blvd., Suite 120, meets the acceptance criteria of ISO 14644-1:2015(Class: ISO-8) for particles ≥ 0.5 µm under Operational/Dynamic conditions.

Refer to TSS Project Report AZ-MTAP25101C-1 for supporting data.

Presented by:

TSS
Technical Safety Services LLC

4225, Executive Square, Suite 370, La Jolla, CA 92037

800.877.7742

Effective Date: 05/22/2025

Expiration Date: 11/21/2025

Approved By: Clara Burtard
Technical Writer
Technical Safety Services (TSS)

Certificate of Compliance

Awarded to:

META PHARMACY

Meta Pharmacy Services

TSS certifies that:

Sterile Ante Room, located at META PHARMACY 8352 W Warm Springs Blvd., Suite 120, meets the acceptance criteria of ISO 14644-1:2015(Class: ISO-7) for particles ≥ 0.5 µm under Operational/Dynamic conditions.

Refer to TSS Project Report AZ-MTAP25101C-1 for supporting data.

Presented by:

TSS
Technical Safety Services LLC

4225, Executive Square, Suite 370, La Jolla, CA 92037

800.877.7742

Effective Date: 05/22/2025

Expiration Date: 11/21/2025

Approved By: Clara Burtard
Technical Writer
Technical Safety Services (TSS)

Certificate of Compliance

Awarded to:

META PHARMACY

Meta Pharmacy Services

TSS certifies that:

Sterile Hazard Buffer Room, located at META PHARMACY 8352 W Warm Springs Blvd., Suite 120, meets the acceptance criteria of ISO 14644-1:2015 (Class: ISO-7) for particles ≥ 0.5 µm under Operational/Dynamic conditions.

Refer to TSS Project Report AZ-MTAP25101C-1 for supporting data.

Presented by:

TSS
Technical Safety Services LLC

4225, Executive Square, Suite 370, La Jolla, CA 92037

800.877.7742

Effective Date: 05/22/2025

Expiration Date: 11/21/2025

Approved By: Clara Burtard
Technical Writer
Technical Safety Services (TSS)

Certificate of Compliance

Awarded to:

META PHARMACY

Meta Pharmacy Services

TSS certifies that:

Sterile Non Hazard Buffer Room, located at META PHARMACY 8352 W Warm Springs Blvd., Suite 120, meets the acceptance criteria of ISO 14644-1:2015(Class: ISO-7) for particles ≥ 0.5 µm under Operational/ Dynamic conditions.

Refer to TSS Project Report AZ-MTAP25101C-1 for supporting data.

Presented by:

TSS
Technical Safety Services LLC

4225, Executive Square, Suite 370, La Jolla, CA 92037

800.877.7742

Effective Date: 05/22/2025

Expiration Date: 11/21/2025

Approved By: Clara Burtard
Technical Writer
Technical Safety Services (TSS)

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Retail Pharmacy

Section 1: General Information	
Inspection Date:	10/28/24
Pharmacy Name:	Meta Pharmacy Services
Pharmacy Address:	8352 W. Warm Springs Rd #120
Pharmacy Phone:	702-754-0172
Pharmacy License #:	PH03433
Pharmacy DEA#:	FB5538458
Managing Pharmacist:	Sean Barclay
Managing Pharmacist License #:	17303
E-mail to be utilized for inspection f/u:	admin@metapharmacyservices.com
Name of Primary Wholesaler:	McKesson
Name of Pharmacist present for Inspection:	Sean Barclay
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. Answers validated during on-site inspection.	☒	☐
2.	Pharmacy Personnel List complete and accurate. Comments: Completed prior to inspection. Document retained for Inlumon verification.	☒	☐
3.	Controlled Substance Biennial Inventory complete and accurate. Comments: Reviewed document dated 7/25/24. Document contains date and time that inventory was completed. Document signed by pharmacist completing form. C-II products separated from remaining controlled substances.	☒	☐
4.	CSOS receiving documents complete and accurate. Comments: Reviewed documents from September 2024. Date and quantity received completed electronically. CSOS document attached to invoice from wholesaler.	☒	☐
5.	Controlled Substance invoices are complete and accurate. Comments: Pharmacist receiving product are signing and dating all invoices. Pharmacist also placing license number on document.	☒	☐
6.	Records of Pharmacy Personnel on duty complete and accurate. Comments: Manual sign-in log. Log contains date, printed name, staff signature, hours worked, temp, and illness symptoms.	☒	☐
7.	Change in Managing Pharmacist controlled substance inventory complete and accurate (if applicable). Comments: N/A	☐	☐
8.	Security of the pharmacy meets all of Nevada Statutes and Regulations.	☐	☒

	Comments: Location has dead-bolt on front door entry. Safe utilized for C-II products. Barrier between public and pharmacy has a barrier less than 5ft tall. Alarm system in place at location. Cameras located throughout pharmacy.		
9.	In-Service training records for pharmacy technicians complete and accurate. Comments: Will review with 2025 inspection.	☐	☐
10.	Immunization CE (1 hour required annually by 10/31) for immunizing pharmacy technicians complete. Comments: N/A – No immunizations at location.	☐	☐
11.	Activity logs for technicians in training complete and accurate. Comments: Reviewed log for Ronalynn Domingo. Document meets all requirements. Employee has completed 1500 hours of training.	☒	☐
12.	Pharmacy labels on medications being dispensed to patients are labeled with an accurate expiration date. Comments:	☒	☐

Section 3: Controlled Substance Audit Report			
Drug Name	Manual count at time of audit	Balance on hand from software system or manual record at time of audit	Discrepancy
Oxycodone 10mg	350	350	0
Oxy/APAP 10/325mg	504	504	0
Morphine Sulfate 15mg ER	162	162	0
Comments: Location utilizes manual perpetual log.			

Section 4: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of Issue	**Response due date**
Must meet all security requirements of NAC 639.520.	Completed by October 2025.

Additional Comments:
Well prepared for inspection.
10-20% retail prescriptions vs compounded prescriptions.
Utilizing Infinite Dynamics for delivery service. 50% delivery. Patients are receiving toll-free number and product information as part of delivery service.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

John Castaldo – jcastaldo@pharmacy.nv.gov
Leo Basch – lbasch@pharmacy.nv.gov
Joe Dodge – j.dodge@pharmacy.nv.gov

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – m.lee@pharmacy.nv.gov
Jenine Davis – jmdavis@pharmacy.nv.gov

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

Recoverable Signature

X 

Signature of Pharmacist on Duty
Signed by: 1d353de8-32fb-4b00-8ad7-4d1f91c64c65

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Sterile Compounding

Section 1: General Information	
Inspection Date:	10/28/24
Pharmacy Name:	Meta Pharmacy Services
Pharmacy Address:	8352 W. Warm Springs Rd #120
Pharmacy Phone:	702-754-0172
Pharmacy License #:	PH03433
Managing Pharmacist:	Sean Barclay
Managing Pharmacist License #:	17303
E-mail to be utilized for inspection f/u:	admin@metapharmacyservices.com
Name of Certification Company:	CEM/TSS
Name of Pharmacist present for Inspection:	Sean Barclay
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. Answers validated during on-site inspection.	☒	☐
2.	List of sterile compounding personnel available for review with associated risk level. Comments: Document retained for Inlumon verification.	☒	☐
3.	Pharmacy compounds high risk sterile products. Comments:	☒	☐
4.	Most recent ISO classified area certification report available for review. Comments: Reviewed document dated March 2024. All pressures passed testing. Meets all air exchanges. Passed all particle testing. Passed all HEPA filter leak tests.	☒	☐
5.	Glove finger-tip results complete and accurate. Comments: Location is using revised guidelines for finger-tip testing. Reviewed document for Maria Vega dated 4/19/24. Document is signed by both employee and person performing assessment.	☒	☐
6.	Media fill results complete and accurate. Comments: Recommend placing employee name on form as opposed to initials. Reviewed document for Maria Vegas dated 4/19/24. Meets all requirements. All hoods passed testing. Location passed all viable testing. Recertification was due in September 2024. CEM/TSS scheduled to come out on 10/29/24 for testing.	☒	☐

7.	Cleaning log completed and available for review for ISO classified areas. Comments: Using manual cleaning log. Document contains initials of person performing compounding. Location is using Pre-empt daily and Peridox monthly.	☒	☐
8.	Compounding record is signed by both technician performing compounding and pharmacist who performs final verification. Comments: Manual document is signed by pharmacist and person completing compounding.	☒	☐
9.	Annual competency documentation complete and accurate. Comments: Reviewed document for Maria Vega dated 4/19/24. Meet all requirements.	☒	☐
10.	Pharmacy assigns beyond use dates in excess of USP-797 guidelines. Comments: Following all revised USP-797 guidelines.	☐	☒
11.	Bubble point testing results complete and accurate if applicable. Comments: Bubble point testing and results are attached to compounding record. List both threshold and actual results on form. Location would discard product with failed bubble point testing.	☒	☐
12.	Biological indicator results complete and accurate if applicable. Comments: BI results documented on compounding record and separate log.	☒	☐
13.	Sterility, Potency, and Endotoxin results available for any products requiring such documentation. Comments: Location is performing sterility and endotoxin testing through ARL. Location plans on following Category 2 with sterility testing.	☒	☐
14.	Pharmacy performs hazardous sterile drug compounding. Comments: Location is compounding hormones and mitomycin	☒	☐
15.	Hazardous compounding is performed in a BSC or CACI. Comments:	☒	☐
16.	Documentation of initial and ongoing training for hazardous compounding staff is available for review. Comments: Specific training for staff members. All employees must sign document regarding risks associated with hazardous compounding.	☒	☐

Section 3: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of Issue	**Response due date**
No follow-up required.	

Additional Comments:
Confirmed that location is not doing any office use compounding.
Well prepared for inspection.
Location has been through multiple FDA, NAPB, and NVBOP inspections. Location may go through another NABP inspection in 2025.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

John Castaldo – jcastaldo@pharmacy.nv.gov
Leo Basch – lbasch@pharmacy.nv.gov
Joe Dodge – j.dodge@pharmacy.nv.gov

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – m.lee@pharmacy.nv.gov
Jenine Davis – jmdavis@pharmacy.nv.gov

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

Recoverable Signature

X 

Signature of Pharmacist on Duty

Signed by: 1d353de8-32fb-4b00-8ad7-4d1f91c64c65

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Non-Sterile Compounding

Section 1: General Information	
Inspection Date:	10/28/24
Pharmacy Name:	Meta Pharmacy Services
Pharmacy Address:	8352 W. Warm Springs Rd #120
Pharmacy Phone:	702-754-0172
Pharmacy License #:	PH03433
Managing Pharmacist:	Sean Barclay
Managing Pharmacist License #:	17303
E-mail to be utilized for inspection f/u:	admin@metapharmacyservices.com
Name of Certification Company:	CEM/TSS
Name of Pharmacist present for Inspection:	Sean Barclay
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. Answers validated during on-site inspection.	☒	☐
2.	List of non-sterile compounding personnel available for review. Comments: Retained for Inlumon verification.	☒	☐
3.	Most recent certification report for powder hoods available for review. Comments: Powder hood certified in March 2024. CEM/TSS will recertify again on 10/29/24.	☒	☐
4.	Annual competency documentation complete and accurate. Comments: Reviewed non-sterile competency assessment for Maria Vega. Last assessment performed on 9/6/23. Competency is past due at this time. See notes below.	☐	☒
5.	Pharmacy assigns beyond use dates in excess of USP-795 guidelines. Comments:	☐	☒
6.	Pharmacy performs potency testing on a sampling of products for validation of compounding process. Comments: Not currently. PIC states that they may this in the near future.	☐	☒
7.	Master formulations meet regulatory requirements. Comments: All master formulations come from Medisca.	☒	☐

8.	Compounding worksheets meet regulatory requirements. Comments: Contains name of the person that performs the compounding and the pharmacist that verified the product. BUD is listed on worksheet.	☒	☐
9.	Pharmacy performs hazardous non-sterile drug compounding. Comments: Hormone compounding only. PIC states that they are ready to implement USP-800.	☒	☐
10.	If performing non-sterile hazardous drug compounding there is documentation of initial and ongoing competency for personnel performing this activity. Comments:	☒	☐
11.	Documentation of cleaning records for non-sterile compounding area. Comments: Manual cleaning record available for review. Location is using Pre-Empt and Peridox for cleaning agents in the area.	☒	☐

Section 3: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of Issue	**Response due date**
PIC to confirm that all non-sterile compounding employees have completed their competency assessment within the last 12 months.	**ASAP**

Additional Comments:
Separate and complete area for non-sterile compounding.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

John Castaldo – jcastaldo@pharmacy.nv.gov
Leo Basch – lbasch@pharmacy.nv.gov
Joe Dodge – j.dodge@pharmacy.nv.gov

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – m.lee@pharmacy.nv.gov
Jenine Davis – jmdavis@pharmacy.nv.gov

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

☐ Recoverable Signature

X 

Signature of Pharmacist on Duty

Signed by: 1d353de8-32fb-4b00-8ad7-4d1f91c64c65

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
▣ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ▣ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $0.00 fee with the application.) * Current license #: PH 04490	▣ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	▣ Retail/Community ▣ Dangerous drugs ▣ Controlled substances DEA #: FR2838211 ▣ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
▣ Monday	▣ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
▣ Tuesday	☐ Saturday	▣ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
▣ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
▣ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Renown Regional Medical Center dba Renown Pharmacy

Physical Address: 10105 Double R Blvd

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 775-982-5364 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 775-982-2616 Contact Email: adam.porath@renown.org

Website: renown.org/pharmacy

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Isabel Ibanez

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19995

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Isabel Ibanez	NV Pharmacist Registration #: 19995
Name: Soheila Baghbanbashi	NV Pharmacist Registration #: 11821
Name: Adam Porath	NV Pharmacist Registration #: 16909
Name: Israa Mahmood	NV Pharmacist Registration #: 19322
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Renown Health

Corporation/Organization Name: Renown Regional Medical Center

Mailing Address: 1155 Mill Street

City: Reno State: NV Zip: 89502

Telephone: 775-982-4100 Email: chris.nicholas@renown.org

Contact Person Name: Chris Nicholas

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President and CEO (title) for Renown Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Brian Erling

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7.21.2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Adam Porath hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Vice President of Pharmacy (title) for Renown Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 21st day of July, 2025

Notary Public

R. DIBATTISTA
Notary Public - State of Nevada
Appointment No. 25-8758-02
My Appointment Expires 05/20/2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Isabel Ibanez Pharmacist Registration #: 19995

Pharmacy Name: Renown Pharmacy

Initial each statement below to indicate you have read and agree with the following:

I	I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.
I	I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.
I	I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.
I	I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).
I	I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

7/21/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian Erling

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

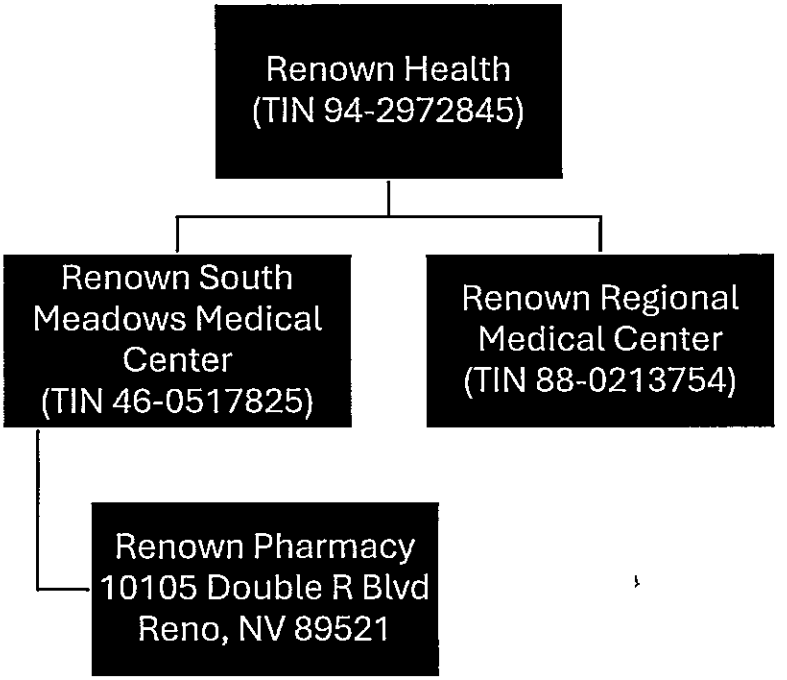
7.21.2025

Date

Board Use Only	Date Received: 7/21/25	Amount: $500 cc

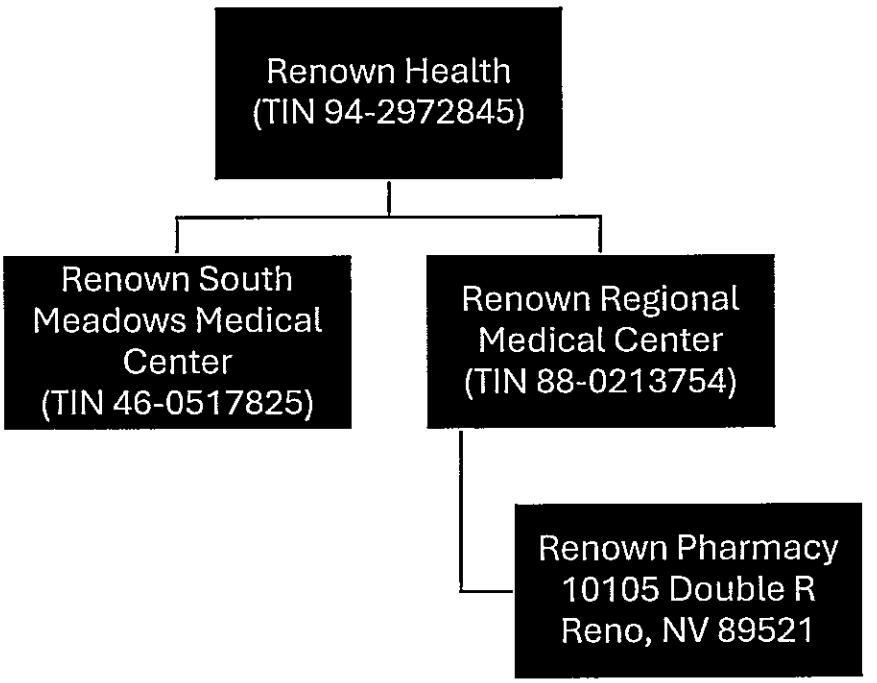
Renown Pharmacy – Double R

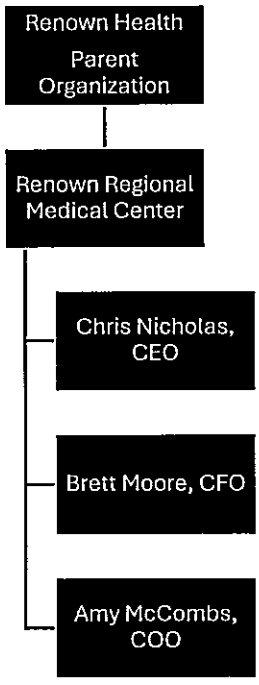
Current Structure



Renown Pharmacy - Double R

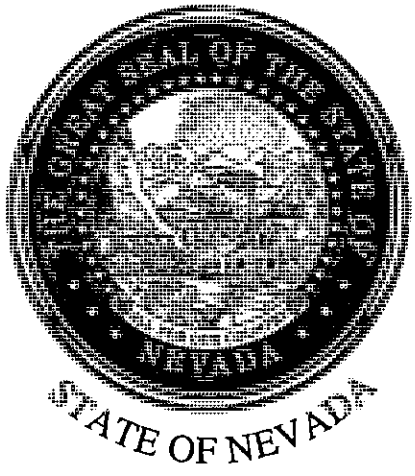
Future Structure





Renown Regional Medical Center, a subsidiary of Renown Health, is a locally owned nonprofit organization. There are no stockholders or owners of the corporation.

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

RENOWN REGIONAL MEDICAL CENTER

Organizational Documents on File	Filing Date
Amended and Restated Articles	02/04/2016
Amendment	10/16/2006
Amendment	11/21/1986
Articles of Incorporation	07/29/1985

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence RENOWN REGIONAL MEDICAL CENTER, as a DOMESTIC NONPROFIT CORPORATION (82) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 07/29/1985, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/02/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507025864763
You may verify this certificate online at
https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Renown Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH04490

Physical Address 10105 Double R Blvd.

City Reno State NV Zip 89521

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 775-982-5364 Website https://www.renown.org/Health-Services/Pharmacy

Licensing Company Email _____

Section 2: Personal Information

First Isabel Middle Eslava Last Ibanez

Alias(es, nicknames, name changes, etc.) none

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted]

City [redacted] State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		08/2015-06/2018	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
College of Southern Nevada		08/2012-06/2015	
Address	**City**	**State**	**Zip**
6375 W Charleston Blvd.	Las Vegas	NV	89146
Diploma/Degree obtained, if any			
Pharmacy prerequisites			

School Name		From - To (MM/YY – MM/YY)	
Las Vegas High School		11/2009-06/2012	
Address	**City**	**State**	**Zip**
6500 E Sahara Ave.	Las Vegas	NV	89142
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2020-current	[redacted]			
07/2018-10/2020				
06/2012-07/2018				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Renown Pharmacy - Double R			05/2023 - current	
Business Address	**City**		**State**	**Zip**
10105 Double R Blvd.	Reno		NV	89521
Phone	**Title**		**Number of Employed Hours**	
775-982-5364	Pharmacy Retail Supervisor		4160~	
Description of Duties				
Managerial duties such as inventories (medications and supplies), recordkeeping of annual board inspections, interviews, performance evaluations of employees and improving daily operations/pharmacy workflow.				

Business Name			From - To (MM/YY – MM/YY)	
Veteran Affairs Sierra Nevada Health Care System - VASNVHCS (Reno VA)			04/2019-05/2023	
Business Address	**City**		**State**	**Zip**
975 Kirman Ave.	Reno		NV	89502
Phone	**Title**		**Number of Employed Hours**	
775-786-7200	Clinical pharmacist (Outpatient)		7280~	
Description of Duties				
Performed discharge medication counseling, managed recall and medication shortage situations, processed pending orders from various VA clinics, trained newly hired outpatient pharmacists, served as a liaison in a call center setting				

Business Name			From - To (MM/YY – MM/YY)	
Walmart Pharmacy (COVID vaccine clinic)			02/2021-03/2022	
Business Address	**City**		**State**	**Zip**
4855 Kietzke Ln	Reno		NV	89509
Phone	**Title**		**Number of Employed Hours**	
775-829-1995	Immunizing pharmacist		208~	
Description of Duties				
Administered COVID-19 immunizations including booster shots - Moderna and Pfizer COVID-19 vaccines				

Business Name			From - To (MM/YY – MM/YY)	
PharMerica/Onco360			10/2018-11/2019	
Business Address	**City**		**State**	**Zip**
4750 Longley Ln 204	Reno		NV	89502
Phone	**Title**		**Number of Employed Hours**	
844-295-3931	Long term care pharmacist		1300~	
Description of Duties				
Verified and processed admission orders from skilled nursing facilities and acute rehabilitation centers, did inventory management specifically controlled substance medications, monitored timely medication delivery to the facilities we manag				

Business Name			From - To (MM/YY – MM/YY)	
CVS Pharmacy			10/2018-03/2019	
Business Address	**City**		**State**	**Zip**
299 E Plumb Ln Suite 170	Reno		NV	89502
Phone	**Title**		**Number of Employed Hours**	
775-786-1884	Pharmacist (Floater)		500~	
Description of Duties				
Provided medication counseling and OTC recommendations, recommended and administered immunizations, managed flu shot clinics, processed and verified prescription orders				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Isabel Ibanez, **certify that as the designated representative for**

Renown Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. II I am at least 21 years of age;
3. II I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. II I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. II I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. II I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. II I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Isabel Ibanez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/17/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Isabel Ibanez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/17/25

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of WASHOE

I, Isabel Ibanez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/17/25

Date

Subscribed and Sworn to before me this 17th day of JULY 2025

Giovanis Montero

Notary Public Signature

GIOVANIS MONTERO
Notary Public, State of Nevada
Appointment No. 16-2850-2
My Appt. Expires Feb 12, 2026

(Seal)

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: In Process ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Smith's Pharmacy #303

Physical Address: 560 N Stephanie St.

City: Henderson State: NV Zip: 89014

Mailing Address (if different from physical address): 1014 Vine St.

City: Cincinnati State: OH Zip: 45202

Telephone: 702-728-5105 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-675-8843 Contact Email: rxlicensing@kroger.com

Website: _____

Nevada Business License # (if applicable) NV20031516470

Supervising/Managing Pharmacist Name (NRS 639.220): Lisa Hammel

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19218

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Lisa Hammel	NV Pharmacist Registration #: 19218
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Ohio

Parent Company (if any): Fred Meyer, Inc.

Corporation/Organization Name: Smith's Food & Drug Centers. Inc.

Mailing Address: 1014 Vine St

City: Cincinnati State: OH Zip: 45202

Telephone: 513-762-1400 Email: N/A

Contact Person Name: William Shinton

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacy Manager (title) for Smith's Pharmacy #303 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Lisa Hammel

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7-11-25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Lisa Hammel hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Manager (title) for Smith's Pharmacy #303 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 11th day of July, 2025

Notary Public

JOEL A MARROQUIN
Notary Public - State of Utah
Comm. No. 740932
My Commission Expires on
Jan 8, 2029

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Lisa Hammel Pharmacist Registration #: 19218

Pharmacy Name: Smith's Pharmacy #303

Initial each statement below to indicate you have read and agree with the following:

LH I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

LH I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

LH I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

LH I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

LH I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

7-11-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lisa Hammel

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7-11-25

Date

Board Use Only	Date Received: 7/24/25	Amount: $500-CK 300059054

NAME	TITLE	DOB
Kammeyer, Todd	President	
Wheatley, Christine	VP & Secretary	
Fike, Carin	VP & Treasurer	
Alsteen, Laura	VP	
DeFrance, John D	VP & Asst Sec	
Lancaster, Robert T.	VP	
Prough, Steven J.	Asst. Sec.	

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **SMITH'S FOOD & DRUG CENTERS, INC.** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 11/14/2003, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/29/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507295947322
You may verify this certificate online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

SMITH'S FOOD & DRUG CENTERS, INC.

Nevada Business Identification # NV20031516470
Expiration Date: 11/30/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/19/2025.

Certificate Number: B202502195452406
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☑ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☑ Other: Parenteral

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☑ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Coram CVS/specialty Infusion Services

Physical Address: 12310 World Trade Drive, Suite 100

City: San Diego State: CA Zip: 92128

Mailing Address (if different from physical address): One CVS Dr., MC 1160

City: Woonsocket State: RI Zip: 02895

Telephone: 858-576-6969 Toll Free # (NAC 639.708, NRS 639.23286): 800-540-7887

Fax: _____ Contact Email: permitinfo@cvshealth.com

Website: N/A

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Amir Nahangi

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24509

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Amir Nahangi	NV Pharmacist Registration #: 24509
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Coram Specialty Infusion Services, LLC

Corporation/Organization Name: Coram Alternate Site Services, Inc.

Mailing Address: One CVS Dr., MC 1160

City: Woonsocket State: RI Zip: 02895

Telephone: 401-765-1500 Email: _____

Contact Person Name: permitinfo@cvshealth.com

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Assistant Secretary (title) for Coram CVS/specialty infusion services (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Leo Lariviere

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

5/7/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Leo Lariviere, Assistant Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

5/7/2025

Date

Board Use Only	Date Received: _____	Amount: 500.00 / V# 30213402

OWNERSHIP				
Coram Alternate Site Services, Inc.,	**Ownership 100%**			
One CVS Dr. Woonsocket, RI 02895				
Coram Alternate Site Services, Inc., does not have any PERSON that own any % of the corporation.				
Coram Alternate Site Services, Inc.	**Corporate Officers**			
Personnel Name	Management Title	Address	Phone	% of Ownership
Emily Field (Director)	President/Treasurer	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%
Tracy L. Smith	Sr. Vice President, Treasurer	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%
Thomas S. Moffatt (Director)	Vice President/ Secretary	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%
Joshua C. Cole	Assistant Treasurer	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%
Paul A. Isabella, Jr.	Assistant Treasurer	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%
Melanie K. St Angelo	Assistant Secretary	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%
Kimberley M. DeSousa	Assistant Secretary	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%
Joshua J. Smith	Assistant Secretary	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%
Leo J. Lariviere	Assistant Secretary	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%
Christy Lynn Letourneau	Assistant Secretary	One CVS Dr., Woonsocket, RI 02895	401-765-1500	0%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CORAM ALTERNATE SITE SERVICES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FOURTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

2112440 8300

SR# 20250690733

Authentication: 203005058

Date: 02-24-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Coram CVS/specialty infusion services

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 12310 World Trade Drive, Suite 100

City San Diego State CA Zip 92128

Mailing Address (if different from physical address) One CVS Dr., MC 1160

City Woonsocket State RI Zip 02895

Telephone 401-765-1500 Website _____

Licensing Company Email permitinfo@cvshealth.com

Section 2: Personal Information

First Amir Middle Alexander Last Nahangi

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Addres[redacted]

City [redacted] State CA Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
University of the Pacific Thomas J Long School of Pharmacy	6/15- 6/18		
Address	**City**	**State**	**Zip**
751 Brookside Rd	Stockton	CA	95211
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name	From - To (MM/YY – MM/YY)		
University of CA Los Angeles	2012-2014		
Address	**City**	**State**	**Zip**
405 Hilgard Ave	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
BS Biology - Evolution & Genetics			

School Name	From - To (MM/YY – MM/YY)		
Capistrano Valley High School	2006-2010		
Address	**City**	**State**	**Zip**
26301 Via Escolar	Mission Viejo	CA	92692
Diploma/Degree obtained, if any			
High-school Diploma			

School Name	From - To (MM/YY – MM/YY)		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/24 - 4/25	[redacted]			
10/21 - 4/24				
10/18 - 10/21				
4/15 - 10/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Coram CVS Specialty Infusion			8/18 - 4/25
Business Address	**City**	**State**	**Zip**
12310 World Trade Dr	San Diego	CA	92128
Phone	**Title**	**Number of Employed Hours**	
858-378-3511	General Pharmacy Manager	13500	
Description of Duties			
Oversee Pharmacy operations and compliance			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Amir Nahangi, **certify that as the designated representative for**

Coram CVS Specialty Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AN I am at least 21 years of age;
3. AN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Amir Nahangi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/9/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amir Nahangi

Print Name (First, Last)

A N 4/11/25

Original Signature (electronic, copies or stamps not accepted)

4/9/25

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Diego

I, Amir Nahangi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

A N

Original Signature

4/11/25

Date

Subscribed and Sworn to before me this 11 day of April 2025.

Notary Public Signature

UISUNG PARK
Notary Public - California
San Diego County
Commission # 2455277
My Comm. Expires Jul 27, 2027

(Seal)

STOCKHOLDERS INFORMATION

Top four: ONLY ONE: Coram Specialty Infusion Services, L.L.C. !00% ownership

10% Ownership or more: Coram Specialty Infusion Services, L.L.C. !00% ownership

LARGEST SHAREHOLDERS



CVS Health 2024 Annual Report

Download



2024 Impact Report

Download

Firm Name	%OS
The Vanguard Group, Inc.	9.3
Dodge & Cox	5.6
Capital World Investors (U.S.)	4.9
BlackRock Fund Advisors	4.8
State Street Global Advisors (SSgA)	4.5
Geode Capital Management	2.1
Capital International Investors	2.1
BlackRock Investment Management (U.K.)	1.7
Fidelity Management & Research Company	1.7
Pzena Investment Management	1.6

As of 12/31/2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Coram CVS/specialty infusion services

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 12310 World Trade Drive, Suite 100

City: San Diego State: CA Zip: 92128

Mailing Address (if different from physical address): One CVS Dr., MC 1160

City: Woonsocket State: RI Zip: 02895

Telephone: 800-540-7887 Toll Free # (NAC 639.708, NRS 639.23286): 800-540-7887

Fax: _____ Contact Email: permitinfo@cvshealth.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Amir Nahangi

Supervising/Managing Pharmacist NV Pharmacist Registration #: _____

Name of Designated Person(s) as defined by revised USP-797 guidelines: Amir Nahangi

Email of Designated Person(s): amir.nahangi@coramhc.com

Telephone of Designated Person(s): 949-241-3209

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? | Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes | No

5. When was the most recent certification for the ISO classified areas? 3/2025

6. What is the frequency of the recertification for the ISO classified areas? twice yearly

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes | No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? monthly

10. Will you be performing sterile hazardous drug compounding? | Yes ■ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

TPN
IV antibiotics in association with TPN orders

12. What laboratory performs your sterility or endotoxin testing?

Name: Fairfield Labs

Address: 2327 Chouteau Ave

City: St Louis State: MO Zip: 63103

Telephone: 314-241-3962

13. What is your procedure for visual inspection of compounded sterile products?

7.5. Visually inspect the compounded solutions for the following:

- 7.5.1. Particulate matter
  - 7.5.1.1. If particulate matter is observed, filter the solution through a 0.22micron filter into another sterile container
  - 7.5.1.2. If particulate matter is suspected to be a precipitated chemical/drug compound, then the solution should be re-compounded
- 7.5.2. Presence of excessive bubble size
- 7.5.3. Container integrity
- 7.5.4. Quantity and final volume as indicated on the dispense screen

14. How often do you perform glove fingertip and medial fill testing?

Twice yearly

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Attached policy

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Attached policy

Peridox / TB1-3300™ / GI-SIPA 70% / Sterile Water for Injection or Irrigation

17. Who performs the sterile compounding process at your facility?

Mixing Technicians compound to be verified by a pharmacist

18. Who is responsible and accountable for the sterile compounding process at your facility?

General Pharmacy manager (Amir Nahangi)

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Cooler packages and ice blocks that have been tested with out pack out procedure to ensure stable storage condition during shipping.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

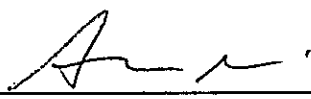
I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amir Nahangi

Name of Person who Completed the Form

General Pharmacy Manager

Title



Signature (copies or stamps not accepted)

4/9/25

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy __X__ Hospital Pharmacy ____ Clinic ____ Exempt Hospital ____ Wholesaler ____ Hypodermic ____

Date: 2/25/2025 Inspector: Joshua Lee

Firm: CORAM CVS/SPECIALTY INFUSION SERVICES Phone: (858) 576-6969

Address: 12310 WORLD TRADE DRIVE SUITE 100 City: SAN DIEGO Zip: 921283793

Ownership: CORPORATION

Permit #: LSC100594 PHY51896 Permit Exp: 5/1/2025 DEA#: BC448368 DEA Exp: 8/31/2026

Date of Self Assessment Form: 6/30/2023 Other Permit #: N/A Date of DEA Inventory: 12/31/2024

Hours M-F: 8am-5pm Hours Saturday: CLOSED Hours Sunday: CLOSED

PIC **AMIR A NAHANGI** RPH79162 Administrator ____

RPH Consultant ____

Staff	RPH Name:	License #:
	JIGISHA R PATEL	RPH83453
	WENDY W HONG	RPH63349
	MIREILLE HAKIM (PREV PIC)	RPH72045
	KHANH Q NGUYEN	RPH79556
	PAULINE L HUYNH	RPH81376
	GOLSAR MIRABOLFATHI	RPH76679
	TRAN B LE	RPH76806
	NANCY N LAM	RPH79220
	KYUNG M KOO	RPH78605
	DOMINIC N GORIA CPD	RPH82163
	PATRICK IRWIN K RECINTO	RPH69548
	KAREN D SIAZON	INT43753

Staff Name:	License #:
AL S HERNANDEZ	TCH130684
ARIANNE M RUSTIA	TCH68130
ASHLEY G SPRAKER	TCH182147
CANDYCE D PEREZ	TCH26371
FRANK PHAM	TCH172570
JENNIFER D MORTON	TCH24183
KATHERINE KHAMPHILAN	TCH156308
KATIE N NGUYEN CPD	TCH86767
KENYETTA T BULLARD	TCH150512
MANUEL P CASANADA CPD	TCH79372
MEIZI SONG CPD	TCH95045
MELISSA J SAN NICOLAS TER	TCH97757
MICHELLE L BROWN	TCH32334
NICOLE A TAYLOR	TCH177270
VICTORIA G HERRERA	TCH120858
VINCENT P SANQUE	TCH45421

Inspector Remarks:

Onsite Annual Sterile Compounding Inspection: Chain retail home infusion/specialty pharmacy. Currently there remains only 3 Coram pharmacies: San Diego, Mendota heights, Malvern. PIC present during inspection. Pharmacy is no longer accredited by PCAB. A routine pharmacy inspection was also conducted today and is detailed on a separate report.

PIC Contact Information:

AMIR A NAHANGI
Amir.Nahangi@coramHC.com
(949) 241-3209

General Information:
- 2023 Community pharmacy and Compounding self-assessments reviewed. Education provided on 2025 requirements.
- Updated list of CSPs: Reviewed during inspection. Compounds TPNs, antibiotics, hydrations, 5FU. Hazardous compounding is rarely conducted, perhaps about every 4-6 months.
- FDA, DEA and/or accreditation inspections with applicable reports issued within the past 12 months: TJC inspection report reviewed.

Designated Persons: PIC Amir only.

Previous BOP Inspection Report: reviewed.

Sterile Compounding Area:

General pharmacy area --> ISO 8 prep room with LOD, sink, light gowning area
ISO 8 prep room --> ISO 7 negative pressure ante room --> ISO 7 HD room with 2 x ISO 5 BSC
ISO 8 prep room --> ISO 8 compounding ante room and ISO 7 compounding room --> 4 x ISO 5 laminar flow hoods. APEX ACD and Baxa repeater pumps utilized for sterile compounding.

- Certification completed by ENV 2/5/25
- Dynamic testing, Non-viable air sampling, HEPA filter leak testing, air changes, smoke study, and viable air and surface sampling: Reviewed.
Every 6 months, all viable sampling is conducted by ENV: Reviewed.
Monthly surface sampling done in house and incubated by ENV: Reviewed.
- Sporicidal, cleaning, and disinfecting agents: TBI 3300 germicidal detergent for ISO 7/8 surfaces, sIPA, sterile Peridox for ISO 5 surfaces.
- Cleaning logs reviewed

Policies and Procedures
- Updated and new PnPs reviewed-documentation of review by PIC.

Record Keeping
-Compounding records/master formula/labeling: Reviewed.
- Sterile compounding equipment calibration and maintenance logs: Reviewed for repeater pump and APEX ACD
- Pressure differential monitoring logs: reviewed.
- Refrigerators/room temperature and humidity logs of sterile compounding areas: reviewed.

Employee training/competencies: Reviewed. Media fill for ACD w/TPN 2L.
- Didactic training, pharmaceutical calculations, gloved fingertip sampling, media fill testing, practical skills training in aseptic area practices, cleaning etc.

Quality Assurance
- End product sterility/potency testing: Fairfield labs

ADRS
- All complaints/ADRs within 12 months have been reported as required: None to report.

Education:

See the following link for proposed compounding regulation status for 2025!
https://pharmacy.ca.gov/laws_regs/pending_regs.shtml
https://www.pharmacy.ca.gov/laws_regs/1735_pt_24.pdf

November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated USP compounding standards.
The Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of federal law and USP General Chapters.
During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the Board's website.
Licensees are reminded to also ensure continuing compliance with other laws, regulations, and requirements that may apply to their activities, including, without limitation: the Federal Food, Drug, and Cosmetic Act (21 USC §§ 321–399i), including Section 503A thereof (21 USC § 353a); provisions of California's Sherman Food, Drug, and Cosmetic Law (Health and Safety Code §§ 109875–111929.4); and laws, regulations, and requirements related to radiopharmaceuticals and/or the handling of hazardous drugs, including requirements established by Cal/OSHA.

1. Revisions to USP Compounding General Chapters <795> and <797> https://go.usp.org/2022_Revisions_795_797
   - BUD Scientific Rationale for the 2021 Proposed Revisions to <795>
   - BUD Reference for the 2021 Proposed Revisions to <795>
   - BUD Scientific Rationale for the 2021 Proposed Revisions to <797>
   - BUD Reference for the 2021 Proposed Revisions to <797>
2. 9/29/23, Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
   https://www.fda.gov/media/94155/download
3. FDA Drug Establishments Current Registration Site:
https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
4. FDA to Compounders: Know Your Bulks and Excipients Suppliers:
https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers

Discussion:

No corrections.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) _____

Inspector (sign) _____

Inspector (print) _____

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 2/25/2025 Permit #: LSC100594

Time of Day: 12:00 AM

Name as shown on permit: **CORAM CVS/SPECIALTY INFUSION SERVICES**

Address: 12310 WORLD TRADE DRIVE SUITE 100 City: SAN DIEGO

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. **A-None**

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) _____ Signed _____

Inspector (print) _____ Print Name _____

Date _____ Title _____

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

2 Sided

Document ID: INFPH-048132	Title: Aseptic Technique Process Validation (I305-015)	
Parent Documents: N/A		
Effective Date: See Document Information Page	**Last Review Date:** See Review and Revision History Section	**Business Process Owner (BPO):** Exec Dir,Patient Safety& Qlty, 0000226311 Safety & Clinical
Exhibit(s): Exhibit A: Aseptic Validation Observation Checklist; Exhibit B: Aseptic Validation Supply List and Media Fill;		
Document Type: Policy and Procedure		

PURPOSE

The purpose of this policy is to set requirements and guidelines for aseptic validation testing and training.

SCOPE

This policy and procedure applies to all Coram CVS Specialty® Infusion Services locations and includes specific requirements for California licensed pharmacies. Coram CVS Specialty® Infusion Services will be referred to as ("the Company") throughout this policy.

POLICY

1. Aseptic technique is validated by the completion of an aseptic validation test which consists of:
   - 1.1. Garbing/Gowning competency (pre-compounding fingertip evaluation)
   - 1.2. Aseptic Manipulation Competency, which consists of:
     - 1.2.1. Media fill unit preparation
     - 1.2.2. Post-compounding fingertip evaluation
     - 1.2.3. Direct Compounding Area (DCA) surface evaluation
2. The aseptic validation test ensures that the compounding personnel can produce a compounded sterile preparation ("CSP") that is free of contamination.
3. Each colleague that is assigned to compound and every pharmacist who works on-site in the pharmacy and is assigned to check or compound sterile products must complete the following training before they can begin their initial aseptic validation testing. Pharmacists and other colleagues who work remotely and perform only front-end functions are exempt from the aseptic technique training program, the initial aseptic validation, and the ongoing annual requirements.
   - 3.1. The Aseptic Technique Training Program, which consists of:
     - 3.1.1. Didactic Training (all competency tests must be filed in the colleague's personnel file)
       - 3.1.1.1. Initial didactic training entails completion of the courses and competency tests included in the Aseptic Training Module in Learning Hub, upon hire.
       - 3.1.1.2. Ongoing didactic training must be repeated annually in the first quarter and must consist of a minimum of 1 hour of sterile compounding

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training and a competency test/quiz with a passing score. Annual didactic training may be chosen from the following sources, and may not be repeated the following year:

3.1.1.2.1. LearningHub Courses (use search term "sterile compounding")

3.1.1.2.2. Pharmacist's Letter, Technician's Letter/Tech University sterile compounding continuing education courses

3.1.1.2.3. Other learning as assigned by the education team

3.2. Completion of all assigned courses under the Aseptic Technique Training Program header in LearningHub.

4. General Pharmacy Managers (GPM)/PIC/Pharmacy Supervisor and designated Aseptic Validation Trainers (AVT) at each pharmacy must retrain on this policy via LearningHub, prior to the start of testing each year.

5. Aseptic Validation Testing

5.1. An aseptic validation test must be:

5.1.1. The most complicated sterile compounding process performed by each compounding technician/compounding pharmacist upon hire and before being allowed to compound or check compounded orders.

5.1.1.1. The most complicated sterile compounding process performed by each California pharmacist or pharmacist checking APEX® orders in a California licensed pharmacy upon hire and before being allowed to compound or check compounded orders.

5.1.2. The most complicated sterile compounding process performed by each GPM, PIC, Pharmacy Supervisor within 3 months of hire and before being allowed to compound, check compounded orders, or proctor aseptic validation tests.

5.1.3. The no equipment sterile compounding process performed by all other pharmacists prior to being allowed to perform the final check of compounded sterile products.

5.1.4. Performed ongoing every six months per USP <797> for category 1 and category 2 compounded sterile product.

5.1.5. Documented on the 'Aseptic Validation Observation Checklist (Exhibit A)' each time.

5.1.6. Scheduled to ensure all aseptic validations are completed in assigned timelines using Aseptic Validation Scheduling Tracker on the Cleanroom Operations SharePoint site at this link: Cleanroom Ops Info (sharepoint.com).

5.2. The aseptic validation testing process includes:

5.2.1. A demonstration of proper scrubbing technique.

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5.2.2. A demonstration of donning compounding room garb and the completion of glove fingertip testing on all fingers of both hands immediately after donning gloves during gowning.

5.2.3. The preparation of the appropriate validation media fill unit to assure competency in aseptic technique, and the completion of glove fingertip testing on all fingers of both hands immediately after preparation of the media fill unit.

5.2.4. Completion of surface sampling of Direct Compounding Area (DCA)

5.2.5. Proper and consistent cleaning and disinfecting technique

5.3. All aseptic validation tests must be observed by the GPM, PIC, Pharmacy Supervisor or a colleague that the GPM, PIC, or Pharmacy Supervisor has qualified to be an Aseptic Validation Trainer (AVT).

5.3.1. The qualification process for a new AVT candidate consists of the candidate completing the steps in the below sequence:

5.3.1.1. Complete the Aseptic Process Validation Training (49200033) in Learning Hub.

5.3.1.2. Complete and pass a full aseptic validation test with the GPM, PIC or Pharmacy Supervisor as proctor and the person completing the Aseptic Validation Observation Checklist (AVOC).

5.3.2. The GPM, PIC or Pharmacy Supervisor must proctor every scheduled aseptic validation test that an AVT performs and also document each on an 'Aseptic Validation Observation Checklist (Exhibit A)'.

5.3.2.1. One AVT cannot ever proctor another AVT's aseptic validation.

5.3.3. The qualification process for GPM, PIC or Pharmacy Supervisor consists of the AVT or another GPM, PIC, or Pharmacy Supervisor observing the candidate while completing every scheduled aseptic validation test. This observation must be documented on the Aseptic Validation Observation Checklist by the trainer.

5.3.4. If the pharmacy is equipped with both vertical and horizontal laminar flow primary engineering controls (PECs) for compounding, the AVT, GPM, PIC or Pharmacy Supervisor must be initially qualified in each airflow PEC.

5.4. Validation of new colleagues requires:

5.4.1. NON-CALIFORNIA LICENSED PHARMACIES

5.4.1.1. That the GPM/PIC/Pharmacy Supervisor/AVT/compounding technicians/compounding pharmacists: Complete three (3) aseptic validation tests in each airflow PEC the new compounding colleague will work in.

5.4.1.2. That the Non-compounding pharmacists, except the GPM/PIC/Pharmacy Supervisor/AVT: Complete three (3) no equipment aseptic validation tests in the most predominant airflow PEC.

5.4.2. CALIFORNIA LICENSED PHARMACIES

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5.4.2.1. That the GPM/PIC/Pharmacy Supervisor/AVT/compounding technicians/compounding pharmacists: Complete three (3) aseptic validation tests in each airflow PEC the new compounding colleague will work in.

5.4.2.2. That the Pharmacists required to check APEX® orders in California licensed pharmacies: Complete three (3) TPN Simulation (APEX®) aseptic validation tests.

5.4.3. That the fingertip and surface plate results are within normal limits, and ALL media fill units are non-turbid after the first 10 days of incubation for a new colleague to be granted clearance to begin compounding patient solutions.

5.5. On-going validation of existing colleagues requires:

5.5.1. NON-CALIFORNIA LICENSED PHARMACIES

5.5.1.1. That a single aseptic validation test, in one airflow PEC be completed every six months per USP <797> for category 1 and category 2 compounded sterile product. The schedule will be published annually by corporate quality team.

5.5.1.2. For GPM/PIC/Pharmacy Supervisor/AVT/compounding technicians/compounding pharmacists, that the aseptic validation test replicates the most complicated sterile compounding process.

5.5.1.3. That non-compounding pharmacists complete the no equipment aseptic validation test.

5.5.2. CALIFORNIA LICENSED PHARMACIES

5.5.2.1. That a single aseptic validation test, in both airflow PECs the compounding colleague works in be completed every six months per USP <797> for category 1 and category 2 compounded sterile product. The schedule will be published annually by corporate quality team.

5.5.2.2. For GPM/PIC/Pharmacy Supervisor/AVT/compounding technicians/compounding pharmacists/pharmacists required to check APEX® orders in California licensed pharmacies, that the aseptic validation test replicates the most complicated sterile compounding process.

5.5.2.3. That non-compounding pharmacists that will not be required to check APEX® orders in a California licensed pharmacy, complete the no equipment aseptic validation test.

5.5.3. That the GPM, PIC, Pharmacy Supervisor or AVT observe the colleague and complete the 'Aseptic Validation Observation Checklist (Exhibit A)'.

5.5.4. That the fingertip and surface plate results are within normal limits, and the media fill unit is non-turbid after the first 10 days of incubation for an existing colleague to maintain clearance to compound patient solutions.

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5.6. Regional Technician Program

5.6.1. Regional Technicians are required to complete their aseptic validation tests per AVT requirements listed in sections 5.4 and 5.5 above as outlined in the PROCEDURE section of this policy.

5.6.2. Documentation of the Regional Technicians validation results are to be maintained at the testing pharmacy, and in the Document Management System (Branch Binders (appserviceenvironment.net)).

PROCEDURE

1. New colleagues must complete three (3) aseptic validation tests. The GPM, PIC, Pharmacy Supervisor, or AVT must observe the new colleague performing all three aseptic validation tests and complete an 'Aseptic Validation Observation Checklist (Exhibit A)' each time, as a competency for the new colleague.

   1.1. A new colleague must complete three (3) aseptic validation tests in each airflow PEC they will compound in.

2. Existing colleagues must complete ongoing aseptic validation tests every six months per USP <797> for category 1 and category 2 compounded sterile product.

   2.1. The GPM, PIC, Pharmacy Supervisor or AVT must observe each existing colleague perform one aseptic validation test and complete the 'Aseptic Validation Observation Checklist (Exhibit A)', as a competency for each colleague.

3. Refer to the Aseptic Validation Material Supply List in Exhibit B for a list of all materials needed to perform one Aseptic Validation test.

4. **The aseptic validation test must include:**

   4.1. Proper scrubbing, garbing and donning sterile glove technique

   4.2. Two sets of fingertip glove samples

      4.2.1. One set immediately after donning sterile gloves in the compounding room (repeat for a total of three tests for initial validation)

      4.2.2. One set at the end of each media fill bag compounded during the process

   4.3. The preparation of a media fill unit

   4.4. One surface sample of the direct compounding area (DCA)

   4.5. Proper and consistent cleaning and disinfecting technique

5. **A validation of correct scrubbing, garbing and gloving technique must be completed.**

   5.1. The GPM, PIC, Pharmacy Supervisor or AVT must observe each colleague scrubbing, garbing and gloving and document observations on the 'Aseptic Validation Observation Checklist (Exhibit A)'.

   5.2. Touch contamination is the most likely source of introducing microorganisms into the CSP. Glove fingertip sampling must be used to evaluate the competency of personnel in performing correct gloving procedures and correct aseptic technique practices that

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include frequent and repeated glove disinfection using sterile isopropyl alcohol 70%, (SIPA 70%).

5.2.1. After the colleague has donned sterile gloves and before the gloves are disinfected with SIPA 70%, the GPM, PIC, Pharmacy Supervisor or AVT shall open and present a sterile Tryptic Soy Agar (TSA) with neutralizing agent plate to the trainee. The colleague must gently roll the pads of thumb and all fingers of one hand across the surface of the agar, followed by the second hand on a second plate.

5.2.2. If too much pressure is applied and the agar in the plate is damaged, dispose of the plate, remove the gloves, aseptically don new gloves and repeat finger and thumb sampling with a new media plate.

5.2.3. Two plates must be used and labeled right and left hand along with the colleague's name and date of testing. Gloves used for the test must be discarded and new gloves must be donned to prepare the media fill unit.

5.2.3.1. If the colleague is submitting more than one validation in a day, ensure the plates are labeled sufficiently so that the samples can be clearly identified and associated with each validation performed.

5.2.3.2. For initial validation, where a new hire completes three aseptic validation tests in one day, the colleague shall perform a separate and complete hand hygiene and full garbing procedure three times. Each time, immediately after donning gloves, the colleague will complete gloved fingertip testing on all fingers of both hands.

6. **The preparation of a media fill unit must be completed.**

6.1. Each GPM, PIC, Pharmacy Supervisor, AVT, compounding technician, compounding pharmacist and pharmacist checking APEX® orders in a California licensed pharmacy must prepare one media fill unit which replicates the most complicated sterile compounding process (Total Parenteral Nutrition (TPN) simulation for APEX®) every six months per USP <797> for category 1 and category 2 compounded sterile product.

6.2. Each pharmacist that does not compound on APEX® and is not required to check APEX® orders in a California licensed pharmacy, and is not the GPM, PIC, Pharmacy Supervisor or AVT, must prepare one media fill unit following the No-Equipment media fill simulation.

6.3. New hires and initial AVT qualification testing for GPMs, PICs, Pharmacy Supervisors and AVTs (if the pharmacy has both vertical and horizontal laminar air flow PECs) must complete a No-Equipment media fill in the second air flow PEC.

6.4. The media fill procedures are outlined below, with each colleague setting up new pump sets for their own validation. Refer to the Media Fill Process Flows in Exhibit B for a visual depiction of each of these processes.

6.5. **TPN-Simulation Media Fill (APEX®):**

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6.5.1. Install the transfer set on the APEX® and complete set-up wizard following this template:

6.5.1.1. Draw up 15 mL of TSB from a TSB bag into 4 separate 20 mL syringes using 4 separate 18g needles and set aside.

6.5.1.2. Attach 2L Sterile Water for Injection bag to line 1.

6.5.1.3. Draw up 50 mL of TSB from the same TSB bag used in step 6.5.1.1 into 4 separate 50 mL syringes, using 4 separate 18g needles, and attach to lines 8, 10, 12 and 14 using the QR TSB syringe code in Exhibit B.

6.5.1.4. Attach Tryptic Soy Broth (TSB) bags to lines 2, 4, 24 and 26 using the QR TSB bag code in Exhibit B.

6.5.2. Attach calibration bag and perform the pump calibration. Change the Universal ingredient (UI) to station 2 TSB and perform the priming and manifold flush process.

6.5.3. A Pharmacist must perform the APEX® setup check.

6.5.4. Manually program the following volumes:

6.5.4.1. Line 2 – 430 mL

6.5.4.2. Line 4 – 450 mL

6.5.4.3. Line 8 – 40 mL

6.5.4.4. Line 10 – 40 mL

6.5.4.5. Line 12 – 40 mL

6.5.4.6. Line 14 – 40 mL

6.5.4.7. Line 24 – 450 mL

6.5.4.8. Line 26 – 450 mL

6.5.5. Program approval by a pharmacist is required.

6.5.6. Attach 2000 mL IV bag to the APEX®.

6.5.7. Pump order until finished.

6.5.8. Remove the media fill bag.

6.5.9. Remove air from the media fill bag (use Air Removal Tubing (ART) when available).

6.5.10. Clamp off the media fill bag.

6.5.11. Inject the 4 syringes containing 15 mL of TSB prepared in step 6.5.1.1 into the final media fill bag.

6.5.12. Perform the post compounding gloved fingertip sampling per step 7 below.

6.5.13. Remove gloves and aseptically don a new pair of sterile gloves.

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6.5.14. Break down the APEX® and clean the PEC.

6.5.15. Record final media fill volume (2000 mL) on the 'Aseptic Validation Observation Checklist (Exhibit A)'.

6.5. **No-Equipment Media Fill:**

6.5.1. Using one bag of TSB, withdraw 7.5 mL into each of 10, 10 mL syringes. From each syringe, inject the 7.5 mL TSB into an empty 150 mL IV bag.

6.6. For all media fill units prepared using the above methods:

6.6.1. Seal the bag and label with marker, including the colleague's name and colleague number, and the date prepared.

6.6.2. Obtain two (2) unused media bags from the same media lot used for the media fill activity and label as "Control". Two unused media bags per lot must be submitted to the CVS Health® Microbiology Laboratory per day of media fill testing.

7. **One set of glove fingertip samples must be collected (following the procedure in 5.2) immediately after the colleague completes compounding the media fill unit.**

7.1 The purpose of the second set of plates is to assure that the colleague sanitized their testing materials appropriately and disinfected their gloves frequently enough to maintain cleanliness throughout the process of preparing the media fill unit, despite touching non-sterile surfaces and moving their hands in and out of the ISO 5 work area.

7.2 Gloves must not be disinfected immediately before touching the media plate.

8. **One surface sample of the direct compounding area (DCA) must be collected.**

8.1 Sample must be collected per Coram Policy 'Environmental Surface and Air Monitoring (I305-017)'

8.2 Sample must be collected after the media fill compounding process and before disinfecting the PEC.

8.3 All test plates must be labeled along with two (2) unused control plates from each lot of media used. All plates must be locked or taped closed.

8.3.1 If the colleague is submitting more than one validation test in a day, ensure the plates are labeled sufficiently so that the samples can be clearly identified and associated with each validation test performed.

8.4 Aseptic validation testing should be performed no later than Thursday of the work week to ensure Tuesday-Friday delivery to the laboratory.

9. **A validation of correct PEC cleaning technique must be completed.**

9.1. The Aseptic Validation Trainer must observe each colleague cleaning the PEC prior to, during (as needed for spills/droplets), and immediately after preparation of the media fill unit. Document observations on the 'Aseptic Validation Observation Checklist (Exhibit A)'.

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10. **Aseptic Validation test samples must be shipped to the CVS Health Microbiology Laboratory to ensure Tuesday – Friday delivery. Pack shipment to avoid extreme temperature variations and damage, per packing and shipping policy. Instructions for shipping and product submission are located on myCoram > Pharmacy > Cleanroom Operations > Micro Lab Information. Each shipment must include:**
    10.1. Two (2) gloving validation (pre-compounding) fingertip plates per colleague.
    10.2. Two (2) post-compounding fingertip plates per colleague.
    10.3. One DCA plate per colleague.
    10.4. Two (2) unopened plates from the same media lot used for fingertip sampling that are labeled as "control".
        10.4.1. Two per each lot of media used
    10.5. One (1) Media Fill unit.
    10.6. Two (2) unused TSB bags from the same lot used for the media fill, that are labeled as "Control" and placed in a resealable bag.
        10.6.1. Two per lot, per day of media fill testing
    10.7. A completed chain of custody (COC) form for each validation submitted.
        10.7.1. A fillable COC form is located on myCoram > Pharmacy > Cleanroom Operations > Micro Lab Information.
        10.7.2. Select correct test type.
11. **Aseptic Validation acceptance criteria and reporting:**
    11.1. The media fill unit must be incubated for no less than 7 days at 30-35°C and then at 20-25°C for no less than an additional 7 days, and TSA plates must be incubated at 30-35°C for no less than 48 hours and then at 20-25°C for no less than 5 additional days. (confirmed by the final results report).
    11.2. The CFUs obtained from glove fingertip testing must be the total obtained from BOTH hands.

Sample	Limit
Total CFU Pre-compounding Sample (Left + Right Gloves)	Action ≥1 CFU
Total CFU Post-compounding Sample (Left + Right Gloves)	Action >3 CFU
Direct Compounding Area Surface Sample	Action >3 CFU

    11.3. A passing result for a media bag is the absence of visual evidence of microbial growth. Failure of the media fill unit is indicated by visible turbidity or other visual manifestations of growth in the media.

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11.3.1. If particulate is found in the TSB media, it must be collected and evaluated to determine whether it is microbial in nature before being reported as a failure.

11.4. If there is no growth within ten days, a new colleague who has achieved satisfactory scores in the electronic and practical exams shall be allowed to prepare compounded sterile preparations.

11.4.1. The Microbiology Laboratory will convey failing preliminary results after 10 days incubation.

11.5. The Microbiology Laboratory will issue a final results report.

12. **Responding to Out of Limit Results.**

12.1. If an out of limit (pre-compounding fingertip, media fill bag , post-compounding fingertip or DCA surface) sample occurs during any of a new colleague's three initial aseptic validation tests or an existing colleague's single aseptic validation test, then the following must be completed:

12.1.1. The colleague must immediately cease sterile compounding activities.

12.1.2. The GPM/PIC/Pharmacy Supervisor/AVT must initiate an internal pharmacy investigation following Coram policy 'Investigation of Cleanroom Incidents (I305-079)'.

12.1.3. If an assignable root cause is not found, The GPM/PIC/Pharmacy Supervisor/AVT must work with the employee to address failures and retrain on aseptic technique. Document training on an In-service log and retain documentation along with the colleagues RCA and retest results.

12.1.4. If the colleague only failed the pre-compounding fingertip sampling portion of the aseptic validation test, they must repeat and pass a pre-compounding fingertip sampling three times in one day. The colleague may not return to sterile compounding until all sets of media plates are found to be within normal limits.

12.1.5. If the colleague failed the media fill bag portion of the aseptic validation test, then they must repeat both the media fill, post media fill fingertip sampling and DCA surface sample three times in one day. The colleague may not return to sterile compounding until all three of the media fill bags have no growth after 10 days.

12.1.6. If the colleague only failed the post-compounding fingertip portion of the aseptic validation test, then they must complete a No-Equipment media fill + post media fill fingertip sampling **one time**. The colleague may return to compounding after the fingertip samples are found to be within limits. The final report issued upon completion of the media bag incubation shall be reviewed by the GPM, PIC, Pharmacy Supervisor or AVT to ensure the media fill bag results are acceptable for the colleague.

12.1.7. If the colleague only failed the direct compounding area portion of the aseptic validation test, then they must complete a No-Equipment media fill and direct

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compounding surface sampling **one time**. The colleague may return to compounding after the DCA sample is found to be within limits. The final report issued upon completion of the media bag incubation shall be reviewed by the GPM, PIC, Pharmacy Supervisor or AVT to ensure the media fill bag results are acceptable for the colleague.

12.1.8. The colleague's aseptic technique must be observed and documented at the time of testing by the GPM, PIC, Pharmacy Supervisor or AVT, utilizing the 'Aseptic Validation Observation Checklist (Exhibit A)'.

12.2. If during a new or existing colleague's repeated aseptic validation test, a second out of specification result occurs, they must:

12.2.1. Continue to refrain from compounding.

12.2.2. The corporate Quality and Pharmacy teams shall review all prior RCA documentation, observation records and all Microlab results. A plan of action will be formulated which may include:

12.2.2.1. Additional training

12.2.2.2. Additional testing

13. The Aseptic Validation Observation Checklist(s) (Exhibit A) and the Certificate of Completion/Final Report(s) document each colleague's validation test. They must be reviewed and/or signed by the GPM or designee and filed in the QC binder.

DEFINITIONS:

1. **Aseptic Validation:** Completing a media fill and fingertip testing using the most complicated process for that pharmacy
2. **Aseptic Validation Trainer (AVT):** The pharmacist-in-charge or qualified designee that oversees the aseptic validation process for each sterile compounding technician and pharmacist
3. **Colleague:** Any full-time, part-time, temporary, or casual employee of CVS Health® subsidiaries and affiliates, along with paid interns and externs employed by CVS Health® subsidiaries and affiliates.
4. **CVS Health®:** An enterprise brand that is used by CVS Pharmacy, Inc. and each of its subsidiaries and affiliates.
5. **CVS Specialty®:** The specialty pharmacy subsidiaries and affiliates of Caremark, L.L.C. that provide prescription drugs, therapies, services, and support to individuals who require complex and expensive drug therapies.
6. **Regional Technician Program:** A group of experienced compounding technicians which supports the needs of their region by traveling, as needed, to various Coram pharmacies.
7. **Tryptic Soy Agar (TSA):** Solid microbiological media used in fingertip sampling
8. **Tryptic Soy Broth (TSB):** Liquid microbiological media used in media fill testing

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9. **Universal Ingredient (UI):** A solution on station 1, 2 or 3 of the APEX® that is used to flush between incompatible components and flush the manifold during the compounding process.

REVIEW AND REVISION HISTORY

Date	Revision No.	Reason for Change	Sections Affected
12/28/14	1.00	CVS Formatting	All
07/10/15	2.00	Correction on Exhibit A	Exhibit A
08/26/15	3.00	Change in Handwashing practice	Exhibit B
01/28/16	4.00	Clarification of training/media fill sequence, Pinnacle competencies and Learnet training added	Background
03/07/16	5.00	Change in incubation temperatures for contact plates	5.4 and 7.9, Exh. A
12/08/16	6.00	Change in practice for recording competency of sterile garbing practice.	5 and Exhibits A and B
06/22/17	7.00	Changed revalidation media fill process to exclude use of ACD and Baxa. Demonstration media fill no longer sent for outside testing. Minor changes to further clarify; 6.5 & 8.11. Change to require Aseptic Validation Log AND approved software reporting (was either/or); 7.7. Add preference of using new tubing for each person's validation; 8.12, 8.13, 8.14, 8.15 Change "positive sample" to "out of specification sample".	All
10/12/17	8.00	Removed process of testing sterile garb during revalidation media fill, redefined procedure for failed media fill and defined documenting demonstration media fill. Updated Exh A and B to reflect the change.	All and Exh A and B
07/09/18	9.00	Clarification of glove fingertip testing and correction on Exh A	Policy 3.2.4 and Exh A
11/28/18	10.00	Clarified that validation process simulations shall be observed by a trainer, technician or supervisor that the PIC has validated; updated Exh B to include that a nail pick is required to clean under each fingernail with water running over fingertips, Added maintaining first air during compounding manipulations, Removed Pharmix section, corrected typos/formatting	Policy 3.3, Procedures 1 & 2, and Exh B.
01/23/19	11.00	Annual review. Didactic training includes review of training material, passing a test, required upon hire and annually. Validation must be performed in both vertical and horizontal ISO5 if branch has both. Media plates to include a neutralizing agent. Roll fingertips when performing glove sampling. Shipments of media to contracted outside lab may be shipped on Friday. Added possibility of using Microlab to process touchplates in future. Exh A: Added Vertical/Horizontal Checkbox and ISO5 area. Added "ENV media fill" to validation types. Added PM/PIC sign off. Exh B: Added Vertical/Horizontal checkbox and ISO5 area. Moved compounder name to top of form. Added column for N/A response. Added persistent activity hand sanitizer. Added more detail to some of the checks. Added "demonstrates competence in surface sampling technique". Added maintains first air over critical sites. Moved signature of compounder,	All

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		trainer and added PM/PIC to area under comments section.	
01/28/19	12.00	Annual review. Didactic training includes review of training material, passing a test, required upon hire and annually. Validation must be performed in both vertical and horizontal ISO5 if branch has both. Media plates to include a neutralizing agent. Roll fingertips when performing glove sampling. Shipments of media to contracted outside lab may be shipped on Friday. Added possibility of using Microlab to process touchplates in future. Exh A: Added Vertical/Horizontal Checkbox and ISO5 area. Added "ENV media fill" to validation types. Added PM/PIC sign off. Exh B: Added Vertical/Horizontal checkbox and ISO5 area. Moved compounder name to top of form. Added column for N/A response. Added persistent activity hand sanitizer. Added more detail to some of the checks. Added "demonstrates competence in surface sampling technique". Added maintains first air over critical sites. Moved signature of compounder, trainer and added PM/PIC to area under comments section.	All
05/31/19	13.00	Updated Exh B to remove reference to closing the cap on the transfer set junction and minor formatting changes.	Exh B
08/22/19	14.00	Clarified process for shipping all samples to the CVS Health Microbiology Lab. Added the requirement for two unused control media bags or contact plates to be sent along with the test media fill or contact plates for analysis. Removed Exhibits A and C. Added reference to Investigation of Cleanroom Incidents policy I305-079 for the investigation and response of actionable results. Renumbered Exh B to Exh A.	All
02/06/20	15.00	Annual review. Removed sterile garb testing. Changed validation schedule to Quarter 2 and Quarter 4, and eliminated partial validation.	Throughout
05/07/20	16.00	Annual review. Introduced specific requirements for being a qualified AVT including required training and post-test, repeated annually. Divided aseptic validation into two distinct parts. Removed the requirement for DCA touch plate testing. Clarified procedures for the first failure of any part of the validation process and requirements which must be completed before the colleague returns to sterile compounding. If a new colleague has > 6 months of full-time sterile compounding experience, removed the requirement for the trainer to demonstrate the process. Identified 3 different media-fill processes. Removed reference for high risk compounding. Updated and renamed Exh A. Added new exhibits B and C.	All
06/11/20	17.00	References to "PIC" updated to "PIC/Pharmacy Supervisor". Reduced the retesting requirement for failed post-compounding fingertip from three retests to one retest.	Throughout

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07/23/20	18.00	Changed the contact person for notifying of a new or existing colleague's retest failures. Added RCA documentation, aseptic validation observation records as required for corporate review. Removed "further organism identification" from the plan of action. Updated exhibit B to reorder the steps for TPN Media fill.	Procedure 11.2.1-11.2.2 and Exh B
01/14/21	19.00	Annual review. Changed requirement for existing colleagues from 1 aseptic validation in each PEC type to 1 aseptic validation in one PEC type. Updated the TPN-Simulation Media Fill process to reorder the steps. Updated exhibit A. Changed branch to pharmacy and pharmacy manager to general pharmacy manager.	Throughout and Exh A
11/11/21	20.00	Annual review. Revised testing requirements: GPM/PIC/Pharmacy Supervisor/AVTs must qualify in both PEC types to initially qualify as AVT, thereafter in the most difficult media fill PEC type. A No-Equipment media fill is required by RPhs that do not compound on APEX. Retest for post-compounding fingertip failures requires a no-equipment media fill and post-compounding fingertip sampling. Added TPN Media Fill simulation using APEX. Clarified that only non-APEX branches perform TPN Media Fill simulation using Pinnacle. Removed No-ACD media fill. Changed requirement for GPM/PIC/Pharmacy Supervisors/RPhs to complete new hire aseptic validations within 3 mos. of hire and/or before compounding. Updated exhibits A, B and C.	Throughout and Exhibits A, B & C
04/22/22	21.00	Annual review. Minor formatting and verbiage changes. Clarified aseptic training program and validation process requirements for pharmacy colleagues who work on-site from those who work remotely and perform front-end activities. Revised exhibit display.	Policy 2, throughout and exhibits
06/17/22	22.00	Minor formatting changes. Added Regional Technician section and updated Definitions. Minor update to Exhibit A.	Policy 4.6-4.6.2, Definitions and Exh A
11/18/22	23.00	Annual review. Formatting and verbiage changes. Updated Scope and clarified Aseptic Technique Training Program requirements. Removed reference to Exhibit C and added hyperlink for Aseptic Validation Scheduling Tracker. Added validation requirements for CA Pharmacies and pharmacists working in CA licensed pharmacies. Removed reference to Pinnacle Media Fill and added incubation criteria for media fill and TSA plates. Updated requirement for failed pre-compounding fingertip sampling. Clarified review of RCA documentation, observation records and all Microlab results. Updated Definitions. Updated Exhibits A and B, and removed Exhibit C.	Throughout and Exhs
11/24/22	24.00	Minor formatting changes. Updated action limit for post-compounding samples.	Procedure 10.2. Table
10/27/23	25.00	Annual review. Updated instructions to complete full gowning process prior to each pre-compounding fingertip sampling. Added DCA sampling. Removed	Throughout

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		trainer demonstration. Clarified new AVT training requirements. Major formatting changes, added hyperlinks and updated Definitions.	
01/09/24	26.00	Changed timeline from 7 days to 10 days to align with current practice.	Policy 5.4.3 and 5.5.4, Procedure 12.1.5
10/11/24	27.00	Annual review. Removed link to the Forms page.	Forms link

EXHIBIT(S):

Exhibit A: Aseptic Validation Observation Checklist (I305-015 Exh A)

Exhibit B: Aseptic Validation Supply List and Media Fill (I305-015 Exh B)

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Document ID: INFPH-073716	Title: Cleanroom Cleaning Procedures - Epic (I305-010 Epic)	
Parent Documents: N/A		
Effective Date: See Document Information Page	**Last Review Date:** See Review and Revision History Section	**Business Process Owner (BPO):** Exec Dir,Pharmacy Ops, 0000228005 Core Operations Area
Exhibit(s): Exhibit A: Cleaning Procedures Competency Checklist - Epic; Exhibit B: Cleaning Activity and Dilution Grid - Epic; Exhibit C: Disinfectant Activity and Contact Time - Epic; Exhibit D: Cleaning Procedures Competency Checklist Negative Pressure Room/BSC Addendum - Epic; Exhibit E: Cleanroom Closure Signage - Epic;		
Document Type: Policy and Procedure		

PURPOSE

The purpose of this policy is to provide accepted guidelines for cleaning and disinfection of the Coram CVS cleanroom suite in pharmacies using Epic. These guidelines are designed to ensure cleanliness of all areas, equipment and other contact surfaces in the rated areas used to produce, test, package and label or hold components or finished goods.

SCOPE

This policy and procedure applies to all Coram CVS Specialty® Infusion Services locations using Epic that maintain a Coram CVS cleanroom suite.

POLICY

1. It is the responsibility of all colleagues to follow this procedure for cleanroom cleaning procedures and use of formulary approved cleaning and disinfecting agents.
2. It is the responsibility of the facility Pharmacist-in-Charge (PIC) or designee to ensure that colleagues are trained on this procedure.
3. Environmental contact is a major source of microbial contamination. Attention must be paid to the use of formulary approved cleaning and disinfecting agents for cleaning and disinfection of the ISO 5 areas, the adjoining work areas and rooms. The introduction of outside contaminants must be minimized by:
    - 3.1. Properly placed tacky mats on the unrated area side of all doorways leading into the cleanroom complex. No tacky mats will be placed inside the rated areas including the prep room, ante room, compounding room or negative pressure room.
    - 3.2. Company approved, lint-free, cleanroom-rated paper for the printing of all documents taken into the cleanroom.
    - 3.3. Appropriate gowning - refer to Coram policy 'Cleanroom Garb (I305-004)' for details.
    - 3.4. Formulary approved cleaning and disinfecting agents used for components and equipment as they are moved into each room of the clean room suite. Refer to Coram policy 'General Compounding and Checking Guidelines – Epic (I305-020 Epic)' for guidance.
4. Cleaning and disinfection using formulary approved agents must occur at the outlined frequency and made a priority by pharmacy management and compounding colleagues to assure patient safety.

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5. The use of non-formulary cleaning and disinfection agents may only occur if approved by the Coram Quality and Patient Safety team.
6. All cleaning equipment must be disinfected with appropriate disinfectant before being brought into the compounding room.
7. If compounding occurs after-hours (on-call), required cleaning includes: ISO 5 work surfaces disinfected with formulary approved cleaning agents before and after the completion of the on-call compounding, trash removal. This cleaning must be recorded in the approved computerized program.
8. Cleaning and disinfecting procedures with formulary approved agents will occur as scheduled and be documented in the approved computerized program upon the completion of the task.
    8.1. All cleaning and disinfection procedures with formulary approved agents will be performed by trained Company personnel or agency personnel who have successfully completed training as documented on the 'Cleanroom Cleaning Procedures Competency Checklist (Exhibit A)'.
    8.2. Cleaning and disinfecting procedures with formulary approved agents completed in the negative pressure room and the biological safety cabinet will be performed by trained Company personnel or agency personnel who have successfully completed training as documented in the 'Cleanroom Cleaning Procedures Competency Checklist Negative Pressure Room/BSC Addendum (Exhibit D)'.
    8.3. Cleaning Procedures Competency must be administered on hire and repeated annually during Quarter 1.
    8.4. Goggles must be worn when completing monthly cleaning of walls and ceilings.
9. Approved vendors working in the clean room suite must follow cleaning and disinfecting procedures, use formulary approved agents and all equipment must be disinfected before being brought into the clean room suite.
10. All areas adjacent to the clean room suite, including the secure drug storage and warehouse areas must be maintained in a clean and orderly fashion.

PROCEDURE

CLEANING IN THE CLEANROOM SUITE

1. Equipment required for cleaning. All cleaning equipment must be stored on the dirty side of the line of demarcation.
    1.1. **Mop heads and handle(s)**. Store mop handles suspended off of the floor. Disinfect with Gamma irradiated SIPA 70% before introducing into compounding room and ISO5 area (when applicable).
        1.1.1. Ceiling and walls – use a dedicated sterile, disposable KleanMax® mop pad system for each ISO-rated area and negative pressure room (NPR).
        1.1.2. Floors – use the sterile, disposable MicroCinch® mop pad.

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1.1.3. For hard-to-reach areas within the ISO 5 area, use the EasyReach® tool or a designated disinfected mop handle for use in the ISO 5 vertical flow workbench area using the KleanMax® mop pad (rated for ISO 5 areas).

1.1.4. All mop systems use disposable, sterile mop pads and are labeled according to these directions:

1.1.4.1. **Ceilings and walls in ISO 7 positive pressure rooms** of the compounding suite must be cleaned with formulary approved cleaning agents using the same mop pads and handles, labeled 'CEILINGS/WALLS – 7.'

1.1.4.2. **Ceilings and walls in ISO 7 negative pressure rooms** of the compounding suite must be cleaned using formulary approved cleaning agents and the same mop pads and handles, labeled 'CEILINGS/WALLS – NPR.'

1.1.4.3. **Ceilings and walls in all ISO 8 rooms** of the compounding suite must be cleaned using formulary approved cleaning agents and the same mop pads and handles, labeled 'CEILINGS/WALLS – 8'. These mops are used during monthly cleaning.

1.1.4.4. **Floors in ISO 7 positive pressure rooms** of the compounding suite must be cleaned with formulary approved cleaning agents, using the same mop pads and handles, labeled 'FLOORS ONLY-7'. The 'FLOORS ONLY-7' mop must be used for both DAILY and MONTHLY cleaning with formulary approved cleaning agents to allow for appropriate disposal of used mop pads.

1.1.4.5. **Floors in ISO 7 negative pressure rooms** of the compounding suite must be cleaned using formulary approved cleaning agents and the same mop pad and handles, labeled 'FLOORS ONLY-NPR'. The 'FLOORS ONLY-NPR' mop must be used for both DAILY and MONTHLY cleaning with formulary approved cleaning agents to allow for appropriate disposal of used mop pads.

1.1.4.6. **Floors in all ISO 8 rooms** of the compounding suite must be cleaned using formulary approved cleaning agents and the same mop pads and handles, labeled 'FLOORS ONLY-8'. The 'FLOORS ONLY-8' mop must be used for both DAILY and MONTHLY cleaning with formulary approved cleaning agents to allow for appropriate disposal of used mop pads.

1.1.4.7. **For hard-to-reach areas within the ISO5** area (i.e. the interior of enclosures in horizontal wall units) a dedicated EasyReach® tool or a designated disinfected mop handle using the KleanMax® mop pad (rated for ISO 5 areas) may be used, labeled 'ISO5 ONLY'. EasyReach® tools used in a BSC or CACI within a negative pressure room must be dedicated to use only within that space and labeled as 'ISO5 NPR ONLY'.

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1.1.5. DO NOT use the mop to clean Digi SmartSense mounted devices. These sensitive electronic devices must be cleaned by hand using a sterile wipe dampened with SIPA.

1.2. Sterile non-woven, non-shedding disposable wipers.

1.3. Disinfectant and Cleaning solutions - approved disinfectants and sporicidals/detergents that must be used in the clean room are:

1.3.1. PeridoxRTU-HC® sporicidal/detergent - label with date of first use and discard any unused solution within 6 months.

1.3.2. Gamma irradiated SIPA 70% (GI-SIPA 70%) - use contents until gone.

1.3.3. TB1-3300™ disinfectant/germicidal detergent - label with date of first use and discard any unused solution within 6 months.

1.3.4. Sterile water for injection or irrigation used to clean up spills. Area should be disinfected with GI-SIPA 70% after cleanup is completed.

1.4. Tacky Mats - Must be changed whenever they show signs of contamination and at the end of the compounding day, removing the top layer from the cleanest area towards the dirtiest area. Pull all sides of the layer toward the center to prevent debris from falling on clean floors and surfaces.

1.5. Appropriate Personal Protective Equipment (PPE) is required based on Safety Data Sheets (SDS).

1.5.1. See Coram policy 'Hazard Communication Plan (SAF-045)' for more information on SDS and how to access them.

1.6. Chemical/splash goggles for full coverage of the eyes for use with PeridoxRTU-HC®.

1.6.1. Colleagues may also use P95 disposable respirator mask for PeridoxRTU-HC®.

1.6.2. Fit testing is not required for voluntary use of the P95 respirator mask, but the colleague must read the CVS Enterprise 'Respiratory Protection Policy'.

1.6.3. The 'Voluntary Use of Filtering Face Piece (FFP) Respirator Acknowledgment (SAF-INF-020 Exh C)' must be signed in lieu of the Exhibit 1 of the Respiratory Protection Policy. File this form in their medical record, review and sign annually during the cleaning competency process. The form is located on the Forms page of myCoram.

1.7. Eye protection for use with TB1-3300™.

1.8. A fit-tested N95 respirator is required while decontaminating the biological safety cabinet and the area under the spill tray of a biological safety cabinet. Fit tested respirators are required for this cleaning activity. Refer to Coram policy 'Biological Safety Cabinet Decontamination (I305-029)'.

DAILY CLEANING PROCEDURE WITH APPROVED CLEANING AND DISINFECTING AGENTS

Compounding Positive and Negative Pressure Rooms (ISO7)

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Prior to beginning compounding day:

1. Disinfect the ISO5 Primary Engineering Controls following the procedure outlined in Coram policy 'Guidelines for Aseptic Technique - Epic (I305-018 Epic)' and using GI-SIPA 70%. Change sterile wipe frequently.
2. Disinfect compounding equipment with GI-SIPA 70%.

During compounding day:

1. Disinfecting ISO5 work surface with GI-SIPA70% between compounding batches and every 30 minutes.
    1.1. The ISO5 work surface used to compound beta-lactam drugs (see Coram policy I305-018 Epic) must be washed with sterile water, allowed to dry, then disinfected with GI-SIPA 70%. The compounder must replace sterile gloves with a new pair prior to compounding non-beta-lactam medications.
    1.2. The work surface of a BSC must be decontaminated between compounding of different hazardous drugs. If compounding hazardous drugs in an ISO5 area other than a BSC, the work surface of the ISO5 area must be decontaminated as outlined in the assessment of risk for the selected drug. Refer to Coram policy 'Handling and Compounding of Hazardous Drugs - Epic (I305-021 Epic)' for details.
2. Any spills must be cleaned up immediately using sterile water and/or disinfected with GI-SIPA 70%.

End of Day:

1. Remove all compounding waste. Discard TPN waste as directed in Coram policy 'TPN Waste Management – California State-Specific (I305-028 CA)'. Clean any spills or splashes on any areas of the ISO5 area with sterile water for injection/irrigation.
2. Clean and disinfect the ISO5 Primary Engineering Controls, including Plexiglas, plastic and compounding equipment, using PeridoxRTU-HC®. Change sterile wipe frequently.
    2.1. Proper procedures outlining the cleaning with formulary approved cleaning agents and decontamination requirements of a biological safety cabinet are located within Coram policy I305-029.
3. Disinfect all horizontal surfaces (i.e. carts, pass-through) and high-touch areas (i.e. door handles, chairs, Epic keyboards, touch screens, scanners and cameras) using TB1-3300™ disinfectant.
4. Removal of trash - this may not occur in the compounding room. The waste receptacle must be moved to the anteroom/area prior to waste removal and liner replacement. Empty as needed throughout the day.
5. Mop the compounding room floor using a dry sterile mop pad if needed to pick up vial caps, needle covers etc. Discard mop pad.
6. Using a new sterile mop pad and TB1-3300™, disinfect floor by pouring disinfectant on the mop pad. Change mop pad whenever it appears soiled.

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7. Clean with overlapping strokes, from cleanest to dirtiest area, leaving surface visibly wet to maximize contact time. **Allow floor to dry before moving carts, chairs, etc. back into place.**

Ante room

End of Day:

1. Remove trash (must occur at least daily)
2. Disinfect work surfaces with TB1-3300™, disinfectant and sterile wipes.
3. Disinfect sink, if applicable, with TB1-3300™, followed by GI-SIPA 70%
4. Disinfect floor by pouring TB1-3300™ disinfectant on the mop pad. Change mop pad whenever it appears soiled. Clean with overlapping strokes, from cleanest to dirtiest area, leaving surface visibly wet to maximize contact time. It is acceptable to use the mop pad that was used in the compounding room to mop the ante room floor. **Allow floor to dry before moving carts, chairs, etc. back into place.**

Prep room

End of Day:

1. Remove trash (must occur at least daily)
2. Disinfect work surfaces with TB1-3300™ disinfectant and sterile wipes.
3. Disinfect sink, if applicable, with TB1-3300™ disinfectant followed by GI-SIPA 70%
4. Disinfect floor by pouring TB1-3300™ disinfectant on the mop pad. Change mop pad when it appears soiled.
5. Clean with overlapping strokes, from cleanest to dirtiest area, leaving surface visibly wet to maximize contact time. **Allow floor to dry before moving carts, chairs, etc. back into place.** It is acceptable to use the mop pad that was used in the ante room to mop the prep room floor.

WEEKLY CLEANING PROCEDURE WITH APPROVED CLEANING AND DISINFECTING AGENTS

1. Weekly cleaning tasks must be completed using formulary approved cleaning agents (See Exhibit B) on the approximate same day, each week.
2. APEX® compounders must be dismantled and cleaned during the weekly cleaning process. This includes removal of load cell plate and cleaning the bottom of the APEX®.
3. Epic stands must be cleaned during the weekly cleaning process.
4. Rooms must be cleaned with formulary approved cleaning agents in succession, not simultaneously, in the following order:
   - 5.1. Compounding Room(s) and Negative Pressure Room
   - 5.2. Ante Room(s)
   - 5.3. Prep Room(s)

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Compounding and Negative Pressure Room

1. Daily cleaning must be completed using formulary approved cleaning agents as described above.
2. In addition, these areas must be disinfected with TB1-3300™ disinfectant:
   2.1. Windowsills and overhang ledges
   2.2. Dedicated equipment (carts, chairs, table legs, ladder, shelving, step stools etc.)
   2.3. Storage bins, totes - emptied and cleaned.
   2.4. Inside of pass through, including floor and all external pass-through surfaces

Ante room

1. Daily cleaning must be completed with formulary approved cleaning agents as described above.
2. In addition, these areas must be disinfected with TB1-3300™ disinfectant:
   2.1. Windowsills and overhang ledges
   2.2. Dedicated equipment (carts, chairs, table legs, ladder, shelving, step stools etc.)
   2.3. Storage bins, totes - emptied and cleaned.
   2.4. Waste containers (including those brought from the compounding room)

Prep room

1. Daily cleaning must be completed using formulary approved cleaning agents as described above.
2. In addition, these areas must be disinfected with TB1-3300™ disinfectant:
   2.1. Windowsills and overhang ledges
   2.2. Dedicated equipment (carts, chairs, table legs, ladder, step stools etc.)
   2.3. Waste containers
   2.4. All exterior surfaces of pass through

MONTHLY CLEANING PROCEDURES WITH APPROVED CLEANING AND DISINFECTING AGENTS

1. All cleaning tasks outlined as daily and weekly tasks in this policy must be completed during the monthly cleaning **substituting** PeridoxRTU-HC® solution **for** TB1-3300™. Monthly cleaning procedures using formulary approved cleaning agents require that appropriate PPE be worn at all times.
2. Additional monthly cleaning must include:
   2.1. Ceiling – Disinfected using PeridoxRTU-HC® solution on a sterile mop pad, using overlapping strokes.

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2.2. Walls - Disinfected using PeridoxRTU-HC® solution on a sterile mop pad. Clean using overlapping strokes, leaving surface visibly wet to maximize contact time. DO NOT use mop and/or PeridoxRTU-HC® to clean Digi SmartSense mounted devices. These sensitive electronic devices must be cleaned by hand using a sterile wipe dampened with SIPA.

2.3. Horizontal and vertical flow hoods – Drip trays/spill trays must be cleaned using PeridoxRTU-HC®.

3. All used disposable pads, mop pads and wipes must be placed in a resealable bag immediately and discarded.
4. Monthly cleaning tasks must be completed on approximately the same day each month using formulary approved cleaning agents.
5. Rooms must be cleaned with formulary approved cleaning agents in succession, not simultaneously, in the following order:
   5.1. Compounding Room(s) and Negative Pressure Room
   5.2. Ante Room(s)
   5.3. Prep Room(s)
6. Monthly cleaning must progress from cleanest area (farthest from door) to dirtiest area (closest to door) in the following order:
   6.1. Ceiling
   6.2. Walls - DO NOT use mop and/or PeridoxRTU-HC® to clean Digi SmartSense mounted devices. These sensitive electronic devices must be cleaned by hand using a sterile wipe dampened with SIPA.
   6.3. Outside and inside of compounding hoods or benches (including curtains and/or enclosures if applicable)
   6.4. Carts, shelving, bins, totes, etc. in all areas
   6.5. Floors

REMEDIAL CLEANING

1. To be performed per Environmental Monitoring Response Grid:
   1.1. Follow monthly cleaning procedure using TB1-3300™ disinfectant cleaning agent on all surfaces. Surfaces should remain wet for at least 1 minute and then be allowed to air dry.
   1.2. Repeat monthly cleaning procedure using PeridoxRTU-HC® solution on all surfaces. Surfaces should remain wet for at least 3 minutes and then be allowed to air dry.

CLEANING IN UNUSUAL SITUATIONS

Trained personnel must initiate a monthly cleaning of the affected area(s) using approved formulary cleaning agents in the following situations:

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1. At the discretion of management if the operational integrity of the clean room has been compromised
2. After room or hood filter certification procedures that require equipment be brought into the room or smoke testing
3. After any maintenance or other events occurring in the clean room that would compromise environmental integrity - refer to 'Management of Cleanroom Repairs/Remodel (I305-016 Exhibit C) and Coram policy 'Cleanroom Specifications, Certification, and Maintenance (I305-016)' for guidance.
4. After new construction of a cleanroom has been completed (refer to 'Facility New Construction Cleanroom Validation Checklist (I305-016 Exhibit B).

Triple Cleaning

Trained personnel must initiate a triple cleaning of the affected area(s) according to Coram policy exhibits: I305-016 Exhibit B or I305-016 Exhibit C. A complete triple cleaning is the equivalent of a repeated monthly cleaning using approved formulary cleaning agents and must consist of cleaning ceilings, walls, floors, equipment, and work areas using the following detergents/disinfectants in this order:

1. PeridoxRTU-HC®
2. TB1-3300™
3. GI-SIPA 70% on all areas except the floor

MAINTAINING AN INACTIVE CLEANROOM

1. Coram pharmacies may have a cleanroom that is inactive for a temporary period of time. These spaces must be maintained so that they are ready for use when needed.
    1.1. Record temperatures, humidity and pressure readings utilizing the continuous monitoring system. Address and correct all alarms and out of limit readings.
    1.2. Perform weekly cleaning procedures as detailed above.
    1.3. Perform monthly cleaning procedures as detailed above.
    1.4. Perform viable environmental monitoring monthly according to Coram policy 'Environmental Surface and Air Monitoring (I305-017)'.
        1.4.1. Air samples may be requested at the direction of the Quality Department.
        1.4.2. If viable environmental monitoring results are outside of acceptable limits, at the discretion of the Quality Department, the required cleaning and/or testing frequency may be increased.
2. To Reinitiate use of a temporarily inactive cleanroom
    2.1. Twenty-four (24) to forty-eight (48) hours prior to initiating use of the inactive cleanroom for patient compounding, perform a monthly clean.
    2.2. Perform environmental monitoring after monthly cleaning is complete.

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2.3. The PIC must review the prior environmental monitoring data, temperatures, humidity, and pressure readings. Obtain direction from Quality Department if there were any out of limit results.

2.4. Compounding may commence once the cleaning and testing is complete, and while environmental results are pending.

3. When a cleanroom is to be permanently inactive, the following steps must be followed:

3.1. The air handling system for a permanently inactive cleanroom will remain functional, unless approved by Senior Leadership in conjunction with Operations and Coram's Quality teams.

3.2. A closure sign (see Exhibit E) shall be posted on the entrance to the cleanroom suite that signifies the room(s) is/are no longer in use

3.3. The permanently inactive cleanroom shall not be used for additional storage.

3.4. Movement in and out of the inactive cleanroom shall be restricted.

4. To reinitiate the use of a permanently inactive cleanroom:

4.1. Senior leadership must approve the re-activation of the cleanroom, in collaboration with Coram Quality, Patient Safety, Regulatory and Clinical teams.

4.2. The entire cleanroom suite must be re-evaluated as if it is a new space.

4.3. All required cleanings, including a triple clean, must be performed.

4.4. Functional and viable testing must be performed by the contracted vendor to qualify the room for use.

4.5. The Board of Pharmacy must be made aware that the room is being re-activated, and all required inspections and licensure must be obtained.

DOCUMENTATION

1. All cleaning tasks using approved formulary cleaning agents must be documented upon completion by trained personnel, utilizing the approved software.
2. Documentation must not be completed in advance and must be completed by one of the colleagues that performed the task whenever possible.
3. If several colleagues participate in a cleaning activity using approved formulary cleaning agents, that participation must be noted in the 'comments' section.
4. The PIC or designee must review the computer data entry at least monthly to ensure that all activities are completed as indicated in this policy.

DEFINITIONS

1. See Coram policy 'Cleanroom Definitions (I305-009)' for all terms and definitions used in this policy.

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2. **Colleague:** Any full-time, part-time, temporary, or casual employee of CVS Health® subsidiaries and affiliates, along with paid interns and externs employed by CVS Health® subsidiaries and affiliates. .
3. **CVS Specialty®:** The specialty pharmacy subsidiaries and affiliates of Caremark, L.L.C. that provide prescription drugs, therapies, services, and support to individuals who require complex and expensive drug therapies.
4. **Inactive Cleanroom:** A cleanroom that is not in use for compounding of patient medications and entrance is restricted to trained cleanroom personnel wearing the appropriate garb per policy.

REVIEW AND REVISION HISTORY

Date	Revision No.	Reason for Change	Sections Affected
12/16/21	1.00	New Document	N/A
04/29/22	2.00	Annual review. Formatting and verbiage changes. Changed "cleaning " to "cleaning and disinfecting". Added requirements for mop handle labels. Added compounder requirements for compounding beta-lactams, ISO-5 clean up, and compounding non-beta-lactam medications. Added decontamination information for BSC. Added end of day cleaning requirements for the compounding pumps. Revised floor drying steps. Changed mop "head" to mop "pad". Added disinfection requirements related to TB1-3300. Removed annual floor maintenance requirement. Added requirement to note colleagues names who participate in cleaning activity in the comments section of approved software. Updated Exhibit C to include reference for TB1-3300 and Peridox contact times.	Throughout
04/29/22	3.00	Revised Exhibit B to align with above policy changes for daily cleaning and disinfecting.	Exhibit B
06/01/22	4.00	Minor changes. Corrected statement related to compounder changing sterile gloves to align with current practice and corrected a Header spelling error.	During Compounding 1.1
11/18/22	5.00	Annual review. Formatting and verbiage changes. Added additional steps for maintaining a temporarily and permanently inactive cleanroom. Added new Exhibit E.	Throughout and Exh E
03/17/23	6.00	Minor formatting and verbiage changes. Added that use of non-formulary cleaning and disinfection agents must be approved by Coram Quality and Patient Safety. Added reference to policy SAF-045 for information on Safety Data Sheets. Removed instruction to dismantle all compounding pumps at the end of the day. Updated Exhibit B.	Throughout and Exh B
03/11/24	7.00	Annual review, minor formatting changes. Changed cleaning of drip trays/spill trays in both vertical and horizontal hoods to monthly with Peridox RTU-HC. Removed references to HC360. Added hyperlinks and updated Definitions.	Throughout
03/10/25	8.00	Annual review, updated BPO, minor formatting changes and removed link to the Forms page. Changed	Throughout and Exhs A-D

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		ThermoFisher to Digi SmartSense throughout policy and exhibit B. Minor formatting changes to exhibits A, C and D.	

EXHIBIT(S):

Exhibit A: Cleaning Procedures Competency Checklist - Epic (I305-010 Epic Exh A)

Exhibit B: Cleaning Activity and Dilution Grid - Epic (I305-010 Epic Exh B)

Exhibit C: Disinfectant Activity and Contact Time - Epic (I305-010 Epic Exh C)

Exhibit D: Cleaning Procedures Competency Checklist Negative Pressure Room/BSC Addendum - Epic (I305-010 Epic Exh D)

Exhibit E: Cleanroom Closure Signage - Epic (I305-010 Epic Exh E)

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CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

License No. PHY 51896
Receipt No. 00197526

Valid Until: 5/1/2026

CORAM CVS/SPECIALTY INFUSION SERVICES
12310 WORLD TRADE DR, SUITE 100
SAN DIEGO, CA 92128-3793

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

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FORM WPHPHY (09/30/19) PHY

CALIC100.RENWALR.031002025.47207.SEQID2568

CORAM CVS/SPECIALTY INFUSION SERVICES
12310 WORLD TRADE DR, SUITE 100
SAN DIEGO, CA 92128-3793 2568

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 51896

NAME: CORAM CVS/SPECIALTY INFUSION SERVICES
LICENSE TYPE: PHARMACY (COMMUNITY)
LICENSE STATUS: CLEAR
ADDRESS
12310 WORLD TRADE DR, SUITE 100
SAN DIEGO CA 92128-3793
SAN DIEGO COUNTY

ISSUANCE DATE
MAY 17, 2014
EXPIRATION DATE
MAY 1, 2026
CURRENT DATE / TIME
MAY 14, 2025
11:30:29 AM

LICENSE RELATIONSHIPS

NAME: CORAM CVS/SPECIALTY INFUSION SERVICES
LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY
LICENSE NUMBER: 100594
PRIMARY STATUS: CLEAR
ADDRESS :
12310 WORLD TRADE DRIVE SUITE 100
SAN DIEGO CA 92128-3793
SAN DIEGO COUNTY

NAME: NAHANGI, AMIR ALEXANDER
LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST
LICENSE NUMBER: 79162 **PRIMARY STATUS:** CLEAR
ADDRESS NOT DISCLOSED

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FH9798159
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☒ Non-sterile Compounding
			☒ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Hillstone Pharmacy

Physical Address: 9947 Kingston Pike

City: Knoxville State: TN Zip: 37922

Mailing Address (if different from physical address): Same as physical address.

City: _____ State: _____ Zip: _____

Telephone: 865-909-9713 Toll Free # (NAC 639.708, NRS 639.23286): 833-778-9713

Fax: 865-909-9397 Contact Email: randym@hillstonepharmacy.com

Website: https://www.hillstonepharmacy.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): David Randall (Randy) Martin

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Stuart Tolman	NV Pharmacist Registration #: 10916
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Tennessee

Parent Company (if any): Arena Compounding TN, LLC

Corporation/Organization Name: Randy Martins Health and Wellness, LLC

Mailing Address: 9947 Kingston Pike

City: Knoxville State: TN Zip: 37922

Telephone: 865-909-9713 Email: randym@hillstonepharmacy.com

Contact Person Name: David Randall (Randy) Martin

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO/Managing Pharmacist (title) for Hillstone Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

David Randall Martin

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/29/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Randall Martin

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

David R Martin — 4/29/25

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 6/23/25	Amount: $500-ck 1000002167

Randy Martins Health and Wellness, LLC		
dba Hillstone Pharmacy		
9947 Kingston Pike, Knoxville, TN 37922		
Owner/Officer List		
Name	**Title**	**Address**
David Randy Martin	Chief Executive Officer, Randy Martins Health and Wellness, LLC	9947 Kingston Pike, Knoxville, TN 37922
Jack Feldman	Chief Growth Officer, Randy Martins Health and Wellness, LLC	9947 Kingston Pike, Knoxville, TN 37922
Randy Martins Health and Wellness, LLC	Owner	9947 Kingston Pike, Knoxville, TN 37922
Arena Compounding TN, LLC	Parent Company	9947 Kingston Pike, Knoxville, TN 37922

Division of Business and Charitable Organizations
Department of State
State of Tennessee
312 Rosa L. Parks Avenue, 6th Floor
Nashville, Tennessee 37243
Phone: 615-741-2286
sos.tn.gov/

Tre Hargett
Secretary of State

MELISSA LESLIE
305 SE CHKALOV DR, SUITE 111-422
VANCOUVER, WA 98683, USA

04/08/2025

Request Type: Certificate of Existence/Authorization

Issuance Date: 04/08/2025

Request #: C2025021152

Document Receipt

Order Number: C2025021152

Verification #: 60AD0E83

Receipt #: 2025-260639

Filing Fee: $20.00

Payment: Credit Card - 3895895078 $20.00

Entity Name:	RANDY MARTINS HEALTH AND WELLNESS LLC		
SOS Control #:	001022643	Initial Filing Date:	04/10/2019
Entity Type:	Limited Liability Company (LLC)	Formation Locale:	TENNESSEE
Status:	Active	Duration Term:	Perpetual
Fiscal Year Close:	December	Annual Report Due:	04/01/2026
Business County:	KNOX		
Managed By:	Member Managed		
Obligated Member Entity:	No		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

RANDY MARTINS HEALTH AND WELLNESS LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;
* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;
* has filed the most recent annual report required with this office;
* has appointed a registered agent and registered office in this State;
* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Verification #: 60AD0E83

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Hillstone Pharmacy

Pharmacy/Wholesaler License # (if applicable): Pending

Physical Address: 9947 Kingston Pike

City: Knoxville State: TN Zip: 37922

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 865-909-9713 Website: https://www.hillstonepharmacy.com/

Licensing Company Email: randym@hillstonepharmacy.com

Section 2: Personal Information

First: Stuart Middle: Elliott Last: Tolman

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: TN Zip: [redacted]

Telephon[redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	City	From - To (MM/YY – MM/YY)	State	Zip
Long Island Univeristy, College of Pharmacy	Brooklyn	09/75 - 06/81	NY	11201
Address: 75 DeKalb Ave				
Diploma/Degree obtained, if any: B.S Pharm.				
Evander Childs High School	Bronx	09/72 - 01/75	NY	10467
Address: 800 East Gun Hill Road				
Diploma/Degree obtained, If any: H.S. Diploma				
N/A				
Address	City		State	Zip
Diploma/Degree obtained, If any				
N/A				
Address	City		State	Zip
Diploma/Degree obtained, If any				
N/A				
Address	City		State	Zip
Diploma/Degree obtained, If any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/24 - Present	[redacted]			
09/17 - 10/24				
06/17 - 09/17				
02/17 - 06/17				
09/98 - 02/17				
N/A				
N/A				
N/A				
N/A				
N/A				

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Hillstone Pharmacy (formerly Heartland Apothecary)			03/25 - Present
Business Address	**City**	**State**	**Zip**
9947 Kingston Pike	Knoxville	TN	37922
Phone	**Title**		**Number of Employed Hours**
865-909-9713	Pharmacist in Charge		Full time

Description of Duties
Final check prior to dispensing, regulatory issues, verify formulations, physician consultations.

Business Name			From - To (MM/YY – MM/YY)
BioHealth Rx			12/24 - 03/25
Business Address	**City**	**State**	**Zip**
15340 Vantage Pkwy E	Houston	TX	77032
Phone	**Title**		**Number of Employed Hours**
866-719-4295	Pharmacist in Charge		Full time

Description of Duties
Verify and compound sterile products, verify sterile formulations, clinic consultations, hire and certify personnel, regulatory issues, set up clean rooms.

Business Name			From - To (MM/YY – MM/YY)
CVS			11/23 - 12/24
Business Address	**City**	**State**	**Zip**
570 HIGHWAY 321 NORTH	LENOIR CITY	TN	37771
Phone	**Title**		**Number of Employed Hours**
865-986-6563	Full Time floater pharmacist		Full time

Description of Duties
Verify and dispense prescriptions, patient consultation, administer vaccinations, prescriber consultation.

Business Name			From - To (MM/YY – MM/YY)
CVS			11/23 - 12/24
Business Address	**City**	**State**	**Zip**
1220 US-321	Hickory	NC	28601
Phone	**Title**		**Number of Employed Hours**
828 -324-7171	Full Time floater pharmacist		Full time

Description of Duties
Verify and dispense prescriptions, patient consultation, administer vaccinations, prescriber consultation.

Business Name			From - To (MM/YY – MM/YY)
Genixus			10/22 - 11/23
Business Address	**City**	**State**	**Zip**
150 N Research Campus Dr	Kannapolis	NC	28081
Phone	**Title**		**Number of Employed Hours**
877-436-4987	Pharmacist In Charge		Full time

Description of Duties
Supervised sterile syringe filling, regulatory issues and review of batch records.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Allivet Pet Pharmacy			12/20 - 10/22
Business Address	**City**	**State**	**Zip**
9894 E 121st St	Fishers	IN	46037
Phone	**Title**	**Number of Employed Hours**	
877-500-9944	Staff Pharmacist	Full time	

Description of Duties

Verified prescriptions both on site and remotely. Owner consultation and set up workflow in regards to use of new Parata machine system.

Business Name			From - To (MM/YY – MM/YY)
Nephron 5038 Compounding Pharmacy			04/17 - 10/22
Business Address	**City**	**State**	**Zip**
12th Street Extension	West Columbia	SC	29172
Phone	**Title**	**Number of Employed Hours**	
803-462-5005	Pharmacist In Charge	Full time	

Description of Duties

Supervise 503b compounding and clean room, regulatory concerns in regards to licensing, supervise registered and certified technicians.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Make copies of this page OR use a separate piece of paper if additional space is needed.

2421

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Stuart Tolman, **certify that as the designated representative for**

Hillstone Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Stuart Tolman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12 June 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Stuart Tolman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12 June 2025
Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Knox

I, Stuart E. Tolman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12 June 2025
Date

Subscribed and Sworn to before me this 12 day of June 2025.

Notary Public Signature

FARIMAH BEHZADI
STATE OF TENNESSEE NOTARY PUBLIC
KNOX COUNTY
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Hillstone Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): Pending

Physical Address: 9947 Kingston Pike

City: Knoxville State: TN Zip: 37922

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 865-909-9713 Toll Free # (NAC 639.708, NRS 639.23286): 833-778-9713

Fax: 865-909-9397 Contact Email: randym@hillstonepharmacy.com

Website: https://www.hillstonepharmacy.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): David Randall (Randy) Martin

Supervising/Managing Pharmacist NV Pharmacist Registration #: N/A

Name of Designated Person(s) as defined by revised USP-797 guidelines: Stuart Tolman

Email of Designated Person(s): setrph@gmail.com

Telephone of Designated Person(s): 561-302-4968

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ■ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? April 2025

6. What is the frequency of the recertification for the ISO classified areas? 6 months (will go to 3 months once start cat 3)

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? weekly

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Testosterone
NAD
Sermorelin
Ascorbic Acid
Glutathione
Methylcobalamin
Trimix

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL

Address: 840 Research Pkwy #546

City: Oklahoma City State: OK Zip: 73104

Telephone: 4052711144

13. What is your procedure for visual inspection of compounded sterile products?

The visual inspection of compounded sterile products (CSPs) requires a qualified individual to check the final preparation for particulates, discoloration, or defects, and to ensure the container is intact with no leaks or cracks. The label must match the prescription. If the CSP is not dispensed the same day, another inspection is required before release. Any CSP that fails inspection must be rejected and separated from usable stock

14. How often do you perform glove fingertip and medial fill testing?

Currently every 6 months but will be moving to every 3 months once we begin category 3 compounding

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Our training program for sterile compounding personnel follows USP <797> and includes initial instruction on aseptic technique, hand hygiene, garbing, cleaning, and equipment use. Personnel must demonstrate competency through gloved fingertip and media-fill testing before compounding independently. Ongoing training and competency assessments are performed at least every 12 months, with gloved fingertip and media-fill testing and every 3 months.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Our cleaning procedure uses Peridox as a sporicidal agent and disinfectant, and sterile 70% isopropyl alcohol (IPA) as a disinfectant. Primary engineering controls are cleaned and disinfected with Peridox and IPA at the start of each shift, before each batch, every 30 minutes during compounding, after spills, and at the end of compounding; Peridox is used as a sporicidal at least monthly (weekly once we start category 3). Secondary engineering controls (buffer and ante-rooms) are cleaned daily with Peridox and IPA, with floors cleaned daily and walls, ceilings, and shelving cleaned monthly (weekly when we start cat 3) or when soiled. All procedures follow USP <797> (2022 revision) and are documented per SOPs.

17. Who performs the sterile compounding process at your facility?

Trained pharmacist and technicians

18. Who is responsible and accountable for the sterile compounding process at your facility?

Ashley Cunningham and Randy Martin

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

We have conducted simulated tests with incubators and had help from Fedex to test our shipping methods to make sure required temperatures are maintained throught entire shipment.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? BSC: Nuaire and Germfree		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Patients or consumers receiving hazardous drug (HD) products or containers are provided with clear instructions on proper handling and disposal to minimize exposure risks. This information includes guidance to avoid direct contact with the medication and its packaging, the use of gloves when handling HD products if appropriate, and instructions to wash hands thoroughly after handling. Patients are advised not to crush, split, or open HD tablets or capsules unless specifically instructed by their healthcare provider. For disposal, patients are informed not to throw HD products or containers in household trash or flush them down the toilet. Instead, they are directed to return unused medication and containers to the pharmacy or a designated take-back program, following local regulations. Educational materials, such as pamphlets or written instructions, are provided to reinforce these safety measures. This approach aligns with USP <800> requirements and best practices for patient safety and environmental protection.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Our initial process for training new employees prior to compounding sterile hazardous drugs follows USP <797> and USP <800> requirements. New employees receive comprehensive instruction on hazardous drug handling, including review of safety data sheets, proper use of personal protective equipment, hand hygiene, garbing, and aseptic technique. Training covers safe receipt, storage, transport, compounding, and disposal of HDs, as well as cleaning, decontamination, and spill management procedures. Employees must demonstrate competency through written assessments and hands-on evaluations, including successful completion of gloved fingertip and thumb sampling and media-fill testing. All training is documented, and employees must be supervised until they have demonstrated proficiency in all required skills.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

As of now we only intend to compound testosterone under Category 3 sterile products

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Every 3 months

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

Monthly

5. What is the frequency for completing surface sampling? At least weekly		
6. What is the frequency for using sporicidal agents? At least weekly		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Randall Martin

Name of Person who Completed the Form

Pharmacist-in-Charge and Chief Executive Officer

Title

Signature (copies or stamps not accepted)

4/29/25

Date

Board Use Only	Date Received: 6/23/25 Date Approved: _____ Approved By: _____

TENNESSEE DEPARTMENT OF HEALTH
HILLSTONE PHARMACY

ID NUMBER: 4499

EXPIRATION DATE: 03/31/2027

THIS IS TO CERTIFY THAT ALL REQUIREMENTS OF THE STATE OF TENNESSEE
HAVE BEEN MET
BOARD OF PHARMACY
PHARMACY
ALL APPLICABLE QUALIFICATIONS AND/OR SPECIALTIES PRINTED ON BACK.

COMMISSIONER OF HEALTH

HILLSTONE PHARMACY
9947 KINGSTON PIKE
KNOXVILLE, TN 37922

State of Tennessee
Department of Health

14682605

Renewal No. 59518

Board of Pharmacy
Pharmacy

HILLSTONE PHARMACY
9947 KINGSTON PIKE,
KNOXVILLE, TN 37922

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 4499

EXPIRATION DATE: March 31, 2027

CONTROLLED SUBSTANCE REGISTRATION
STERILE COMPOUNDING

Commissioner, Dept. of Health

Assistant Commissioner, Health Licensure & Regulation

Last Updated: 6/21/2025

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy
County = All
Results = 1

Click here to return to the search page

1

Hillstone Pharmacy
9947 Kingston Pike
Knoxville, TN 37922
865-909-9713

Qualifications
Controlled Subs, Sterile Compoun

Pharmacist: MARTIN, DAVID R

Facility License Number: 00004499
Status: Licensed
Date of Original Licensure: 09/29/2008
Date of Expiration: 03/31/2027
No Disciplinary Actions

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FH9798159	10-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	09-11-2023

HILLSTONE PHARMACY
9947 KINGSTON PIKE
KNOXVILLE, TN 37922

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FH9798159	10-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	09-11-2023

HILLSTONE PHARMACY
9947 KINGSTON PIKE
KNOXVILLE, TN 37922

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Form DEA-223 (9/2016)

sterile

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY	Heartland Apothecary
STREET	9947 Kingston Pike
CITY	Knoxville
ZIP	37922
DATE OPENED	
TELEPHONE NO.	(865)909-9713
LICENSE NO.	4499
EXPIRY DATE	8/31/24
DEA NO.	FH9798159
EXPIRY DATE	10/31/24
PHARMACIST IN CHARGE/Duty	Randy Martin
LIC NO.	34265
EXPIRY DATE	7/31/24

Inspected by Shannon Kelly, Rebecca Meade — Date 6/6/24

This Inspection Satisfactory: Yes ☐ No ☒

☐ Opening ☐ Relocation ☐ New Ownership ☐ Follow-up ☐ Counseling Compliance ☒ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
✓		1. Appropriate identification/Name Tags
✓		2. D. Ph./Tech ration
✓		3. Personnel/apparel clean
✓		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
✓		5. Certificates Displayed
✓		6. RX Dept. – Sufficient Space/Counseling
✓		7. Fully enclosed when applicable
✓		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
✓		9. Dispensing area clean, orderly, well lighted
✓		10. Sink, hot and cold water
✓		11. Refrigeration
✓		12. References, periodicals
✓		13. Vials and closures (child-proof)
✓		14. Shelves and drug stock clean
✓		15. Drugs in-date
✓		16. Labels correct on repackaging
✓		17. Legend drugs stored in RX Dept.
✓		18. Syringes/insulin, restricted products non-accessible

Pharmacy Hours 9A-5P M-F

Compliance Yes	Compliance No	
✓		19. RXs numerically filed
NA		☐ All C's together ☐ C-11's separate ☐ Multiple file method
✓		20. Patients identifiable C3-5's & Non controls
✓		21. Prescribers identifiable
	✓	22. New verbal RXs initialed by appropriate personnel
✓		23. Date of original dispensing
✓		24. Initials of dispensing D.Ph.
		25. Quantity dispensed indicated
NA		26. Appropriate Emergency C-11 RXs
	✓	27. Computer labels applied appropriately to RXs
✓		(28) Pharmacist Signature Log
NA		29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
✓		(30) Authorization documented on Rx
✓		31. Manufacturer indicated on Rx or System
✓		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
✓		33. Patient profiles
✓		34. Drug Utilization Review
✓		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
✓		36. Readily retrievable
NA		37. All C-11 records separate
NA		38. DEA Form 222 Copy 3 on hand & completed
✓		39. Drug Receipt date on invoices
✓		40. Record of drug transfers
NA		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
		42. Last DEA Inventory (date) 1/19/23 2/23/23 (Hez NH)
✓		42. Last Theft/loss report (date) _____
NA		43. Access to Control Substance Monitoring Database
✓		

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** YES ☒ NO ☐

Immediately	22	28	30				
Needs Improvement	42						
Within 30 Days							

Remarks or Recommendations: (42) DEA Inventory must all be done on the same day. Make sure prescriber signature (not stamp) is on Rxs for control substances that are faxed or hard copy (28) All pharmacists working need to sign S.L. Log (30) Make sure to document who authorizes changes to Rx's for VO's at offices. NABP USP 797 inspection available for review.

I _____ Pharmacist Signature hereby acknowledge and understand all notations made on this report; and confirm that Make sure CS Rxs have patient physical Rx on it.
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

Follow-up to occur.

PH-4031 REV 01/18 RDA SW-30

Scanned with CamScanner

The National Association of Boards of Pharmacy (NABP) developed this inspection form for sole use by NABP and its member boards of pharmacy for inspection of facilities licensed by a member board. Disclosure of the form to or use of the form by a third party, other than a facility being inspected by NABP or a member board, is strictly prohibited without NABP's prior written permission or unless required by state law.

National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Heartland
e-Profile ID:
Inspection Date: 6/6/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)			
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."*** ***If no, go to compliance statements.***	Yes	Scotty Wyatt	1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Heartland
e-Profile ID:
Inspection Date: 6/6/2024

		Observation	Inspector Notes	USP Reference(s)
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes	continuous review.	2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, go to compliance statements.***	Yes		17
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).	Yes	Category 2	1.5

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		Observation	Inspector Notes	USP Reference(s)
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.	Yes		2, 2.2, 10 Box 1, Box 2, Table 2, Table 3
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***	Yes		3, 3.3
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.	Yes		4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.	Yes		5, 5.1

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2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.	Yes		6, 6.1, 6.2, 6.3
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.	Yes		7, 7.2 Box 7, Box 8
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.	Yes		9.1, 10, 20
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.	Yes		9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.	Yes		11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.	Yes		12, 18, 20

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		Observation	Inspector Notes	USP Reference(s)
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.	Unknown	identified absence of prescriber information on "Prescription Log Report". Field populated with "," only.	13
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.	No	unvalidated system of packaging.multiple methods of rx deliver to include patient pick-up, provider pick up, delivery, shipment over night.	19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***	Yes	Compounding records, RX logs were retrievable as requested	20
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***	N/A		10

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		Observation	Inspector Notes	USP Reference(s)
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***	N/A		1.3
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***	Yes		1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***	N/A		21
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived			1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use?	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.***	N/A		1.3
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	N/A		1.3
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	N/A		1.3
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	N/A		1.3
4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to the compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	N/A		1.4

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		Observation	Inspector Notes	USP Reference(s)
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	N/A		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	N/A		1.4
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only compounds sterile preparations (eg, does not prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	N/A		1.4
6.1	The product is prepared as a single dose for an individual patient.			1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.			1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	Yes	eye serum	1.1.2

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		Observation	Inspector Notes	USP Reference(s)
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	Yes		1.1.2
	Facility Design and Engineering Controls			**4**
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A		4.2.1, 4.2.3 Table 5
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	N/A		4.2.1 Glossary
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A		4.5
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	N/A		4.2.1, 4.3.2

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10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? *Inspector note: this is a recommendation by USP.* *If no, describe in comments Inspector Notes (eg, peeling of Formica countertops).*	Yes		4.3.2
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? *Inspector note: this is a recommendation by USP.* *If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).*	Yes		4.2.1, 4.3.2
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? *Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.* *If no, go to compliance statements.* *If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.*	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5
12.1	Access to the cleanroom suite is restricted to authorized personnel. *Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.*	Yes	Approved personnel list posted on exterior doors of all rooms	4.2.1

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12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes	humidity is not well controlled. FOLLOW-UP	4.2.1
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	N/A		4.1.2, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes		4.1.2, 4.2.1, 4.2.3
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	Yes		4.2.1
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	Yes	Performed today, observed by Moak	4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	Yes	Thin black permanent marker	4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	N/A		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes		4.2.1, 4.3.1
12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	N/A		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes		4.2.1, 4.3.1

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12.20	If overhangs or ledges are present, they are easily cleanable. *If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.*	Yes		4.2.1, 4.3.1
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? *Inspector to review certification reports and observe compounding area(s) to evaluate.* *If no, go to compliance statements.*	Yes	ISO 7 buffer	4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2

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Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Heartland
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		Observation	Inspector Notes	USP Reference(s)
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes	10/23, 4/24, retest today with addition of 2 PECs	4.2.2, 4.2.3, 5
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes		4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3
13.5	**Category 2 and Category 3**: PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.2.3 Table 5

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		Observation	Inspector Notes	USP Reference(s)
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3 Table 5
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3

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		Observation	Inspector Notes	USP Reference(s)
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** ***If no, go to compliance statements.***	Yes		4.5
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes		4.5
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		4, 9.1, 19.1

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		Observation	Inspector Notes	USP Reference(s)
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	N/A		4.4
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	Yes		4.4

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		Observation	Inspector Notes	USP Reference(s)
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	Training.	4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	N/A		4.2.1
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected.*** ***If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes		4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes		4.2.1
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	Yes		4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	N/A		4.5

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		Observation	Inspector Notes	USP Reference(s)
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***	No	Humidity is not well controlled. FOLLOW-UP	4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	No	Humidity is not well controlled. FOLLOW-UP. Dehumidifer located in adjacent unclassified space.	4.2, 9.3.4, 19.1
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	Data Logger with notification to staff-calibration certificates not available.	4.2, 9.3.4, 19.1
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes	Data Logger with notification to staff-humidity not consistently maintained below 60%. Installation of dehumidifier scheduled. FOLLOW-UP	4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes		4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes		4.2, 9.3.4, 19.1
18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb.*** ***CRT is defined as 20°C-25°C per USP <659>.***	Yes	Drugs stored in cleansuite do not have humidity restrictions per labeling with tightly closed lid (non-sterile APIs).	4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	No	not calibrated/traceable	4.2, 9.3.4

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		Observation	Inspector Notes	USP Reference(s)
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	No	not nist calibrated/traceable	4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	Yes		4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	No		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	Yes	69.7 degrees F	4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	Yes	70%-dehumidifier to be installed this month-FOLLOW-UP	4.2, 9.3.4, 19.1
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	No	see notes above	4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***If no, go to compliance statements.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***	Yes		4.2.1, 4.2.5, 5
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	Yes		4.2.1, 4.2.5, 5
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	Yes	0.2 inches WC buffer to ante , ante to GP 0.1 " WC. Magnehelic gauges not calibrated.	4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes		4.2.1, 4.2.5, 5
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	No		4.2.5
27.0	Does the facility perform both sterile and nonsterile compounding?	Yes		4.2.1

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28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	Yes		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	N/A		4.2.1, 4.2.6
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	N/A		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	Yes		4.2.1
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	Yes		4.2.1
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes	Cat 2	4.2.1, 4.2.6

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31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? *If no, go to compliance statements.*	Yes		4.2.6
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). *Inspector note: This statement only applies for Category 2 and Category 3.*	Yes		4.2.6
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. *Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.*	No		4.2.6
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? *If no, go to compliance statements.* *Inspector is to review current certification reports.*	Yes	Email reports for todays certification as FOLLOW-UP	5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes		4.2, 5, 20
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 5

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		Observation	Inspector Notes	USP Reference(s)
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes	PECs X 2 installed this week. Testing performed day 2 of inspection.	5
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes	Recommend DP initial reports when reviewed.	4.2, 5
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.2.3, 5
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4

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32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.1.1, 4.1.2, 5.1 Table 4
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***	Yes	.comprehensive smoke studies performed during inspection day 2.	5, 20

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33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes		5.1, 6.1, 20
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	Yes		5
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	Yes	Steris paragraph at end of the report.	5, 20

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		Observation	Inspector Notes	USP Reference(s)
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH)**. ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	Yes	23 ACH	4.2.4, 5 Table 6
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	N/A		4.2.4, 5 Table 6
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	Yes		4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes	0.2 inches WC buffer to ante , ante to GP 0.1 " WC	4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	Yes		5
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A	No repairs.	5
33.12	**PEC:** (**Dynamic airflow**) **Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	Yes	reviewed 4/24 digital recording- be sure to record smoke test across more comprehensive area inside PEC. Day 2 R. Moak present during testing. More comprehesive evaluation completed.	4.2.2, 4.2.3, 5

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		Observation	Inspector Notes	USP Reference(s)
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. *Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."*	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1
33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. *Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."*	Yes		5, 5.1
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). *Inspector note: The certification report for each PEC should show air velocities within the PEC.*	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. *If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).* *If no repairs were needed, inspector should answer statement as N/A.*	N/A	No repairs.	5
33.17	**PEC-IVLFZ**: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. *Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."* *If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.*	N/A		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3
34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	Yes	Will need to be performed with addition of new equipment.DAY 2 of inspection smoke testing performed.	5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***	No	Established program. Monthly surace sample processes do not meet standard of single media (TSA) incubation at two temperature ranges. COAs not available.	6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes	See notes above	6, 6.1, 6.2
35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		6, 6.1, 6.2
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	No	Installation and certification during inspection window. EM To be performed immediately.FOLLOW-UP	6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes	would	6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	No	not currently "trending" results. Growth within limits ante and buffer last two VA sampling	6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	Yes	retraining and documenting for surface sample collection, incubation, documentatin. Positive Control results need to be recorded.FOLLOW-UP	6, 6.1, 6.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Unknown		6.1, 6.3

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		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	Yes		6.2.2
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	No	internally processed surface samples. Outside Q6 months in conjunction with certification	6.3
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab.*** ***If no, describe observations.***	Yes		6.2.2

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		Observation	Inspector Notes	USP Reference(s)
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to the compliance statements.***	Yes		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	Yes		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes		6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes	TSA ,	6.2.2 Box 5
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 6
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	Yes		6.2.3 Table 7
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	N/A		6.2.3

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40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to the compliance statements.***	No	Incubation of Surface Samples internally not performed with dual temperatures. Ovservations and temperatures no recorded daily.	6.3
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	N/A		6.3, 6.3.1

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		Observation	Inspector Notes	USP Reference(s)
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes	MONTHLY sampling is performed. Sampling is not complete. See notes above. FOLLOW-UP	6.3, 6.3.1, 14.4.2
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes		6.3.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	No	See notes above	6.3.2 Box 6
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.3.2 Box 7

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41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	Yes		6.3.3 Table 8
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	N/A	none exceeded	6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	N/A		6.3.3
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes	Posting	3.1

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42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	Yes		3, 3.1
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	Yes		3, 3.1
42.3	Any accommodations permitted by the designated person(s) are documented.	N/A		3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes		3.1
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3

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43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		3.3
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. *If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.*	Yes		3.3

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	N/A		3.3
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3

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		Observation	Inspector Notes	USP Reference(s)
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? *Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."* *If no, go to compliance statements.*	Yes	Review process to confirm "most challenging" with consideration of length of process, time of day, # of transfers, personnel in room	2.3
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Unknown	see notes above	2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	Yes	Suggest review	2.3, 20
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	No	COA's not maintained.	2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	No	see notes above	2.3

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		Observation	Inspector Notes	USP Reference(s)
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	Yes	Review process to confirm "most challenging" with consideration of length of process, time of day, # of transfers	Box 2
	Cleaning and Disinfection			7

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		Observation	Inspector Notes	USP Reference(s)
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? *If no, go to compliance statements.*	Yes		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint.	Yes		7.1.2
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes		7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes		7.1.2
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. *Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.* *Per USP, Inspector should check to see if agent is effective against Clostridium difficile.*	Yes		7.1.1 Box 7 <1072>

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		Observation	Inspector Notes	USP Reference(s)
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes		7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes		7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" formulations are diluted using sterile water. ***If only ready-to-use formulations are used, inspector should answer statement as N/A.***	Yes		7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2 Table 10
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	N/A		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	N/A		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2, 14.4.2 Table 10
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	N/A		7.2 Table 10
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes		7.2 Table 10
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		4.4, 7.2 Table 10
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
	Components			9
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.***	Yes		9.3
50.1	**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	Yes		9.3.1
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	Yes		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. *Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.*	Yes		9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	Yes		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	Yes		9.3.1
50.6	All **non-API components** used are manufactured by an FDA-registered facility. *Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."*	Yes		9.3.1

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51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	Yes		9.3.2, 9.3.3
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	Yes		9.3.2, 9.3.3
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	Yes		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	Yes		9.3.1, 9.3.2, 9.3.3

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51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	Yes		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	Yes		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	Yes		9.3.2, 9.3.3
	Equipment and Supplies			9

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		Observation	Inspector Notes	USP Reference(s)
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. *Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).*	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes	utilize sterile supplies. Autoclave and oven not utilized.	9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. *Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.*	Yes		9.1

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Heartland
e-Profile ID:
Inspection Date: 6/6/2024

		Observation	Inspector Notes	USP Reference(s)
52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	Yes	filtered	9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes		9.1, 9.3.4

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		Observation	Inspector Notes	USP Reference(s)
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	No		9.1
53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes		6.1, 6.2.2, 6.3.2
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes	not documenting daily temps (min max during incubation cycle) thermometer not calibrated	6.2.2, 6.3.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1
54.2	Makeup and/or cosmetics are removed.	Yes		3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes		3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. *If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.*	Yes		3.1
54.9	Any accommodations permitted by the designated person(s) have been documented. *Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.*	N/A		3.1
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. *Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.*	Yes		3.2 Box 3

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		Observation	Inspector Notes	USP Reference(s)
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2 Box 3
55.6	Soap containers are not refilled or topped off.	Yes		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes		3.2 Box 3
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	Yes		3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA.	Yes		3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***	Yes		3.3
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing).*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	Yes		3.3
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.		mocked up transers and filtering DAY!, autologous eye serem 25% DAY 2.	
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		1, 2.1, 2.3

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		Observation	Inspector Notes	USP Reference(s)
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes		8.1

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		Observation	Inspector Notes	USP Reference(s)
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	Yes		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to compliance statements.***	Yes		15
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	Yes		15.1, 16.2

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		Observation	Inspector Notes	USP Reference(s)
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	Yes		14.5, 15.2, 16.1
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	Yes		15.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	Yes		15.3

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		Observation	Inspector Notes	USP Reference(s)
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates). These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes		2 Table 2, Table 3

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		Observation	Inspector Notes	USP Reference(s)
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? *If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."* *If no, go to compliance statements.*	Yes	discussion with technician responsible for cleaning	7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes		7
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes		7.1.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. *Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."*	Yes		7.1.1, 7.1.2
62.6	Only sterile supplies and equipment are permitted for use in the PEC. *Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.*	Yes		7.1.1, 7.1.2

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		Observation	Inspector Notes	USP Reference(s)
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning.*** ***Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7

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		Observation	Inspector Notes	USP Reference(s)
	Sterilization and Depyrogenation			**10**
63.0	Does the pharmacy compound preparations with any nonsterile starting components?	Yes		10
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? *If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.* *If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.*	Yes		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? *View compounding records for CSPs sterilized by filtration to verify.* *Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.* *If no, go to compliance statements.* *If the pharmacy does not use this sterilization method, inspector should answer question as N/A.*	Yes		10.2 USP <1229.4>

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		Observation	Inspector Notes	USP Reference(s)
65.1	Sterilization by filtration is performed in an ISO 5 environment.	Yes		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	Yes		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. ***Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."***	Yes		10.2
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2

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		Observation	Inspector Notes	USP Reference(s)
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	N/A		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	Yes	No failed filters in last 12 months.	10.2
65.7	Single-use filters are only used once.	Yes		4.1.2, 10.2

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.3 USP <1229.1>
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	N/A		10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	N/A		10.3
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.3

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		Observation	Inspector Notes	USP Reference(s)
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	N/A		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	N/A		10.3
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	N/A		10.3 USP <1229.5> USP <1229.9>

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		Observation	Inspector Notes	USP Reference(s)
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	N/A		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	N/A		10.3, 20
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.4 USP <1229.8>

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		Observation	Inspector Notes	USP Reference(s)
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	N/A		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	N/A		10.4
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	N/A		10.4
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	N/A		10.4 USP <1229.5>

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		Observation	Inspector Notes	USP Reference(s)
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	N/A		10.4, 20
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***	N/A		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	N/A		10.1
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	N/A		10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	N/A		10.1 USP <1228.4>

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		Observation	Inspector Notes	USP Reference(s)
	Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**			**11**
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to A14compliance statements.***	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes		11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	Yes		11.2 Box 10
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	N/A	no immediate use CSPs	11.2 Box 10
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include…Calculations."***	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	No	FOLLOW-UP	13 USP <7>
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	No		13
71.2	Labeling meets any state or federal regulatory requirements.	No		13

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		Observation	Inspector Notes	USP Reference(s)
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	No	incomplete ingredients	13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	No		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes	states date only	13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	No		13
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes	Does not indicate single dose or multi dose	13

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		Observation	Inspector Notes	USP Reference(s)
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	No		13
71.12	Labeling includes the route of administration, as applicable.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	No		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	No	not on immediate container	13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	Unknown		13 USP <7>
	Establishing BUDs			**14**
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3

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73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 12
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, Table 13

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73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		14.3
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	N/A		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	Yes		14.3 Table 14
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3 Table 15
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	N/A		14.4.1 Table 14
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14

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		Observation	Inspector Notes	USP Reference(s)
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	N/A		14.4.3 Table 14 USP <1225>
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	N/A		14.4.4 Table 14 USP <71>
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	N/A		12.3, 14.4.4 Table 14 USP <85>
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	N/A		14.4.3 Table 14 USP <788>, <789>
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	N/A		14.4.3 Table 14 USP <1207>

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		Observation	Inspector Notes	USP Reference(s)
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? *If no, go to compliance statements.* *If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.*	Yes		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	Yes		14.5
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	Yes	phenol-semiglutide	14.5

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		Observation	Inspector Notes	USP Reference(s)
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	Yes		14.5 USP <51>

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		Observation	Inspector Notes	USP Reference(s)
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	Yes		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	Yes		14.5 USP <1207>
	Finished Preparation Release Checks and Tests			**12**
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***	Yes		12.2, 14.2.3 USP <71>
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	Yes		12.2, 14.2.3

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		Observation	Inspector Notes	USP Reference(s)
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	N/A		12.2 USP <71>, <1223>
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented."*** ***Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	Yes	No failures in last 12 months	12.2

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		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	N/A		12.3 USP <85>
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	N/A		12.3

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		Observation	Inspector Notes	USP Reference(s)
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. *If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.*	N/A		12.3
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. *Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.*	N/A		12.3 Table 13 USP <85>
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	N/A		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. *View testing records and note any products with failed results and actions taken.*	N/A		12.2, 12.3
	CSP Packaging, Shipping and Transport			**19**
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? *If no, go to compliance statements.*	No		19.1, 19.2, 19.3

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		Observation	Inspector Notes	USP Reference(s)
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Unknown	no validation information available for packaging- FOLLOW-UP	19.2
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes		19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Unknown	Overnight delivery via carriers, clinic personnel pick up. Again, no validated studies	19.3
	Quality Assurance and Quality Control			18
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18 USP <1163>

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		Observation	Inspector Notes	USP Reference(s)
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	No	verbally reviewed. Please provide procedure as FOLLOW-UP	18.1, 18.2
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes	Incomplete patient contact information, dispensing logs have gaps with "," as physician-FOLLOW-UP	18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***	No		18, 20

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		Observation	Inspector Notes	USP Reference(s)
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Unknown		18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Unknown	complaints not currently documened. Staff education required-FOLLOW-UP	18.2, 20
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Unknown	Review reporting and documenting with all staff. Confirm with follow-up.	18.2, 18.3, 20

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		Observation	Inspector Notes	USP Reference(s)
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	No		18.2, 20
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes		18.1, 18.2

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		Observation	Inspector Notes	USP Reference(s)
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to compliance statements.***	Yes		18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	Yes	There is a process; however, several instances of incompolete patient and prescriber information noted.	18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	Yes		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	Yes		18.1
	Personnel Training and Evaluation - **Verify records of all compounding personnel (up to 10).** **Use the records tab to document records reviewed.**			**2**

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		Observation	Inspector Notes	USP Reference(s)
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? *Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.* *If no, refer to the records review worksheet (columns G-J) for details.*	No	Initial GFT/MF not available.JS not qualified with 3 initial and RM GFT/MF just overdue.	2.2, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? *Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.* *If no, refer to the records review worksheet (columns K-O) for details.*	Yes		2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? *Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.* *If no, refer to the records review worksheet (columns P-S) for details.*	Yes		2, 2.1, 17 Table 2, Table 3

Prescriptions for a Log Report

For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

Formula: SEMAGLUTIDE/L-CARNITINE 2.5MG/50MG/ML INJ

Generic Name: SEMAGLUTIDE/L-CARNITINE 2.5MG/50MG/ML INJ

Schedule	Date Made	Lot Number	Qty Made	Qty Remaining	Exp. Date
L	06/13/2024	06102024%16 110 @13	500	0	07/28/2024

Pharmacist: Martin, Randy
Technician: McGill, Patsy

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
654503	06/21/2024	2 ML	KELLER, KENDALL DAWN	HEIDEL, WENDY	2
	Patient Info:	418 S GAY ST KNOXVILLE, TN 37902			
	Rx Status:	Dispensed		Patient # 8659193713	
654933	06/18/2024	2 ML	THUMMA, COURTNEY	MEYER, MINDY	2
	Patient Info:	2467 CLINGING VINE LANE KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient # 8656596851	
656414	06/18/2024	2 ML	EAGIN, LINDSAY	GLENN, JENNIFER	2
	Patient Info:	5819 RHYNE COVE LN KNOXVILLE, TN 37931			
	Rx Status:	Dispensed		Patient # 8652564474	
657000	06/17/2024	2 ML	MARROW, CAITLYN	LUTTRELL, DOUGLAS	2
	Patient Info:	251 Highland Dr HARRIMAN, TN 37748			
	Rx Status:	Dispensed		Patient # (702)-683-3979	
657943	06/17/2024	2 ML	WILKINSON, CAREN	DESCAMPS, PEGGY	2
	Patient Info:	2517 WINDJAMMER LANE KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # 8653843171	
658292	06/21/2024	2 ML	ROUSE, AMANDA	CARROLL, JOHN	2
	Patient Info:	7934 Juneau Lane KNOXVILLE, TN 37931			
	Rx Status:	Dispensed		Patient # (865)-924-9316	
660053	06/17/2024	2 ML	KRONK, PHIL	BROOKS, GEORGE	2
	Patient Info:	956 BLUFF VIEW RD KNOXVILLE, TN 37919			
	Rx Status:	Dispensed		Patient # 8659714612	
662523	06/17/2024	4 ML	KIRK, MICHAEL	LESTER, KAREN	4
	Patient Info:	7125 HARREL RD KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient #	

Prescriptions for a Log Report

For Lot Number: 06102024%16110 @13

Heartland Apothecary
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Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
662524	06/17/2024	4 ML	KIRK, MELISSA	LESTER, KAREN	4
	Patient Info:	7123 HARRELL RD KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient #	
663519	06/17/2024	4 ML	OVERTON, ASHLEY	DESCAMPS, PEGGY	4
	Patient Info:	1521 HOLMAN DR KNOXVILLE, TN 37909			
	Rx Status:	Dispensed		Patient # 8656802040	
664062	06/16/2024	2 ML	HARDEN, BROOKE	MCMILLAN-BUCHANAN, GINGER	2
	Patient Info:	253 RD 1199 PLANTERSVILLE, MS 38862			
	Rx Status:	Dispensed		Patient # 6623225513	
664089	06/19/2024	2 ML	RASNAKE, DOUG	SELLERS-MOONEY, DEBORAH	2
	Patient Info:	206 PRUNER ST LEBANON, VA 24266			
	Rx Status:	Dispensed		Patient # 2766984272	
664351	06/17/2024	2 ML	OLSEN, KIM	SCHOENTHALER, AMY	2
	Patient Info:	708 trail ridge dr MARYVILLE, TN 37803			
	Rx Status:	Dispensed		Patient # 8653635961	
664602	06/17/2024	4 ML	BRITTS, ALLISON	MATHIS, EMILY	4
	Patient Info:	9947 KP KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient #	
664903	06/18/2024	2 ML	BUTLER, JULIE	SMITH, MICHELLE	2
	Patient Info:	1543 BAILEY PARK LANE KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8658059313	
665186	06/21/2024	2 ML	COLE, RICHARD	LUTTRELL, DOUGLAS	2
	Patient Info:	11712 Ridgeland Dr KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # (865)-603-7986	
665552	06/19/2024	2 ML	ASHBURN, TAMMY	HEIDEL, WENDY	2
	Patient Info:	3336 OLD AIRPORT RD KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient # (423)-231-0797	
666869	06/17/2024	2 ML	MALLORY, PHILLIP	OCULAM, ALEONA	2
	Patient Info:	4720 W SUNSET RD KNOXVILLE, TN 37914			
	Rx Status:	Dispensed		Patient # 8652423352	
666939	06/17/2024	2 ML	CUSICK, JODY	BROWN, SARAH	2
	Patient Info:	2160 Cusick Cir LENOIR CITY, TN 37772			
	Rx Status:	Dispensed		Patient # (865)-679-8565	

Prescriptions for a Log Report

For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
667370	06/21/2024	2 ML	NOLAND, KAREN	COOK, LANE	2
	Patient Info:	1025 MISTY SPRINGS RD KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # 8655676724	
667799	06/19/2024	2 ML	HESTER, KAREN	HART, TADHG	2
	Patient Info:	11722 Grove Hill Ln KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # (865)-308-2150	
668152	06/19/2024	2 ML	WHITEHOUSE, PATRICIA	MILHOLLIN, JAMES	2
	Patient Info:	457 AMANDA CIR CONCORD, TN 37922			
	Rx Status:	Dispensed		Patient # 8657052182	
668616	06/17/2024	4 ML	FOXWORTH, LEA	WILLIAMS, JOHN	4
	Patient Info:	108 Hickory Hollow Drive OAK RIDGE, TN 37830			
	Rx Status:	Dispensed		Patient # 8654824489	
669155	06/21/2024	2 ML	MCGHEE, BRENDA	HEIDEL, WENDY	2
	Patient Info:	470 CARMEL HILL GREENEVILLE, TN 37743			
	Rx Status:	Dispensed		Patient # 4236209039	
669525	06/17/2024	2 ML	NICHOLSON, CASSANDRA	JACOBS, MIKKI	2
	Patient Info:	3309 GILLENWATER KNOXVILLE, TN 37917			
	Rx Status:	Dispensed		Patient # 8656032012	
670299	06/19/2024	4 ML	CRUGER, COURTNEY	COUSTURIAN, MARGAUX	4
	Patient Info:	2111 OYSTER HARBORS OSTERVILLE, MA 02655			
	Rx Status:	Dispensed		Patient # 6175431611	
670741	06/20/2024	2 ML	Morrell, Sandra	HINKLE, STACEY	2
	Patient Info:	5231 Sullivan Gardens Pkwy KINGSPORT, TN 37660			
	Rx Status:	Dispensed		Patient # 4237373159	
671249	06/17/2024	2 ML	Kosko, Melanie	CARROLL, JOHN	2
	Patient Info:	3227 Great Plains Ln KNOXVILLE, TN 37931			
	Rx Status:	Dispensed		Patient # 8652066478	
671386	06/16/2024	6 ML	LOGAN, CHRISTIE	COE, SAVANNAH	6
	Patient Info:	225 E ATHENS ST ENGLEWOOD, TN 37329			
	Rx Status:	Dispensed		Patient #	
671422	06/16/2024	6 ML	JACKSON, TAMERA	COE, SAVANNAH	6
	Patient Info:	505 KILGORE STREET ATHENS, TN 37303			
	Rx Status:	Dispensed		Patient # 8656613585	

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For Lot Number: 06102024%16110 @13

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KNOXVILLE, TN 37922
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Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
671509	06/19/2024	2 ML	TURPIN, KEVIN	LUTTRELL, DOUGLAS	2
	Patient Info:	2623 Bainbridge Way POWELL, TN 37849			
	Rx Status:	Dispensed		Patient # (865)-604-9427	
671583	06/20/2024	2 ML	ROBERTS, LISA	GLENN, JENNIFER	2
	Patient Info:	1016 WILLIAMS ST MARYVILLE, TN 37803			
	Rx Status:	Dispensed		Patient # 8653888547	
671633	06/21/2024	2 ML	BOST, SHIRLEY	BROWN, SARAH	2
	Patient Info:	4816 Saint Paul Rd MORRISTOWN, TN 37813			
	Rx Status:	Dispensed		Patient # 8652924568	
671726	06/20/2024	2 ML	SHULTZ, KATHERINE	COLLIER, MICHAEL	2
	Patient Info:	1700 ALCOTT MANOR LANE KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8656593802	
671761	06/20/2024	2 ML	CORDERO, RACHEL	ROBERTS, KIMBERLY	2
	Patient Info:	917 VIEW HARBOUR ROAD KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # (865)-405-6873	
671777	06/20/2024	2 ML	LOHMAN, MICHELLE	SMITH, MICHELLE	2
	Patient Info:	10513 RIVER RIDGE RD KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8655561275	
671797	06/17/2024	2 ML	BLAIR, REBECCA	JACKSON, REBECCA	2
	Patient Info:	10204 GREENSPRING LANE KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # 8654067476	
672136	06/21/2024	2 ML	LINTON, BARBARA	FLEMING, BETH	2
	Patient Info:	9758 CLINGMANS DOME DR KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8653100099	
672481	06/17/2024	2 ML	SCHMID, MATT	FOWLKES, JENNA	2
	Patient Info:	10428 EAGLES VIEW LANE KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8658092967	
672585	06/19/2024	2 ML	CAMPBELL, LAURA	PARDUE, RANDY	2
	Patient Info:	1408 BAYHILL RIDGE LANE KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8652019934	
672610	06/17/2024	4 ML	BLAIR, JANET	JACKSON, REBECCA	4
	Patient Info:	565 OLD SEVIERVILLE PIKE SEYMOUR, TN 37865			
	Rx Status:	Dispensed		Patient # (865)-410-2410	

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For Lot Number: 06102024%16110 @13

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KNOXVILLE, TN 37922
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Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
672617	06/17/2024	2 ML	LANDRUM, BRANDY	HILTON, ABIGAIL	2
	Patient Info:	207 S CHILHOWEE DR KNOXVILLE, TN 37914			
	Rx Status:	Dispensed		Patient # (865)-541-1279	
672858	06/19/2024	2 ML	WINSTON, CAYLA	COLLIER, MICHAEL	2
	Patient Info:	7108 DOLPHIN LANE POWELL, TN 37849			
	Rx Status:	Dispensed		Patient # 8652077546	
673242	06/19/2024	2 ML	Corzo, Melina	HINKLE, STACEY	2
	Patient Info:	6535 Pine Bluff Blvd Apt 109 KNOXVILLE, TN 37909			
	Rx Status:	Dispensed		Patient # 8652820065	
673293	06/17/2024	2 ML	IVEY, BRITTANY	YANG, CHRISTINA	2
	Patient Info:	729 GRATZ ST KNOXVILLE, TN 37917			
	Rx Status:	Dispensed		Patient # 8656849258	
673309	06/17/2024	2 ML	HORROCKS, TERRY	HEIDEL, WENDY	2
	Patient Info:	3116 HEATHER GLEN DR MARYVILLE, TN 37801			
	Rx Status:	Dispensed		Patient # 3045732752	
673357	06/19/2024	2 ML	FERGUSON, JAMES	MATHISON, CLYDE	2
	Patient Info:	171 E NEWTON ST ALCOA, TN 37701			
	Rx Status:	Dispensed		Patient #	
673524	06/20/2024	2 ML	GRIFFIS, BRENDA	FLEMING, BETH	2
	Patient Info:	335 GALLAHER RD KINGSTON, TN 37763			
	Rx Status:	Dispensed		Patient # 8658515757	
674075	06/18/2024	2 ML	MORGAN, CHRIS	BORUFF, JEFFREY	2
	Patient Info:	12405 FORT WEST DR KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # 2607057519	
674408	06/17/2024	2 ML	SPOON, LACEY	LUTTRELL, DOUGLAS	2
	Patient Info:	1615 Avery Cir LENOIR CITY, TN 37772			
	Rx Status:	Dispensed		Patient # 8653890803	
674749	06/18/2024	2 ML	HARRISON, COLLEEN	STAFFORD, DEBORAH	2
	Patient Info:	1400 Vale View Road KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 4239561984	
675020	06/19/2024	2 ML	STRUNK, MICHELLE	GOINS, ANDREW	2
	Patient Info:	2020 JEFFERS RD HUNTSVILLE, TN 37756			
	Rx Status:	Dispensed		Patient # 8656179051	

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For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
675077	06/17/2024	2 ML	SEIBER, DONNA	GOINS, ANDREW	2
	Patient Info:	PO BOX 251 PETROS, TN 37845			
	Rx Status:	Dispensed		Patient # 8655862453	
675094	06/17/2024	2 ML	LOY, MYRA "LYNN"	ZERILLA, ANYA	2
	Patient Info:	1550 BIG FOUR ROAD LA FOLLETTE, TN 37766			
	Rx Status:	Dispensed		Patient # (865)-712-4258	
675207	06/18/2024	2 ML	DAUGHERTY, TANYA	FLEMING, BETH	2
	Patient Info:	2720 E 5th Ave KNOXVILLE, TN 37914			
	Rx Status:	Dispensed		Patient # 8657669885	
675408	06/16/2024	2 ML	HUGHES, ANGELA	MCMILLAN-BUCHANAN, GINGER	2
	Patient Info:	84 CR 8120 RIENZI, MS 38865			
	Rx Status:	Dispensed		Patient #	
675414	06/16/2024	2 ML	FLAKE, WHIT	MCMILLAN-BUCHANAN, GINGER	2
	Patient Info:	1326 Hwy 348 GUNTOWN, MS 38849			
	Rx Status:	Dispensed		Patient # 6624198048	
675503	06/18/2024	2 ML	LYONS, JORDAN	DYAR, MADISON	2
	Patient Info:	2500 Cedar Hurst Ln KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # (865)-773-2687	
675545	06/19/2024	2 ML	KIRBY, TYLER	ISBER, JAMAL	2
	Patient Info:	939 ISLAND FORD RD JACKSBORO, TN 37757			
	Rx Status:	Dispensed		Patient # 4238711564	
675954	06/19/2024	2 ML	SEWELL, SHAUEN	HEIDEL, WENDY	2
	Patient Info:	7228 REMAGEN LANE KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8657427531	
676021	06/16/2024	6 ML	GARNER, AMBER	COE, SAVANNAH	6
	Patient Info:	1912 SEMINOLE LANE ATHENS, TN 37303			
	Rx Status:	Dispensed		Patient #	
676022	06/16/2024	6 ML	ABSHER, LEXIA	COE, SAVANNAH	6
	Patient Info:	408 FAIRVIEW DR TELLICO PLAINS, TN 37385			
	Rx Status:	Dispensed		Patient #	
676089	06/17/2024	2 ML	Cunningham, Pamela	BELL, ALANAH	2
	Patient Info:	3102 Spicewood Ln KNOXVILLE, TN 37921			
	Rx Status:	Dispensed		Patient # (865)-599-4222	

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For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
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Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
676119	06/18/2024	2 ML	BEST, MICHAEL	MATHIS, EMILY	2
	Patient Info:	1705 HOLDER RD MARYVILLE, TN 37803			
	Rx Status:	Dispensed		Patient #	
676127	06/17/2024	2 ML	FARABOLLINI, BRITTANY	MATHIS, EMILY	2
	Patient Info:	NEED INFO KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient #	
676159	06/18/2024	2 ML	GRIFFETH, KARA	RIDDLE, ROBIN	2
	Patient Info:	NEED ADDRESS STREET CONCORD, TN 37922			
	Rx Status:	Dispensed		Patient # 8658035816	
676161	06/18/2024	2 ML	STEFFEN, CYNTHIA	COLLIER, MICHAEL	2
	Patient Info:	190 MAPLE SHORES LANE KINGSTON, TN 37763			
	Rx Status:	Dispensed		Patient # 4142172746	
676385	06/19/2024	2 ML	WATSON, MANDY	MEYER, MINDY	2
	Patient Info:	2329 ROBINSON RD KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient # (865)-406-0168	
676500	06/17/2024	2 ML	STAFFORD, DAVID	LUTTRELL, DOUGLAS	2
	Patient Info:	8255 Ford Rd LENOIR CITY, TN 37772			
	Rx Status:	Dispensed		Patient # (865)-803-1588	
676729	06/17/2024	2 ML	BENOIT, MATTHEW	COLLIER, MICHAEL	2
	Patient Info:	360 willingham drive LENOIR CITY, TN 37771			
	Rx Status:	Dispensed		Patient # 9729518410	
676948	06/18/2024	2 ML	HARDIN, SUSAN	GLENN, JENNIFER	2
	Patient Info:	11301 WRENS NEST LN KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # 8656597412	
676952	06/20/2024	2 ML	CAPPS, TAMMY	MCWILLIAMS, SONYA	2
	Patient Info:	214 HAMILTON RIDGE DR MARYVILLE, TN 37801			
	Rx Status:	Dispensed		Patient # 9416236116	
676987	06/17/2024	2 ML	PAPILLON, LYON	FLEMING, BETH	2
	Patient Info:	8412 Vinings Way KNOXVILLE, TN 37919			
	Rx Status:	Dispensed		Patient # (865)-919-9920	
677032	06/19/2024	2 ML	CASPERSON, THOMAS	RIDDLE, ROBIN	2
	Patient Info:	1157 BEECH TREE COVE MARYVILLE, TN 37801			
	Rx Status:	Dispensed		Patient # 9702746761	

Prescriptions for a Log Report

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

For Lot Number: 06102024%16110 @13

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
677033	06/19/2024	2 ML	CASPERSON, DARRAH	RIDDLE, ROBIN	2
	Patient Info:	1157 BEECH TREE COVE MARYVILLE, TN 37801			
	Rx Status:	Dispensed		Patient # 9702746760	
677053	06/18/2024	4 ML	HOLTERMAN, ELIZABETH	MATHIS, EMILY	4
	Patient Info:	NEED KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient #	
677103	06/17/2024	2 ML	WARD, ANN	HART, TADHG	2
	Patient Info:	1138 Bishops View Lane KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # 4237914257	
677157	06/17/2024	4 ML	Vance, William	RIVERS, JAMES	4
	Patient Info:	8556 Festival Loop CHATTANOOGA, TN 37419			
	Rx Status:	Dispensed		Patient # (901)-581-6113	
677283	06/19/2024	2 ML	LAMONT, SHARON	RIDDLE, ROBIN	2
	Patient Info:	495 CONKINNON DRIVE LENOIR CITY, TN 37772			
	Rx Status:	Dispensed		Patient # (865)-399-9608	
677430	06/17/2024	2 ML	KELLER, BRENDA	MATHIS, EMILY	2
	Patient Info:	306 HIDDEN COVE CT MARYVILLE, TN 37803			
	Rx Status:	Dispensed		Patient #	
677461	06/18/2024	2 ML	Shinault, William	RIVERS, JAMES	2
	Patient Info:	409 Little Switzerland Rd KNOXVILLE, TN 37920			
	Rx Status:	Dispensed		Patient # (865)-679-5181	
678004	06/17/2024	2 ML	GAMBLE, MONICA	WILLETT, DWIGHT	2
	Patient Info:	120 CEDAR POINT DR KINGSTON, TN 37763			
	Rx Status:	Ready for Pick Up		Patient # 8654666625	
678183	06/17/2024	2 ML	PHILLIPS, MARY	ROBERTS, KIMBERLY	2
	Patient Info:	315 BIG TREE DR KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # 8655483839	
678214	06/17/2024	2 ML	TAYLOR, BETTY	BROWN, SARAH	2
	Patient Info:	956 McKenzie Meadows Way KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # (281)-382-1986	
678303	06/20/2024	2 ML	WEBB, KIRSTE	SMITH, MICHELLE	2
	Patient Info:	2717 Birdwell drive MARYVILLE, TN 37804			
	Rx Status:	Dispensed		Patient # 8652571490	

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For Lot Number: 06102024%16110 @13

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Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
678368	06/17/2024	2 ML	Humphrey, Ashley	MEYER, MINDY	2
	Patient Info:	407 Douglas Ln CLINTON, TN 37716			
	Rx Status:	Dispensed		Patient # (865)-309-9986	
678624	06/17/2024	2 ML	LOY, DOLYNN	GRAY, NATHAN	2
	Patient Info:	10009 GREYLOCK WAY KNOXVILLE, TN 37931			
	Rx Status:	Dispensed		Patient # 8652501493	
678691	06/17/2024	2 ML	Doman, Matthew	LUTTRELL, DOUGLAS	2
	Patient Info:	10656 Castlepointe Way Apt 107 KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # (858)-699-6165	
678711	06/17/2024	2 ML	LOY, ERIC	GRAY, NATHAN	2
	Patient Info:	10009 Greylock Way KNOXVILLE, TN 37931			
	Rx Status:	Dispensed		Patient # 8652079754	
678810	06/18/2024	2 ML	MILLER, STEVEN	MEYER, MINDY	2
	Patient Info:	8312 Corteland Dr KNOXVILLE, TN 37909			
	Rx Status:	Dispensed		Patient # 8654410877	
679254	06/20/2024	4 ML	DANIELS, CHARLES	BELL, DONNA	4
	Patient Info:	12792 MORNING MIST PLACE VENICE, FL 34293			
	Rx Status:	Ready for Pick Up		Patient # 5204313663	
679255	06/20/2024	4 ML	DANIELS, JESSICA	BELL, DONNA	4
	Patient Info:	12792 MORNING MIST PLACE VENICE, FL 34293			
	Rx Status:	Dispensed		Patient #	
679906	06/20/2024	2 ML	LINKOUS, JOHN	LUTTRELL, DOUGLAS	2
	Patient Info:	154 Carrie Reagan Ln KNOXVILLE, TN 37931			
	Rx Status:	Dispensed		Patient # 8653898214	
680085	06/17/2024	2 ML	HUBER, MARY	PAGE, CASEY	2
	Patient Info:	800 ASHLEY MICHELLE COURT KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # 8653231400	
680144	06/17/2024	2 ML	HELLAND, APRIL	MATHISON, CLYDE	2
	Patient Info:	NEED INFO KNOXVILLE, TN 37923			
	Rx Status:	Ready for Pick Up		Patient # 8658512936	
680264	06/17/2024	2 ML	DEMOINY, ANN MARIE	MATHIS, EMILY	2
	Patient Info:	208 A BERRY WAY SEYMOUR, TN 37865			
	Rx Status:	Dispensed		Patient #	

Prescriptions for a Log Report

For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
680516	06/17/2024	2 ML	JOHNSON, ERICA	MATHIS, EMILY	2
	Patient Info:	3039 NEW BLOCKHOUSE RD MARYVILLE, TN 37803			
	Rx Status:	Dispensed		Patient #	
680601	06/20/2024	2 ML	HUFFAKER, KACIE	LANEY, DANA	2
	Patient Info:	1329 ROBERT RIDGE RD SEVIERVILLE, TN 37876			
	Rx Status:	Dispensed		Patient #	
680638	06/17/2024	2 ML	CRAVENS, SCOTT	BORUFF, JEFFREY	2
	Patient Info:	1617 CAPITOL BLVD KNOXVILLE, TN 37931			
	Rx Status:	Dispensed		Patient # 8658969856	
680757	06/17/2024	2 ML	Quisenberry, Melonie	GOINS, ANDREW	2
	Patient Info:	8933 WAVETREE DR KNOXVILLE, TN 37931			
	Rx Status:	Dispensed		Patient # 8652423487	
681259	06/18/2024	2 ML	JONES, PAUL	JONES, BILLY	2
	Patient Info:	828 WEATHERLY HILLS BLVD KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # 8658032260	
681388	06/18/2024	2 ML	MOORE, TABATHA	GRAY, NATHAN	2
	Patient Info:	1838 Shadyside Ln KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8654052944	
681511	06/17/2024	4 ML	CHANDLER, JEANNIA	WILLIAMS, JOHN	4
	Patient Info:	4620 TOPSAIL WAY KNOXVILLE, TN 37918			
	Rx Status:	Dispensed		Patient # 8658248827	
681753	06/20/2024	4 ML	HARDING, ELIZABETH	EVANS, AMBER	4
	Patient Info:	350 FOX RD KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 6463442993	
681835	06/20/2024	2 ML	BAGWELL, LEIGH	EVANS, AMBER	2
	Patient Info:	210 Kennon Rd KNOXVILLE, TN 37909			
	Rx Status:	Dispensed		Patient # 6156318657	
682102	06/20/2024	2 ML	CUTSHAW, STACY	MILLER, TAMARA	2
	Patient Info:	335 CHILHOWEE VIEW RD MARYVILLE, TN 37803			
	Rx Status:	Dispensed		Patient # 8652036561	
682167	06/20/2024	2 ML	KRAUS, HANNAH	KALLMER, SUNNY	2
	Patient Info:	1221 BELLE POND AVE KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # 8657765240	

Prescriptions for a Log Report

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

For Lot Number: 06102024%16110 @13

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
682375	06/18/2024	2 ML	Grund, Gabriella	SMELTZER, JONATHAN	2
	Patient Info:	6717 Padgett Hill Ln KNOXVILLE, TN 37931			
	Rx Status:	Dispensed		Patient # (615)-525-9413	
682829	06/17/2024	2 ML	BOSHEAR, KELLY	VALJI, SHAAN	2
	Patient Info:	509 E KENTUCKY AVE LA FOLLETTE, TN 37766			
	Rx Status:	Dispensed		Patient # 4234943775	
683420	06/19/2024	4 ML	Rogers, Keith	HEIDEL, WENDY	4
	Patient Info:	PO BOX 2431 ROBBINSVILLE, NC 28771			
	Rx Status:	Dispensed		Patient # 8287350213	
683844	06/17/2024	4 ML	EVANS, ELAINE	MCMAHON, HALEY	4
	Patient Info:	3119 ORCHARD AVE KNOXVILLE, TN 37917			
	Rx Status:	Dispensed		Patient #	
683845	06/17/2024	4 ML	BAILEY, TESSA	MCMAHON, HALEY	4
	Patient Info:	420 HWY 160 NEWPORT, TN 37821			
	Rx Status:	Dispensed		Patient # 8659191825	
683863	06/17/2024	4 ML	MORRIS, AMANDA	COUSTURIAN, MARGAUX	4
	Patient Info:	PO BOX 70824 KNOXVILLE, TN 37938			
	Rx Status:	Dispensed		Patient # 8657552543	
683868	06/17/2024	2 ML	ROWAN, SHERILU	LUTTRELL, DOUGLAS	2
	Patient Info:	2240 Allen Shore Dr LENOIR CITY, TN 37772			
	Rx Status:	Dispensed		Patient # 8653883395	
683882	06/17/2024	2 ML	SIMCOX, JOHN	BROCKMYRE, ANDREW	2
	Patient Info:	240 LONWOOD DR KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # 4233432927	
683883	06/17/2024	2 ML	HENNESSY, KIMBERLY	MATHIS, EMILY	2
	Patient Info:	3606 EDGEWATER WAY LOUISVILLE, TN 37777			
	Rx Status:	Dispensed		Patient #	
683884	06/17/2024	2 ML	MCFARLAND, KEESHA	MATHIS, EMILY	2
	Patient Info:	2237 CHINQUIPIN RD SNEEDVILLE, TN 37869			
	Rx Status:	Dispensed		Patient #	
683941	06/17/2024	2 ML	BAKER, JENNIFER	MATHIS, EMILY	2
	Patient Info:	NEED ADDRESS ST CONCORD, TN 37922			
	Rx Status:	Dispensed		Patient #	

Prescriptions for a Log Report

For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
683950	06/17/2024	2 ML	GASS, DANIEL	RIDDLE, ROBIN	2
	Patient Info:	4707 PAPERMILL DR NW STE 200 KNOXVILLE, TN 37909			
	Rx Status:	Dispensed		Patient #	
683953	06/17/2024	2 ML	BYRD, APRIL	BENTLEY, RHONDA	2
	Patient Info:	75 CRESCENT DR CHRISTIANSBURG, VA 24073			
	Rx Status:	Dispensed		Patient # 2764928119	
684005	06/18/2024	2 ML	SEAVER, PATRICIA	GARRETT, COURTNEY	2
	Patient Info:	118 NORTH PETERS RD #227 KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient # 8654052192	
684017	06/18/2024	2 ML	BLANKINSHIP, APRIL	RYAN, BRITTANY	2
	Patient Info:	1298 Coventry Ct MARYVILLE, TN 37803			
	Rx Status:	Dispensed		Patient # (865)-324-3977	
684018	06/18/2024	4 ML	PERRY, JEAN	LARSON, JILL	4
	Patient Info:	117 GREY WOLFWAY LENOIR CITY, TN 37771			
	Rx Status:	Dispensed		Patient #	
684020	06/18/2024	4 ML	CAMPBELL, CYNTHIA	LARSON, JILL	4
	Patient Info:	6740 LAKE VIEW RD LENOIR CITY, TN 37772			
	Rx Status:	Dispensed		Patient #	
684024	06/18/2024	4 ML	NICEWANDER, CAROLINE	ROGERS, ANDREW	4
	Patient Info:	442 MASSENGILL PARK RD BLUFF CITY, TN 37618			
	Rx Status:	Dispensed		Patient #	
684043	06/18/2024	2 ML	Coffield, James	LUTTRELL, DOUGLAS	2
	Patient Info:	393 Stonebrook Ln LENOIR CITY, TN 37772			
	Rx Status:	Dispensed		Patient # (407)-625-8390	
684098	06/18/2024	2 ML	BRYANT, JULIA	GREEN, R	2
	Patient Info:	9014 Lanntair Farm Ln KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # (865)-250-9387	
684105	06/18/2024	2 ML	THOMAS, SHIRLEY	HIMEBAUGH, KAREN	2
	Patient Info:	442 E HILLVALE TURN KNOXVILLE, TN 37919			
	Rx Status:	Dispensed		Patient # 8656802444	
684121	06/19/2024	2 ML	BEATY, RACHEL	NORRIS, ROBYN	2
	Patient Info:	1079 STANLEY CREEK RD ONEIDA, TN 37841			
	Rx Status:	Dispensed		Patient # 4232239111	

Prescriptions for a Log Report

For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
684122	06/18/2024	2 ML	BELL, MICHELLE	KOWALESKI, RACHEL	2
	Patient Info:	12111 BUTTERNUT CIRCLE KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # 7014269736	
684127	06/18/2024	4 ML	VAN CLEAVE, AMBER	RIDDLE, ROBIN	4
	Patient Info:	1852 PIERCESON POINT LANE KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # 8659639473	
684129	06/18/2024	4 ML	DULL, KATHERINE	RIDDLE, ROBIN	4
	Patient Info:	1514 MOORGATE DRIVE KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # (865)-214-2736	
684130	06/18/2024	4 ML	WRIGHT, TINA	RIDDLE, ROBIN	4
	Patient Info:	127 PRIVATE LANE WINFIELD, TN 37892			
	Rx Status:	Dispensed		Patient # 4232155555	
684141	06/19/2024	4 ML	HAHN, SONIA	RIDDLE, ROBIN	4
	Patient Info:	113 FIDDLERS CANYON RD KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient # 4352380593	
684142	06/19/2024	8 ML	MANUEL, JOSH	COUSTURIAN, MARGAUX	8
	Patient Info:	1300 WOODBRIDGE DR LATROBE, PA 15650			
	Rx Status:	Dispensed		Patient # 9015706557	
684143	06/19/2024	4 ML	TEAGUE, DENA	RIDDLE, ROBIN	4
	Patient Info:	353 KENDALL HUNT ST KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # 8656072425	
684150	06/19/2024	2 ML	DODD, MCKENZIE	MATHIS, EMILY	2
	Patient Info:	NEED KNOXVILLE, TN 37923			✓
	Rx Status:	Dispensed		Patient #	
684167	06/19/2024	2 ML	GLASGOW, BRENDA	GOINS, ANDREW	2
	Patient Info:	234 MORNING COVE RD KINGSTON, TN 37763			
	Rx Status:	Dispensed		Patient # 9364467581	
684173	06/19/2024	4 ML	CHARLES, CHRISTIE	RIDDLE, ROBIN	4
	Patient Info:	2203 BUCK HOLLOW RD NEW MARKET, TN 37820			
	Rx Status:	Dispensed		Patient # 8657124763	
684245	06/19/2024	4 ML	HERNANDEZ, RUTH	RIDDLE, ROBIN	4
	Patient Info:	6342 FLAT LEMON DR WINTER GARDEN, FL 34787			
	Rx Status:	Dispensed		Patient # 8653079088	

Prescriptions for a Log Report

For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
684246	06/19/2024	2 ML	DANIELS, LISA	BELL, DONNA	2
	Patient Info:	12792 MORNING MIST PLACE VENICE, FL 34293			
	Rx Status:	Dispensed		Patient #	
684246	06/20/2024	2 ML	DANIELS, LISA	BELL, DONNA	2
	Patient Info:	12792 MORNING MIST PLACE VENICE, FL 34293			
	Rx Status:	Ready for Pick Up		Patient #	
684269	06/19/2024	2 ML	REYNOLDS, BRONWEN	SHUEY, CHRISTINA	2
	Patient Info:	1116 Chula Vista Dr FRIENDSVILLE, TN 37737			
	Rx Status:	Dispensed		Patient # 8658505355	
684274	06/19/2024	2 ML	MORRELL, JORDAN	BORUFF, JEFFREY	2
	Patient Info:	370 OAKLEY DR APT 813 NASHVILLE, TN 37211			
	Rx Status:	Dispensed		Patient # 8655918166	
684275	06/19/2024	2 ML	CLAWSON, BILLY	VALJI, SHAAN	2
	Patient Info:	259 CLAWSON RD KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 4234945088	
684278	06/19/2024	2 ML	BLANEY, REBECCA	ROGERS, THOMAS	2
	Patient Info:	1610 SKYVIEW DR KINGSPORT, TN 37660			
	Rx Status:	Dispensed		Patient #	
684303	06/19/2024	2 ML	WELLS, VICKIE	WEBB, HOLLY	2
	Patient Info:	405 HUXLEY RD KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # (865)-599-5103	
684306	06/20/2024	4 ML	STANCELL, TASHA	ROGERS, THOMAS	4
	Patient Info:	188 GUY WAY CANTON, NC 28716			
	Rx Status:	Dispensed		Patient #	
684341	06/19/2024	2 ML	GILREATH, RUSSELL	VALJI, SHAAN	2
	Patient Info:	PO BOX 244 LA FOLLETTE, TN 37766			
	Rx Status:	Dispensed		Patient # 8653048919	
684418	06/20/2024	2 ML	Brinker, Kathryn	HASTEY-WITT, KERRY	2
	Patient Info:	628 Augusta National Way KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # 3178686012	
684420	06/20/2024	6 ML	VITCHNER, JANICE	CANTRELL, MATTHEW	6
	Patient Info:	10701 BOLD CYPRESS LN CONCORD, TN 37922			
	Rx Status:	Dispensed		Patient #	

Prescriptions for a Log Report

For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
684422	06/20/2024	4 ML	ITEM, CATIE	COUSTURIAN, MARGAUX	4
	Patient Info:	106 BARNACLE DRIVE MARSTONS MILLS, MA 02648			
	Rx Status:	Dispensed		Patient # 5087375505	
684423	06/20/2024	4 ML	LUSTER, CAROLINE	RIDDLE, ROBIN	4
	Patient Info:	4121 WAITSFIELD WAY KNOXVILLE, TN 37920			
	Rx Status:	Dispensed		Patient # 8652163208	
684432	06/20/2024	2 ML	YORK, TERESA	EVANS, AMBER	2
	Patient Info:	210 DEERFIELD LANE CLINTON, TN 37716			
	Rx Status:	Dispensed		Patient # 8652500712	
684440	06/20/2024	2 ML	MURR, AMANDA	COUSTURIAN, MARGAUX	2
	Patient Info:	1932 FAIRWOOD AVE KNOXVILLE, TN 37917			
	Rx Status:	Dispensed		Patient # 8657420923	
684459	06/20/2024	2 ML	SIMPSON, SHAY	WHITWORTH, BRYNN	2
	Patient Info:	1866 SILVER CLOUD LANE KNOXVILLE, TN 37909			
	Rx Status:	Dispensed		Patient # 8652024768	
684460	06/20/2024	2 ML	TYRRELL, MAX	LUTTRELL, DOUGLAS	2
	Patient Info:	626 St John Court KNOXVILLE, TN 37934			
	Rx Status:	Dispensed		Patient # 8656711897	
684526	06/20/2024	2 ML	BERRIER, ARTIE	MEYER, MINDY	2
	Patient Info:	1301 KENSINGTON DR KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8652018614	
684527	06/20/2024	2 ML	CHAPPELL, DARIAN	PARDUE, RANDY	2
	Patient Info:	1451 ARMIGER LANE KNOXVILLE, TN 37932			
	Rx Status:	Dispensed		Patient # 4103225536	
684543	06/20/2024	4 ML	CREECH, STEPHANIE	VICK, GEORGE	4
	Patient Info:	7285 STAGE COACH ROAD WHITESBURG, TN 37891			
	Rx Status:	Dispensed		Patient # 4232312246	
684544	06/20/2024	4 ML	DAVIS, BRENDA	VICK, GEORGE	4
	Patient Info:	8921 MONEYMAKER DR KNOXVILLE, TN 37923			
	Rx Status:	Dispensed		Patient #	
684545	06/20/2024	2 ML	MCCARTER, BROOKE	VICK, GEORGE	2
	Patient Info:	709 TIMBERLAKE DR SEVIERVILLE, TN 37862			
	Rx Status:	Dispensed		Patient #	

Prescriptions for a Log Report

For Lot Number: 06102024%16110 @13

Heartland Apothecary
9947 Kingston Pike
KNOXVILLE, TN 37922
865-909-9713

Rx Number	Rx Fill Date	Rx Quantity	Patient Name	Prescriber Name	Qty Used
684556	06/21/2024	2 ML	MYERS, ELIZABETH	GRAY, NATHAN	2
	Patient Info:	1409 KENTON WAY KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8652742441	
684563	06/21/2024	4 ML	MOORE, MONICA	LARSON, JILL	4
	Patient Info:	1010 MCKEE AVE LENOIR CITY, TN 37771			
	Rx Status:	Dispensed		Patient #	
684565	06/21/2024	2 ML	SMITH, DEBRA	ROGERS, THOMAS	2
	Patient Info:	846 HARRTOWN RD BLOUNTVILLE, TN 37617			
	Rx Status:	Dispensed		Patient #	
684566	06/21/2024	2 ML	SALLEY, JUDY	ROGERS, THOMAS	2
	Patient Info:	PO BOX 264 CHURCH HILL, TN 37642			
	Rx Status:	Dispensed		Patient #	
684568	06/21/2024	4 ML	WELCH, VICTORIA	ROGERS, THOMAS	4
	Patient Info:	336 ARBOR TERR KINGSPORT, TN 37660			
	Rx Status:	Dispensed		Patient # 4236128358	
684572	06/21/2024	2 ML	TUCKER, BRETT	ROGERS, THOMAS	2
	Patient Info:	213 HIARA DR KINGSPORT, TN 37660			
	Rx Status:	Dispensed		Patient #	
684573	06/21/2024	6 ML	ALANIZ, MARY	CANTRELL, MATTHEW	6
	Patient Info:	322 E CROSS ROAD DANDRIDGE, TN 37725			
	Rx Status:	Dispensed		Patient # 8654057604	
684576	06/21/2024	2 ML	SPRINKLE, HALEY	RIDDLE, ROBIN	2
	Patient Info:	9841 ST GERMAINE DR KNOXVILLE, TN 37922			
	Rx Status:	Dispensed		Patient # 8657196483	
				Total Used from this Log:	438

QI MEDICAL INC

Grass Valley, CA 95945

www.qimedical.com • (530) 272-8700

EnviroTest™ LOG

Test Date	Sample #	Prepared by	Hood #	Media Lot#	Incubation Temperature	RESULTS: Colony Forming Units (CFUs)	RESULTS: Comments
4/23/24			MAZ	ET 1000 Exp 5/10/24	30°C	Positive Growth	
"			Door handle entry	Lot# 19/5337	"	"	
"			Door Handle Enter to Hazard Room	"	"	"	
"			Sink in Ante Area Hazard Room	"	"	"	
"			MAZ	ET 3000 Exp 11/6/24	"	Positive Growth	
"			Door Handle enter to AR Hazard	Lot# 1918505	"	"	
"			Door Handle Enter to Hazard Room	"	"	"	
			Sink in Hazard AR	"	"	"	

Robert McCall 4/23/24

DFU004 P 08/19

Solution for the Positive Growth

#1 clean door handle at the beginning ~~end~~ or end of day on Both doors with Peridox and let set for 3 min + clean with alcohol.
#2 clean May machaine with towel soaks in Peridox and let stand 3min and clean with Alcohol

QI MEDICAL INC

Quality Control Certificate

Catalog #: ET3000

Description: EnviroTest™ MEA (malt extract agar) Media Plates

Lot #: 1918505

Expiration: 16NOV24

The Agar Media in this lot was formulated, manufactured, and tested in accordance with USP General Chapter <797>. Representative samples of this lot were tested and the results are listed below. Validated sterile if the tube is not damaged or opened.

Procedure: Standardized aliquots of the listed cultures were inoculated onto selected samples for growth promotion performance testing. Aggressive growth must occur within 48 hours. Samples were visually examined and tested for physical characteristics.

USP Test Organisms	**Results**
Aspergillus niger (ATCC # 16404)	Positive Growth
Candida albicans (ATCC # 10231)	Positive Growth

Additional Test Organisms	**Results**
Saccharomyces cerevisiae	Positive Growth
Rhodotoruia rubra	Positive Growth
Pencillium commanne	Positive Growth
Pseud. Aeruginosa (ATCC 27853)	Growth inhibited
Escherichia Coli 1	No Growth

Physical Characteristics

Sterility:	No growth at specified time and temperature
Media:	Malt Extract Agar, filtered during filling
Appearance:	Clear
pH:	4.7 – 5.5

FDA Device Establishment Registration # 2950467 DOC370 C 10/14

530-272-8700 | qimedical.com | 1415 Whispering Pines Ln., Suite 150, Grass Valley, CA 95945

TIRZEPATIDE/L-CARNITINE 20MG/50MG/ML INJ
Lot#: 06102024%16391 @15 Discard after:
07/29/2024
2ml Multiple Dose Container - Keep frozen
Heartland Apothecary

SOP No. 1.072

Title of SOP: Patient Grievances

Original: Yes __ No __ Revision: Yes __ No __ Revision No.: _____

Responsibility:

The pharmacist-in-charge is responsible for this procedure.

Purpose:

The purpose of this standard operating procedure is to establish a procedure for the administration of all grievances and to offer, upon request, a means for all patients to voice complaints and seek resolution of problems.

Equipment/Supplies Required:

- Patient Grievance Form

Procedure:

1. Any complaint or issue concerning a compounded product will be made in writing to the responsible personnel. The grievance will include the party's plan for adjudication of the grievance.

2. In the event that a patient telephones in a grievance, it will be immediately recorded in writing by the appropriate personnel.

3. The responsible personnel will immediately review and respond to the grievance in writing. The patient will be contacted within 24 to 48 business hours, and the grievance will be discussed.

4. The results of the grievance will be documented completely and patient agreement or disagreement with the decision will be noted.

5. All details of the grievance, verbal or otherwise, will be documented on the Patient Grievance Form.

Approved by _____ **Date** _____
Implemented by _____ **Date** _____

Patient Grievance Form

Name:_____ Date:_____

Telephone No.:_____ Date of Event:_____

Nature of Complaint:

Received By:_____ Date:_____

Assigned To:_____ Date:_____

Resolved By:_____ Date:_____

Approved by _____ **Date** _____

Implemented by_____ **Date**_____

SOP No. 1.069

Title of SOP: Incident Reporting

Original: Yes __ No __ Revision: Yes __ No __ Revision No.: _____

Responsibility:

The pharmacist-in-charge is responsible for this procedure.

Purpose:

The purpose of this standard operating procedure is to provide a means to document occurrences involving a patient or caregiver that is consistent with routine care and treatment of the patient and/or to document any unusual occurrences involving a patient or caregiver.

Equipment/Supplies Required:

- Incident Report Form
- Equipment required to take vital signs

Procedure:

1. The incident report form will be used to document any actual or potential untoward event that has occurred regarding patient care. Examples include, but are not limited to, the following:

    a. Loss/Breakage:

        I. Patient/caregiver reports article missing from home after home visit

        II. Staff involved in damage/breakage of patient's personal belonging or equipment

        III. Staff discovery of personal belongings or equipment missing from the home

    b. Any untoward event dealing with equipment or medical devices:

        I. Lack of equipment

        II. Equipment failure or malfunction

        III. Any injury resulting from the use of the equipment or medical device

    c. Any event dealing with patient endangerment:

I. Abuse by a caregiver

II. Inadequate care for a confused or otherwise helpless patient

d. An event that may endanger the staff while providing care/service:

I. Verbal abuse

II. Physical abuse

e. The patient is unwilling to accept or follow appropriate instructions.

f. Any problem or error dealing with the completion of a procedure or protocol:

I. Failure to follow a procedure

II. Care performed outside the scope of practice of the clinician

g. Any untoward outcomes related to drug administration, intravenous therapy or treatment modality:

I. Adverse or toxic drug reactions

II. Anaphylaxis

III. Treatment of overdoses

IV. Extravasation

V. Infiltration

VI. Phlebitis

VII. Hematoma

VIII. Catheter-related sepsis

IX. Transfusion reactions

h. Noncompliance by the patient/caregiver that results in emergency intervention or hospitalization.

i. Any problems associated with inadequate or improper consent forms, such as lack of consent.

j. Any medication error including the patient's failure to follow the physician/nurse/pharmacist instructions as well as delays in the administration sequence or failure of the patient to receive a dose.

k. Any other occurrence that requires documentation.

I. Cardiac arrest

II. Resuscitation

III. Reference to legal action by the patient or family

l. Any occurrence or observation that the staff member or patient/caregiver believes may involve actual or potential injury to the patient, the company, or its employees.

2. The incident report is NOT part of the client's medical record. No reference should be made to the preparation of an incident report in the patient's medical record.

3. An incident report will be initiated by the person who first becomes aware that an incident has occurred.

4. The incident should be completed accurately and no later than 24 hours after the discovery of the occurrence. All sections of the report are to be completed, leaving no blanks. If a section does not apply, the words "not applicable" should be written in the space.

5. When applicable, include vital signs and a post-incident assessment of the patient.

6. If the incident requires treatment by a physician or an emergency room visit, this should be included in the documentation.

7. The Quality Assurance Committee will review all incidents.

Incident Report Form

PATIENT NAME	DATE OF INCIDENT __/__/__
ADDRESS	PHONE NO. ( ) -
TYPE OF THERAPY (Check Below)	PATIENT INJURY [ ] NO [ ] YES
[ ] TPN [ ] ENT [ ] Antibiotic [ ] Chemo [ ] Pain Management [ ] Other, Specify	

I. TYPE OF INCIDENT

1. [ ] Service (Describe)	3. [ ] Pump Mfg. Serial No. Tubing / Set Code Rate Volume Time
2. [ ] Product Describe Mfg. Lot / Serial No.	At Time of Incident [ ] AC or battery malfunction [ ] Blood back-up [ ] Over / Under infusion rate [ ] Alarm malfunction [ ] Air in line [ ] Other

II. TYPE OF PROBLEM (Check appropriate boxes)

[ ] Non delivery	[ ] Incorrect prescription	[ ] Miscommunication
[ ] Delivery off schedule	[ ] Compounding error	[ ] Documentation error
[ ] Wrong product delivered	[ ] Stability problem	[ ] Packaging problem
[ ] Incomplete delivery	[ ] Labeling error	[ ] Defective product
[ ] Product damaged in transit	[ ] Non adherence to procedure	[ ] Other
Brief description of incident(s) as indicated above:		

III. IMMEDIATE ACTION / COMMENTS

IV. PLAN FOR FOLLOW UP

Reported By:	Date:	Signature:
Reviewed By:	Date:	Signature:

Approved by _____ Date _____

Implemented by _____ Date _____

STERIS
Life Sciences

Controlled Environment Certification Services, Inc.
A Subsidiary of STERIS Corporation
177 N Commerce Way
Bethlehem, PA 18017

800-523-9852 or 610-867-5302
Fax: 610-954-7803
email: cecs_info@steris.com
www.sterislifesciences.com

CERTIFICATE OF CALIBRATION

MANUFACTURER *Bioscience International* **MODEL** *SAS Super 180*

SERIAL NUMBER *20-D-15224* **DESCRIPTION** *Viable Air Sampler*

Controlled Environment Certification Services, Inc. does hereby certify that all performance and acceptance tests required were successfully conducted according to required specifications. All calibration data and test instrumentation used have been obtained using standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST), have been derived from accepted values of natural physical constants, or by the use of ratio type of self calibration. The calibration system complies with ISO/IEC 17025:2017.

August 5, 2023
Date of Calibration

August 4, 2024
Next Calibration is Due

Dave Matos 08-Aug-2023
Authorized Name/Signature/Date

130782
MCI#

500344673
REPORT#

CECS, Inc.
Client Name

BIOSCIENCE INTERNATIONAL
Innovative Microbiology Products
11333 Woodglen Drive • Rockville, Maryland 20852
301.231.7400 • www.biosci-intl.com • fax: 301.231.7277

CERTIFICATE OF CALIBRATION

Model:	SAS Super 180
Air Sampler Serial #:	20-D-15224
Air Sampler Head Serial #:	23403
Customer:	CECS
Customer Asset ID #:	MCI:130782
Calibration performed at:	JBW site 10242 Little Rock Ln Frederick, MD 21702

Cal. Date:	5 Aug 2023	
Cal. Due:	5 Aug 2024	(12 months)
Procedure:	EOP-030	
Certificate #:	20-D-15224-3143	
Volume sampled (L):	1000	
Calibrated w/media type:	Remel TSA W/L & Poly	
Plate Lot #:	663424	
Plate Exp Date:	10/23/2023	

	As Found	*In Tolerance*	*As Left*	*In Tolerance*	*Acceptable Range*
Battery output (Volts):	9.9	n/a	9.6	n/a	>8.2
Temperature (F°):	73.7	n/a	73.7	n/a	59 - 95
Barometric pressure (in. HG):	29.90	n/a	29.90	n/a	n/a
Time to sample 1000 Liters (min)	5.34	n/a	5.55	n/a	n/a
Temp. & Pressure Standardization Factor:	0.99	n/a	0.99	n/a	n/a
Air velocity reading (ft/min)	105.0	n/a	101.0	n/a	n/a
Air velocity reading (m/sec)	0.533	n/a	0.513	n/a	n/a
Standardized air velocity reading (m/sec)	0.529	n/a	0.509	n/a	n/a
Standardized Air Flow (L/min)	187.3	Yes	180.1	Yes	171 - 189

Additional heads inspected and determined to be within +/-2%:	53071, 24303 and 53049
Additional service, preventative maintenance, or calibration notes:	n/a

QA REVIEWED TAK 09Aug2023

Bioscience International certifies that the above described instrument conforms to the original manufacturer's tolerances for the parameters listed (not applicable to As Found data) & has been calibrated in accordance with ISO 17025:2017 guidelines using standards whose accuracies are traceable to the U.S. National Institute of Standards & Technology, have been verified with respect to instrumentation whose accuracy is traceable to NIST, or are derived from accepted values of physical constants. CMC test uncertainty is +/-2.2%. Instruments are calibrated with a test uncertainty ratio of 4:1 or greater whenever possible, with uncertainty defined as within a 95% confidence interval using a coverage factor of k = 2. In all cases, statistical methods are used to minimize uncertainty using the best commercially available methods. In Tolerance conditions are based on test results falling within the Acceptable Range. Measurement uncertainty is provided separately & independent of the decision rule. Voltage readings are for preventative maintenance purposes & not part of the calibration; values other than voltage, temperature, pressure, & air velocity are calculated values. Calibration results relate only to the items listed above; e.g., the instrument should be recalibrated prior to switching to a different media size (e.g., from 90mm Petri dishes to 55mm contact plates or vice versa).

Measurement Standards

ID	*Description*	*Last Cal.*	*Cal. Due*
J-T95452022004	Velocity	5/11/2023	5/10/2024
J-6530-181788940	Temperature & Pressure	9/19/2022	9/19/2024

Work performed by / date: 05Aug2023 Reviewed by / date: 05Aug2023

CERTIFICATE OF COMPLIANCE

This certificate is presented to

HEARTLAND INFUSION
KNOXVILLE, TN

To verify that the Ante & Non-HD Buffer rooms meet the Airborne Particulate Cleanliness Classification
of
ISO Class 8 & 7, respectively, for size 0.5 µm and larger, Operational,
Per ISO Std 14644-1:2015 as depicted in test report # 301170969

Next Verification is due: October 2024

17April2024
COMPLETION DATE

SIGNATURE

STERIS

STERIS
Life Sciences

Controlled Environment Certification Services, Inc.
A Subsidiary of STERIS Corporation
5960 Heisley Rd, Mentor, OH 44060

800-523-9852 (Customer Service)
Ph: 610-867-5302 Fax: 610-954-7803
Email: cecs_info@steris.com

ACCEPTANCE CRITERIA SUMMARY REPORT

TEST REPORT NO.: 301170969
COMPLETION DATE: 17APR2024
CLIENT: HEARTLAND INFUSION LLC
9943 KINGSTON PIKE
KNOXVILLE, TN 37922
ATTN: CHRIS NEILSON
TEMPLATE REVIEW: TAZ 23MAY2024

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA
RETEST DATE: OCT2024

PAGE	DOCUMENTATION OR DATA TITLE	TEST STATUS: PASS; FAIL; NO TEST; FOR REFERENCE ONLY	ACCEPTANCE CRITERIA: NOT APPLICABLE; AS PER DESIGN; CLIENT CRITERIA; USED FOR DIAGNOSTIC PURPOSES
1 & 2 OF 12	ACCEPTANCE CRITERIA SUMMARY REPORT	FOR REFERENCE ONLY	NOT APPLICABLE
3 OF 12	IDENTIFICATION DRAWING	FOR REFERENCE ONLY	NOT APPLICABLE
4 OF 12	AIRFLOW VOLUME PROFILE	PASS	SUFFICIENT TO ACHIEVE AIR CHANGES PER HOUR
5 OF 12	FILTER HISTORICAL DATA	FOR REFERENCE ONLY	USED FOR DIAGNOSTIC PURPOSES
6 OF 12	AIR CHANGES PER HOUR	PASS	≥ 30 ACPH – NON-HD A MINIMUM OF 15 ACPH MUST COME FROM SUPPLY
7 OF 12	ROOM DIMENSIONS	FOR REFERENCE ONLY	NOT APPLICABLE
8 OF 12	ROOM DIFFERENTIAL PRESSURES/ ROOM PRESSURIZATION & AIRFLOW DIRECTIONAL SMOKE PATTERN TESTS	PASS	NON-HD TO ANTE ≥ 0.020" W.C. ANTE TO Rx ≥ 0.020" W.C.
9 OF 12	AEROSOL CHALLENGE INSTALLATION LEAK TEST SMOKE DETECTOR YES ☐ NO ☒ Verify prior to test	PASS	≤ 0.010% PENETRATION
10 OF 12	FILTER MEDIA REPAIR TRACKING	PASS	LESSER DIMENSION OF EACH REPAIR NO GREATER THAN 1.50" TOTAL OF ALL REPAIRS NOT TO EXCEED 3.00% OF THE EFFECTIVE FILTER AREA

BRW 17APR2024

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ACCEPTANCE CRITERIA SUMMARY REPORT

TEST REPORT NO.: 301170969

PAGE	DOCUMENTATION OR DATA TITLE	TEST STATUS: PASS; FAIL; NO TEST; FOR REFERENCE ONLY	ACCEPTANCE CRITERIA: NOT APPLICABLE; AS PER DESIGN; CLIENT CRITERIA; USED FOR DIAGNOSTIC PURPOSES
11 OF 12	AIRBORNE PARTICLE COUNT SURVEY	PASS	ISO Class 7 – NON-HD ≤ 352,000 PPCM @ 0.5 MICRON & LARGER ISO Class 8 – ANTE ≤ 3,520,000 PPCM @ 0.5 MICRON & LARGER per ISO Std 14644-1:2015 OPERATIONAL
12 OF 12	TEMPERATURE & RELATIVE HUMIDITY	FOR REFERENCE ONLY	NOT APPLICABLE

Tested in Accordance With CECS, Inc. WI CR- 0621 CERT and CETA CAG-003-2006-13

Reviewed by CECS, Inc.: Technician Print Name BRANDON WHITE
Signature _____ Date 17APR2024

CECS, Inc. QA Reviewed by: Print Name Peyton Abner
Signature _____ Date 11JUN2024

Reviewed by Client: Print Name _____
Signature _____ Date _____

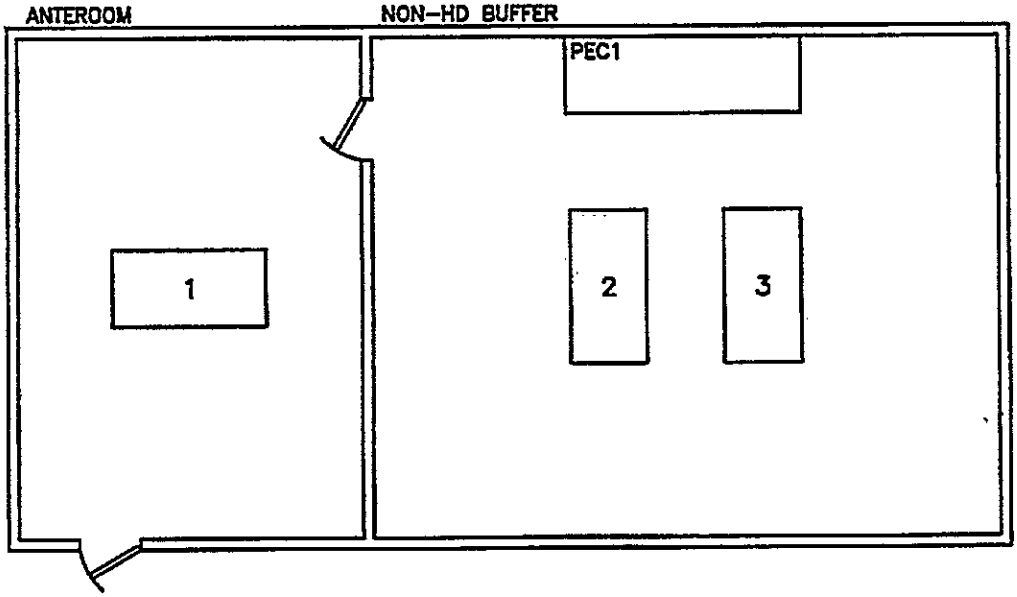
Total of 2 individual[s] present during testing of the PEC unit. 2 technician[s] were preforming the certification of the hood while 1 pharmacy technician[s] joined us during the smoke pattern video testing reflecting in Dynamic conditions.
Total of 1 pharmacy technician[s] present during Dynamic particle count testing in PEC unit.
Template Update - BRW 17APR2024

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TEST REPORT NO. 301170969

CLIENT: HEARTLAND INFUSION LLC
ADDRESS: 9943 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA



IDENTIFICATION DRAWING

QA REVIEWED
11/14/2024

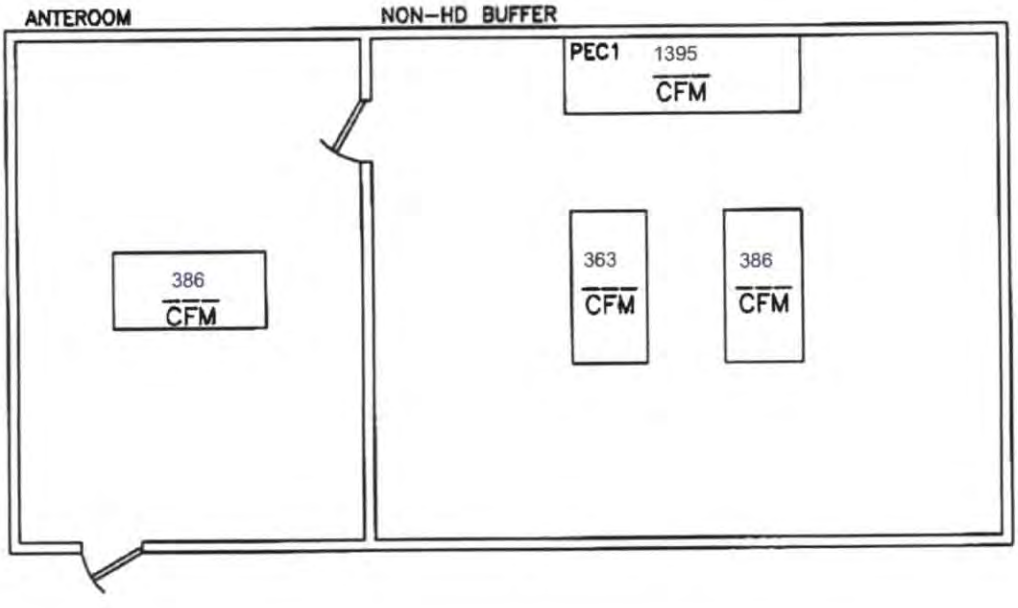
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TEST REPORT NO. 301170969

CLIENT: HEARTLAND INFUSION LLC
ADDRESS: 9943 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA

TEST EQUIPMENT – DIM : Mfg. ALNOR Model EBT731 S/N EBT732012001
CAL DUE 28FEB2025



AIRFLOW VOLUME PROFILE
READINGS RECORDED IN CUBIC FEET PER MINUTE (CFM)
USING A CAPTURE HOOD
(ALL READINGS: BACKPRESSURE COMPENSATED)

PRIMARY ENGINEERING CONTROL (PEC1) FROM REPORT # 102396391 ; 93 FPM
TIMES AREA 30" x 72" = 15.0 SQ FT

QA REVIEWED
11JUN2024

BRW 17APR2024

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FILTER HISTORICAL DATA

TEST REPORT NO.: 301170969

CLIENT: HEARTLAND INFUSION LLC
ADDRESS: 9943 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA

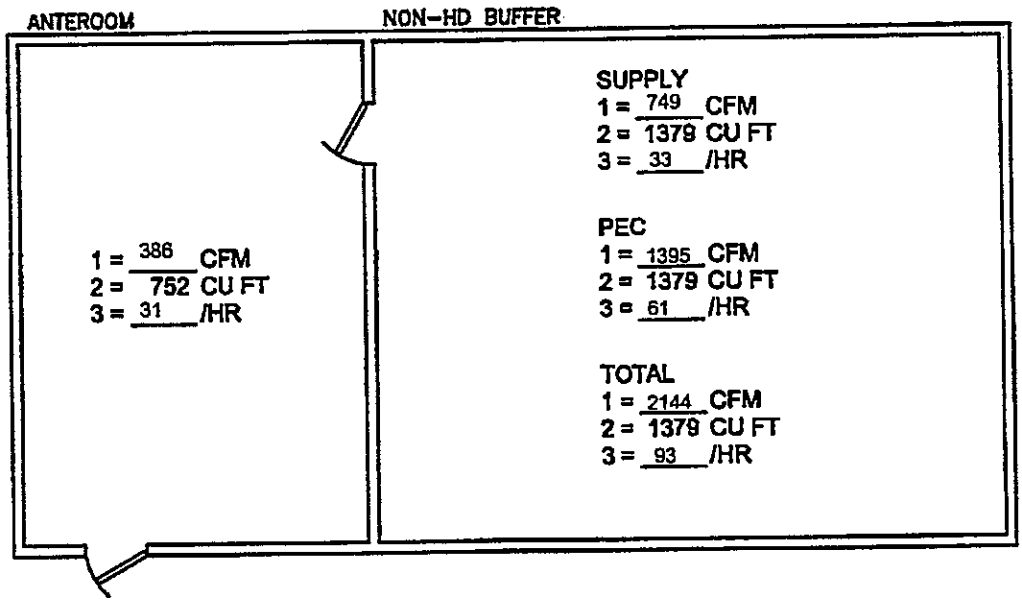
FILTER ID	FILTER REPLACEMENT DATA	S/N	DATE	INITIAL VOLUME
1	NA	NA	NA	NA CFM
2	NA	NA	NA	NA CFM
3	NA	NA	NA	NA CFM

QA REVIEWED
11JUN2024

TEST REPORT NO. 301170969

CLIENT: HEARTLAND INFUSION LLC
ADDRESS: 9943 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA



AIR CHANGES PER HOUR

1 = TOTAL AIRFLOW VOLUMES IN CUBIC FEET PER MINUTE (CFM)
(CFM1 + CFM2 + CFM3 +...) = CFMTOTAL
2 = ROOM VOLUME IN CUBIC FEET (CU FT) (L"xW"xH"/1728)
3 = AIR CHANGES/HOUR (/HR) (CFM/CU FT x 60)

QA REVIEWED
11 JUN 2024

BRW 17APR2024

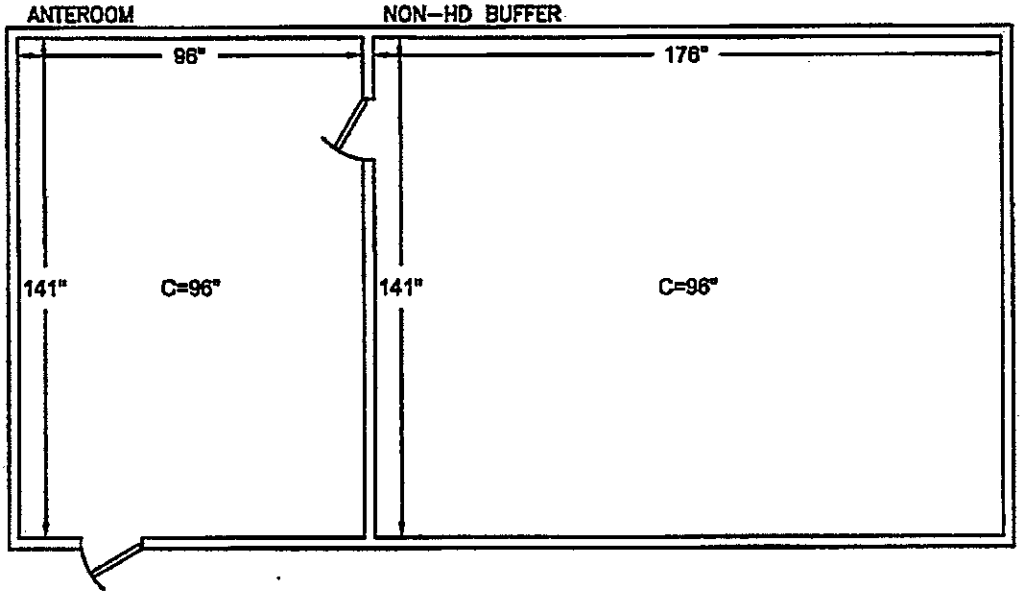
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7HVJ9PA-REV-220523.DWG

TEST REPORT NO. 301170969

CLIENT: HEARTLAND INFUSION LLC
ADDRESS: 9943 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA



ROOM DIMENSIONS
MEASURED TO THE NEAREST INCH
C = CEILING HEIGHT

QA REVIEWED
11JUN2024

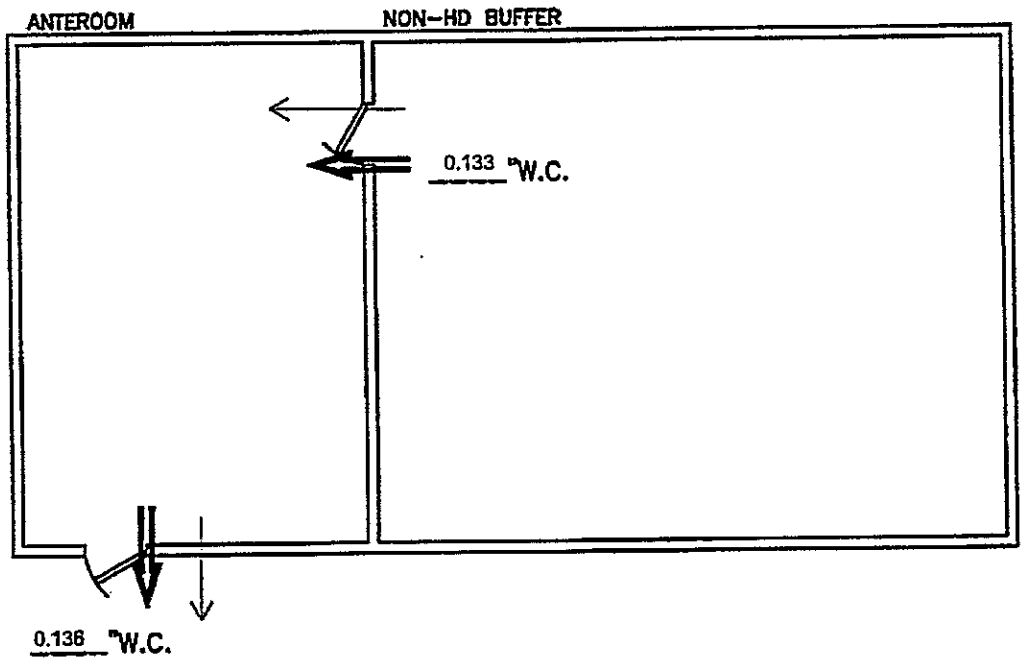
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CLIENT: HEARTLAND INFUSION LLC
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KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA

TEST EQUIPMENT – ANEMOMETER: Mfg. TSI Model 9565-P S/N 9565P2334031
CAL DUE 14MAY2024



ROOM PRESSURIZATION

ROOM-TO-ROOM PRESSURES ARE INDICATED IN INCHES OF WATER COLUMN ("W.C.) ADJACENT TO AIRFLOW DIRECTIONAL ARROW. AIRFLOW DIRECTION VERIFIED WITH A VISUAL SMOKE SOURCE.

CURRENT AIRFLOW DIRECTION → NEUTRAL ↔

DESIGN AIRFLOW DIRECTION ⟹ NO DESIGN DIRECTION ⟺

PRESSURES TAKEN ON 17APR2024 @ 1030

BRW 17APR2024

QA REVIEWED
11JUN2024

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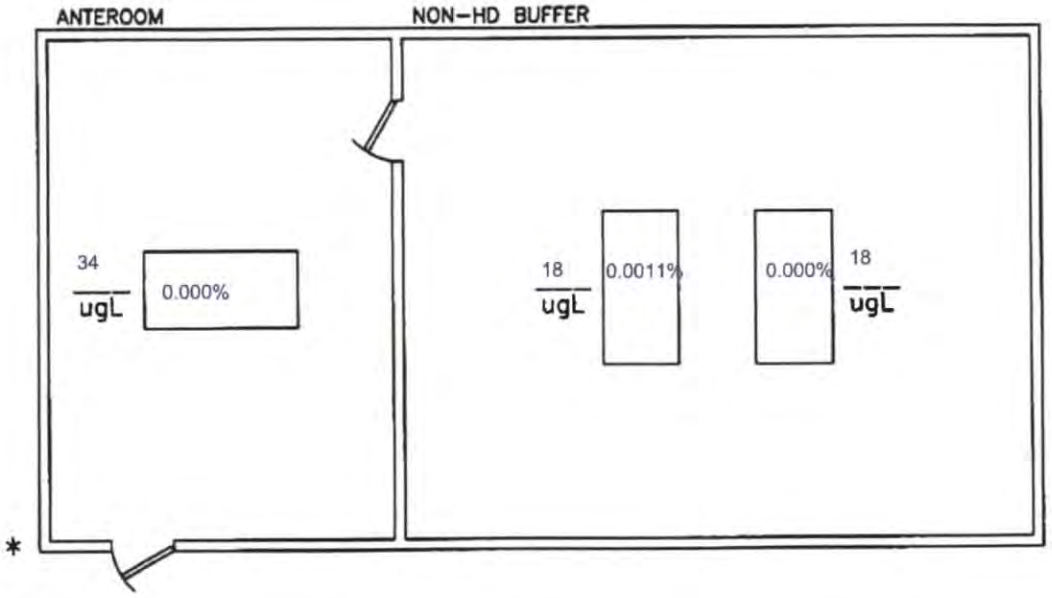
TEST REPORT NO. 301170969

CLIENT: HEARTLAND INFUSION LLC
ADDRESS: 9943 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA

TEST EQUIPMENT – Photometer: Mfg. ATI Model 21 S/N 71723
CAL DUE 23JUL2024

ALL ~~UG/L CALCULATED~~ (1)
SCANNED BY BRW



(1) Spoke to tech, challenges were taken upstream. PA 11JUN2024

QA REVIEWED
11JUN2024

AEROSOL CHALLENGE INSTALLATION LEAK TEST

A MINIMUM OF 10 ug/L COLD NOZZLE PAO WAS INTRODUCED INTO RETURN IN CEILING FOR ALL FILTERS*. A 100% SCAN OF THE FILTER MEDIA AND SURROUNDING FRAME / SEAL WAS CONDUCTED. RESULTS INDICATED ON DIAGRAM.

BR=BEFORE REPAIR, AR=AFTER REPAIR (REPAIRS MADE WITH RTV SILICONE), //=MEDIA LEAKAGE, XX=FRAME LEAKAGE

SMOKE DETECTORS: NO
CHALLENGE RECORDED IN MICRO-GRAMS PER LITER (ugL)

BRW 17APR2024

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FILTER MEDIA REPAIR TRACKING

TEST REPORT NO. 301170969

CLIENT: HEARTLAND INFUSION LLC

ADDRESS: 9943 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED

MFG: PHARMACY CLEANROOM

IDENTIFYING NO.: NA

LOCATION: PHARMACY

ROOM: ANTE & NON-HD BUFFER

OTHER: MCI# 7HVJ9PA

FILTER #	FILTER MEDIA AREA (dimensions in inches)	PATCH SIZE (dimensions in inches)	UP/DOWN STREAM	DATE OF REPAIR	% AREA	TOTAL REPAIR %
1	0.00 x 0.00 = 0.00 SQ IN	0.00 x 0.00 = 0.00 SQ IN	NA	NA	0.00	0.00
2	0.00 x 0.00 = 0.00 SQ IN	0.00 x 0.00 = 0.00 SQ IN	NA	NA	0.00	0.00
3	0.00 x 0.00 = 0.00 SQ IN	0.00 x 0.00 = 0.00 SQ IN	NA	NA	0.00	0.00

QA REVIEWED
11 JUN 2024

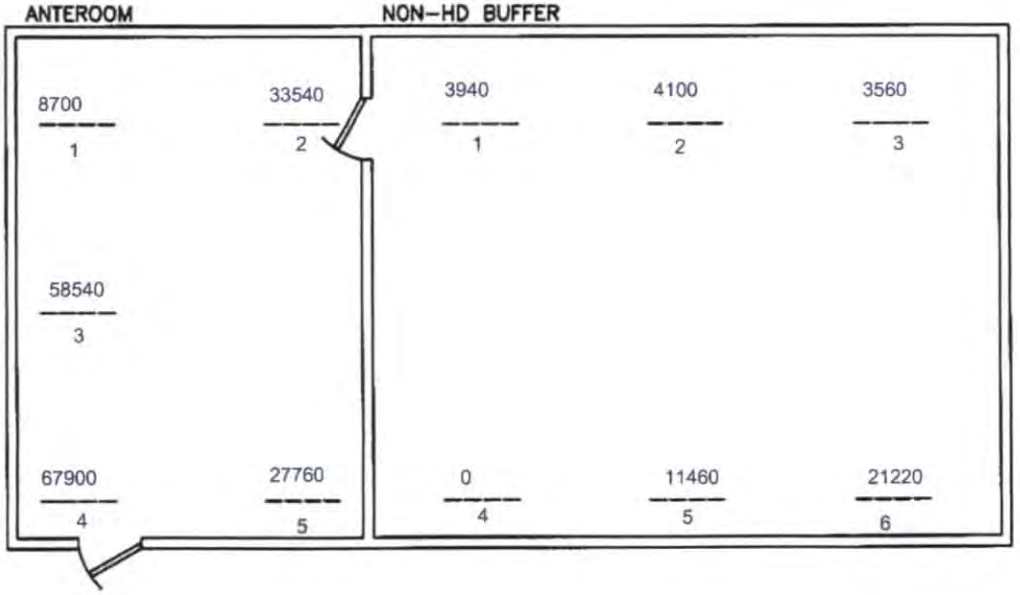
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TEST REPORT NO. 301170969

CLIENT: HEARTLAND INFUSION LLC
ADDRESS: 9943 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA

TEST EQUIPMENT – Particle Counter: Mfg. TSI Model 9350-02 S/N 93501723004
CAL DUE 15MAY2024



AIRBORNE PARTICLE COUNT SURVEY

TAKEN AT 46" WORK SURFACE ELEVATION. ROOM IN OPERATIONAL CONDITIONS WITH 2 PERSON(S) IN ROOM.

GOWNING LEVEL = ASEPTIC

ISO CLASS 7 & 8
MINIMUM SAMPLE VOLUME 2 LITERS @ 50 LPM FOR 1 MINUTE(S)

SURVEY TO BE READ AS FOLLOWS:
0.5 MICRON & LARGER PARTICLES PER CUBIC METER (PPCM)

QA REVIEWED
11JUN2024

BRW 17APR2024

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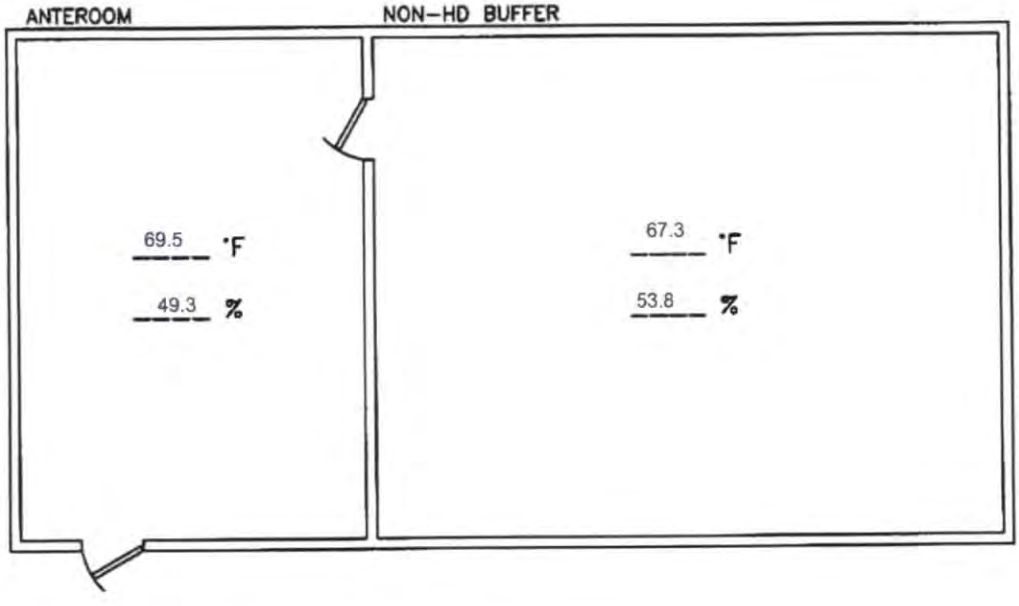
TEST REPORT NO. 301170969

CLIENT: HEARTLAND INFUSION LLC
ADDRESS: 9943 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: PHARMACY CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE & NON-HD BUFFER
OTHER: MCI# 7HVJ9PA

TEST EQUIPMENT – Temperature Probe: Mfg. TSI Model 966 S/N P23360079
CAL DUE 14MAY2024

TEST EQUIPMENT – Humidity Gauge: Mfg. TSI Model 966 S/N P23360079
CAL DUE 14MAY2024



BRW 17APR2024

TEMPERATURE / RELATIVE HUMIDITY
TEMPERATURE - DEGREES FAHRENHEIT (°F)
RELATIVE HUMIDITY - RELATIVE HUMIDITY (%)

QA REVIEWED
11JUN2024

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7HVJ9PA-REV-220523.DWG



Serial # 93501723004
Sample 1 of 1
Sample # 445
Date/Time 4/17/2024, 10:23:00
Zone Zero
Location Zero
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 0

Serial # 93501723004
Sample 1 of 1
Sample # 446
Date/Time 4/17/2024, 10:25:05
Zone ANTE
Location Location01
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3
Size Cumul Alarm
0.5 8700

Serial # 93501723004
Sample 1 of 1
Sample # 447
Date/Time 4/17/2024, 10:26:27
Zone ANTE
Location Location02
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 33540

Serial # 93501723004
Sample 1 of 1
Sample # 448
Date/Time 4/17/2024, 10:27:52
Zone ANTE
Location Location03
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 58540

Serial # 93501723004
Sample 1 of 1
Sample # 449
Date/Time 4/17/2024, 10:29:11
Zone ANTE
Location Location04
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 67900

Serial # 93501723004
Sample 1 of 1
Sample # 450
Date/Time 4/17/2024, 10:30:32
Zone ANTE
Location Location05
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 27760

Serial # 93501723004
Sample 1 of 4
Sample # 451
Date/Time 4/17/2024 10:32:19
Zone NHBR
Location Location01
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3
Size Cumul Alarm
0.5 3940

Sample 2 of 4
Sample # 452
Date/Time 4/17/2024, 10:33:43
Zone NHBR
Location Location02
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 4100

Sample 3 of 4
Sample # 453
Date/Time 4/17/2024, 10:35:02
Zone NHBR
Location Location03
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 3560

Sample 4 of 4
Sample # 454
Date/Time 4/17/2024, 10:36:21
Zone NHBR
Location Location04
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 0

Serial # 93501723004
Sample 1 of 1
Sample # 455
Date/Time 4/17/2024, 10:39:42
Zone NHBR
Location Location05
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 11480

Serial # 93501723004
Sample 1 of 1
Sample # 456
Date/Time 4/17/2024, 10:41:12
Zone NHBR
Location Location06
Recipe Recipe01
Sample Time 00:01:00
Volume 50.0 L
Flow OK
Laser OK

Particles / m3:
Size Cumul Alarm
0.5 21220

QA REVIEWED
11JUN2024

STERIS
Life Sciences

Controlled Environment Certification Services, Inc.
A Subsidiary of STERIS Corporation
177 N Commerce Way
Bethlehem, PA 18017

800-523-9852 or 610-867-5302
Fax: 610-954-7803
email: cecs_info@steris.com
www.sterislifesciences.com

CERTIFICATE OF CALIBRATION

MANUFACTURER TSI **MODEL** 966

SERIAL NUMBER P23360079 **DESCRIPTION** VelociCalc Thermoanemometer(Probe)

Controlled Environment Certification Services, Inc. does hereby certify that all performance and acceptance tests required were successfully conducted according to required specifications. All calibration data and test instrumentation used have been obtained using standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST), have been derived from accepted values of natural physical constants, or by the use of ratio type of self calibration. The calibration system complies with ISO/IEC 17025:2017

February 15, 2024
Date of Calibration

May 14, 2024
Next Calibration is Due

Todd Stevens 15 FEB 2024
Authorized Name/Signature/Date

138097
MCI#

301062790
REPORT#

CECS, Inc.
Client Name

STERIS
Life Sciences

Controlled Environment Certification Services, Inc.
A Subsidiary of STERIS Corporation
177 N Commerce Way
Bethlehem, PA 18017

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Fax: 610-954-7803
email: cecs_info@steris.com
www.sterislifesciences.com

CERTIFICATE OF CALIBRATION

MANUFACTURER *Air Techniques International* **MODEL** *2i*

SERIAL NUMBER *71723* **DESCRIPTION** *Aerosol Photometer*

Controlled Environment Certification Services, Inc. does hereby certify that all performance and acceptance tests required were successfully conducted according to required specifications. All calibration data and test instrumentation used have been obtained using standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST), have been derived from accepted values of natural physical constants, or by the use of ratio type of self calibration. The calibration system complies with ISO/IEC 17025:2017.

January 24, 2024
Date of Calibration

July 23, 2024
Next Calibration is Due

Kelly Saharic *Kelly Saharic 26Jan2024*
Authorized Name/Signature/Date

138084
MCI#

301060468
REPORT#

CECS, Inc.
Client Name

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email: cecs_info@steris.com
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CERTIFICATE OF CALIBRATION

MANUFACTURER TSI **MODEL** 9350-02

SERIAL NUMBER 93501723004 **DESCRIPTION** Laser Particle Counter

Controlled Environment Certification Services, Inc. does hereby certify that all performance and acceptance tests required were successfully conducted according to required specifications. All calibration data and test instrumentation used have been obtained using standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST), have been derived from accepted values of natural physical constants, or by the use of ratio type of self calibration. The calibration system complies with ISO/IEC 17025:2017.

November 16, 2023
Date of Calibration

May 15, 2024
Next Calibration is Due

Dave Matos 20 NOV 2023
Authorized Name/Signature/Date

127863
MCI#

301069072
REPORT#

CECS, Inc.
Client Name

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Fax: 610-954-7803
email: cecs_info@steris.com
www.sterislifesciences.com

CERTIFICATE OF CALIBRATION

MANUFACTURER TSI / Alnor **MODEL** EBT731

SERIAL NUMBER EBT732012001 **DESCRIPTION** Micromanometer / Balometer

Controlled Environment Certification Services, Inc. does hereby certify that all performance and acceptance tests required were successfully conducted according to required specifications. All calibration data and test instrumentation used have been obtained using standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST), have been derived from accepted values of natural physical constants, or by the use of ratio type of self calibration. The calibration system complies with ISO/IEC 17025:2017.

February 29, 2024	February 28, 2025
Date of Calibration	**Next Calibration is Due**

Thomas Dahl 04MAR2024
Authorized Name/Signature/Date

135366	301064121
MCI#	**REPORT#**

CECS, Inc.
Client Name

CERTIFICATE OF COMPLIANCE

This certificate is presented to

HEARTLAND APOTHECARY
KNOXVILLE, TN

To verify that the Ante & Non-HD Buffer rooms meet the Airborne Particulate Cleanliness Classification
of
ISO Class 8 & 7, respectively, for size 0.5 µm and larger, Operational,
Per ISO Std 14644-1:2015 as depicted in test report # 301170334

Next Verification is due October 2024

17April2024
COMPLETION DATE

SIGNATURE

STERIS

2597

STERIS Life Sciences
Controlled Environment Certification Services, Inc.
A Subsidiary of STERIS Corporation
5960 Heisley Rd, Mentor, OH 44060
800-523-9852 (Customer Service)
Ph: 610-867-5302 Fax: 610-954-7803
Email: cecs_info@steris.com

ACCEPTANCE CRITERIA SUMMARY REPORT

TEST REPORT NO.: 301170334
COMPLETION DATE: 17APR2024
CLIENT: HEARTLAND APOTHECARY
9947 KINGSTON PIKE
KNOXVILLE, TN 37922
ATTN: RANDY MARTIN
TEMPLATE REVIEW: 17APR2023

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE, NON-HD BUFFER RM
OTHER: MCI# KK0113
RETEST DATE: OCT2024

PAGE	DOCUMENTATION OR DATA TITLE	TEST STATUS: PASS; FAIL; NO TEST; FOR REFERENCE ONLY	ACCEPTANCE CRITERIA: NOT APPLICABLE; AS PER DESIGN; CLIENT CRITERIA; USED FOR DIAGNOSTIC PURPOSES
1 & 2 OF 12	ACCEPTANCE CRITERIA SUMMARY REPORT	FOR REFERENCE ONLY	NOT APPLICABLE
3 OF 12	IDENTIFICATION DRAWING	FOR REFERENCE ONLY	NOT APPLICABLE
4 OF 12	AIRFLOW VOLUME PROFILE	PASS	SUFFICIENT TO ACHIEVE AIR CHANGES PER HOUR
5 OF 12	FILTER HISTORICAL DATA	FOR REFERENCE ONLY	USED FOR DIAGNOSTIC PURPOSES
6 OF 12	AIR CHANGES PER HOUR	PASS	≥ 30 ACPH – NON-HD ≥ 20 ACPH – ANTE
7 OF 12	ROOM DIMENSIONS	FOR REFERENCE ONLY	NOT APPLICABLE
8 OF 12	ROOM DIFFERENTIAL PRESSURES/ ROOM PRESSURIZATION & AIRFLOW DIRECTIONAL SMOKE PATTERN TESTS	PASS	NON-HO TO ANTE ≥ 0.020" W.C. ANTE TO AMBIENT ≥ 0.020" W.C
9 OF 12	AEROSOL CHALLENGE INSTALLATION LEAK TEST SMOKE DETECTOR YES ☐ NO ☒ Verify prior to test	PASS	≤ 0.010% PENETRATION
10 OF 12	FILTER MEDIA REPAIR TRACKING	PASS	LESSER DIMENSION OF EACH REPAIR NO GREATER THAN 1.50" TOTAL OF ALL REPAIRS NOT TO EXCEED 3.00% OF THE EFFECTIVE FILTER AREA
11 OF 12	AIRBORNE PARTICLE COUNT SURVEY	PASS	ISO Class 7 – NON-HD ≤ 352,000 PPCM @ 0.5 MICRON & LARGER ISO Class 8 – ANTE ≤ 3,520,000 PPCM @ 0.5 MICRON & LARGER per ISO Std 14644-1:2015

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QA REVIEWED
JH11JUN2024

BRW 17APR2024

ACCEPTANCE CRITERIA SUMMARY REPORT

TEST REPORT NO.: 301170334

PAGE	DOCUMENTATION OR DATA TITLE	TEST STATUS: PASS; FAIL; NO TEST; FOR REFERENCE ONLY	ACCEPTANCE CRITERIA: NOT APPLICABLE; AS PER DESIGN; CLIENT CRITERIA; USED FOR DIAGNOSTIC PURPOSES
12 OF 12	TEMPERATURE & RELATIVE HUMIDITY	FOR REFERENCE ONLY	NOT APPLICABLE

Tested in Accordance With CECS, Inc. WI CR- 0621 CERT AND CETA CAG-003-2006-13

Reviewed by CECS, Inc.: Technician Signature BRANDON WHITE — Date 17APR2024

CECS, Inc. QA Reviewed by: Print Name JAIDE HOWARD — Signature JH — Date 11JUN2024

Reviewed by Client: Print Name _____ — Signature _____ — Date _____

Total of 2 individual[s] present during testing of the PEC unit. 2 technician[s] were preforming the certification of the hood while 1 pharmacy technician[s] joined us during the smoke pattern video testing reflecting in Dynamic conditions.
Total of 1 pharmacy technician[s] present during Dynamic particle count testing in PEC unit.
Template Update - BRW 17APR2024

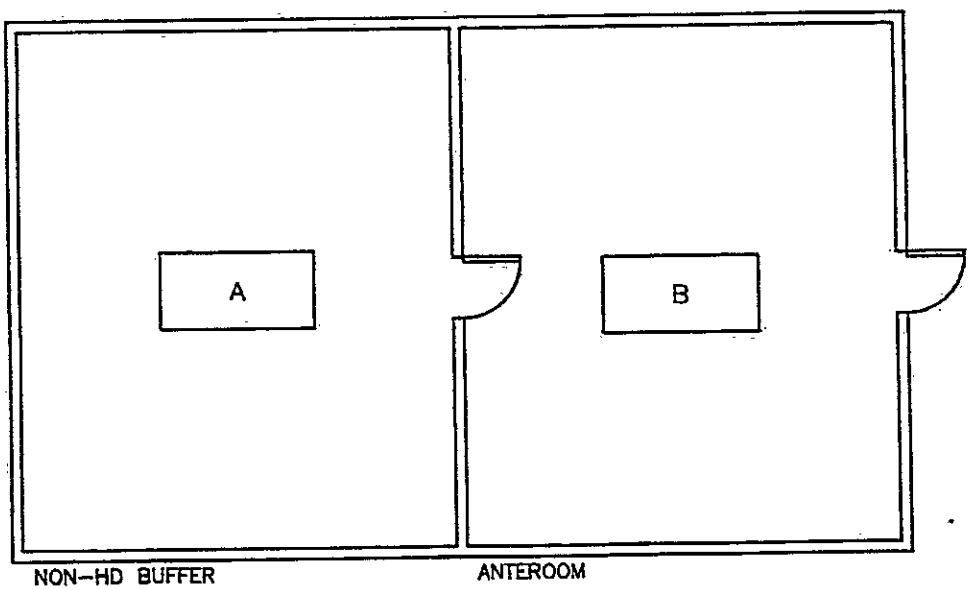
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QA REVIEWED
JH 11JUN2024

TEST REPORT NO. 301170334

CLIENT: HEARTLAND APOTHECARY
ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE, NON-HD BUFFER RM
OTHER: MCI# KK0113



IDENTIFICATION DRAWING

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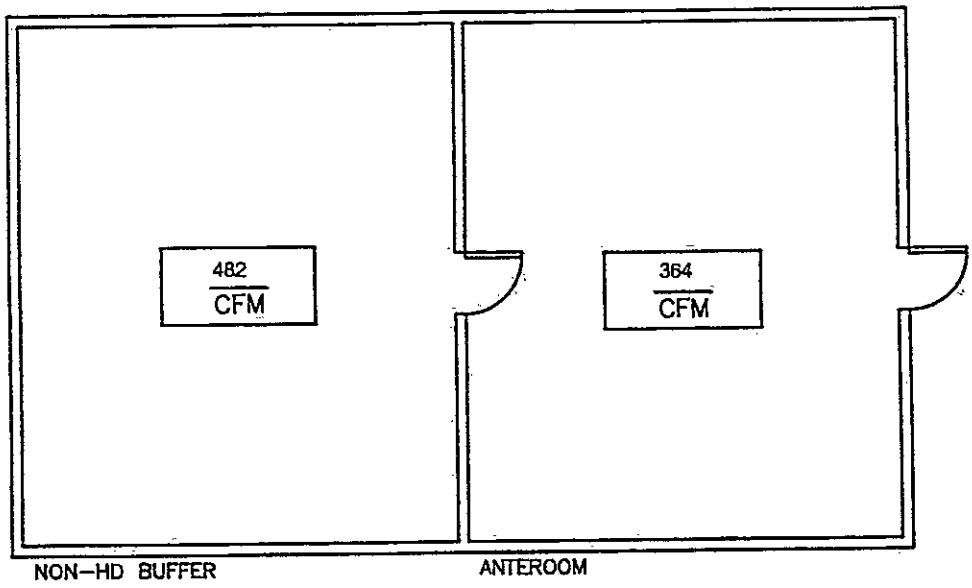
QA REVIEWED
ZH 11JUN2024

TEST REPORT NO. 301170334

CLIENT: HEARTLAND APOTHECARY
ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE, NON-HD BUFFER RM
OTHER: MCI# KK0113

TEST EQUIPMENT – DIM : Mfg. ALNOR Model EBT731 S/N EBT732012001
CAL DUE 28FEB2025



AIRFLOW VOLUME PROFILE
READINGS RECORDED IN CUBIC FEET PER MINUTE (CFM)
USING A CAPTURE HOOD
(ALL READINGS: BACKPRESSURE COMPENSATED)

BRW 17APR2024

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KK0113-REV-230412.DWG

QA REVIEWED
JH 11JUN2024

FILTER HISTORICAL DATA

TEST REPORT NO.: 301170334

CLIENT: HEARTLAND APOTHECARY
ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE. NON-HD BUFFER RM
OTHER: MCI# KK0113

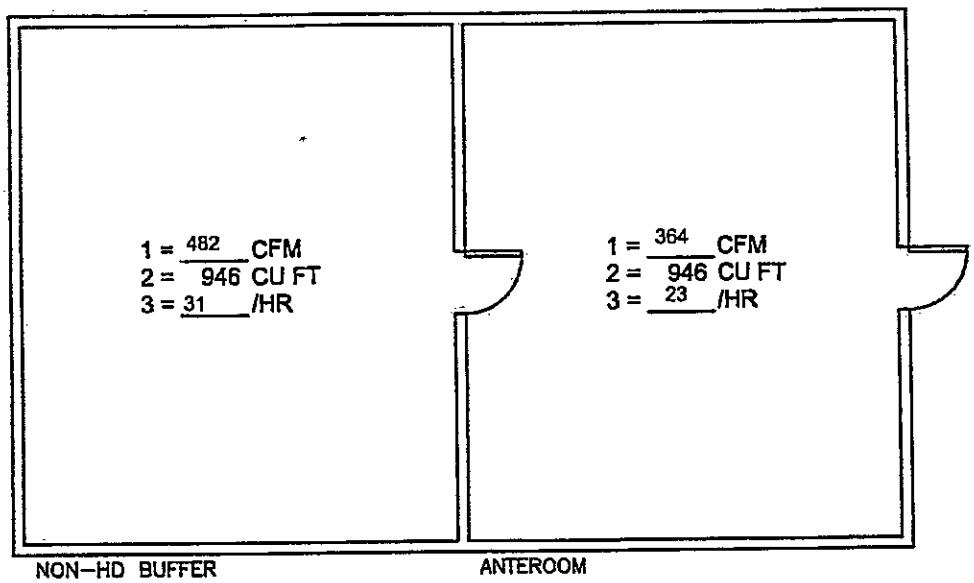
FILTER ID	FILTER REPLACEMENT DATA	S/N	DATE	INITIAL VOLUME
A	NA	NA	NA	NA CFM
B	NA	NA	NA	NA CFM

QA REVIEWED
JA 11 JUN 2024

TEST REPORT NO. 301170334

CLIENT: HEARTLAND APOTHECARY
ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE, NON-HD BUFFER RM
OTHER: MCI# KK0113



AIR CHANGES PER HOUR

1 = TOTAL AIRFLOW VOLUMES IN CUBIC FEET PER MINUTE (CFM)
($CFM_1 + CFM_2 + CFM_3 + ...$) = CFM_{TOTAL}
2 = ROOM VOLUME IN CUBIC FEET (CU FT) (L"xW"xH"/1728)
3 = AIR CHANGES/HOUR (/HR) (CFM/CU FT x 60)

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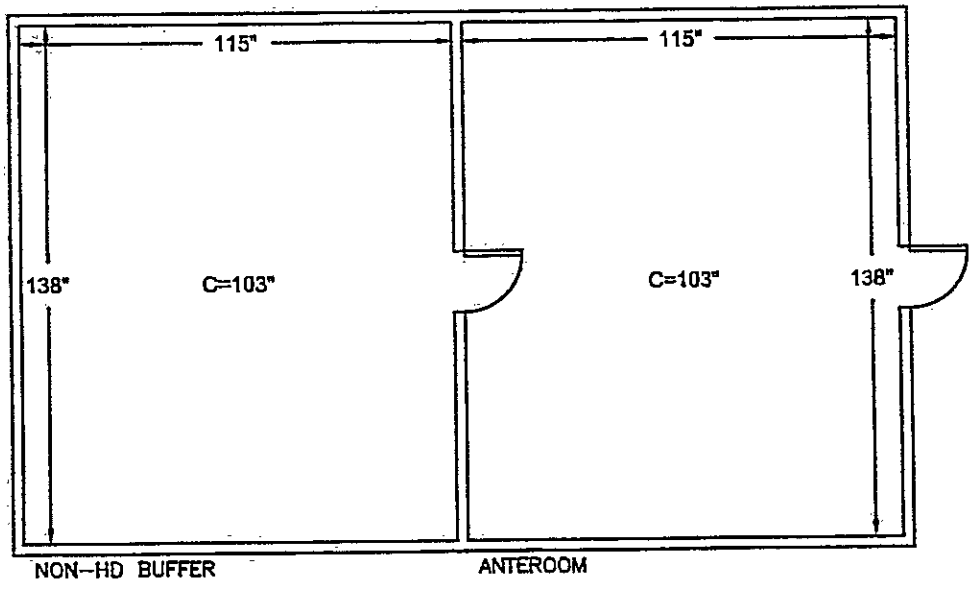
KK0113-REV-230412.DWG

QA REVIEWED
JH 11JUN2024

TEST REPORT NO. 301170334

CLIENT: HEARTLAND APOTHECARY
ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE, NON-HD BUFFER RM
OTHER: MCI# KK0113



ROOM DIMENSIONS
MEASURED TO THE NEAREST INCH
C = CEILING HEIGHT

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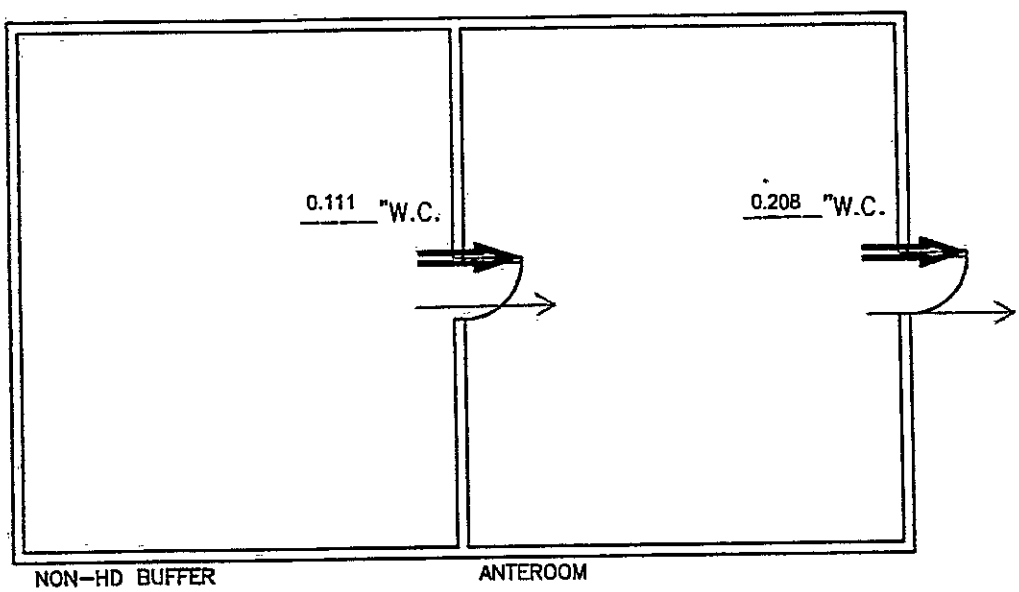
QA REVIEWED
FH 11JUN2024

TEST REPORT NO. 301170334

CLIENT: HEARTLAND APOTHECARY
ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE, NON-HD BUFFER RM
OTHER: MCI# KK0113

TEST EQUIPMENT – ANEMOMETER: Mfg. TSI Model 9565-P S/N 9565P2334031
CAL DUE 14MAY2024



ROOM PRESSURIZATION

ROOM-TO-ROOM PRESSURES ARE INDICATED IN INCHES OF WATER COLUMN ("W.C.) ADJACENT TO AIRFLOW DIRECTIONAL ARROW. AIRFLOW DIRECTION VERIFIED WITH A VISUAL SMOKE SOURCE.

CURRENT AIRFLOW DIRECTION → NEUTRAL ↔

DESIGN AIRFLOW DIRECTION ⇒ NO DESIGN DIRECTION ⇔

PRESSURES TAKEN ON 17APR2024 @ 1120

BRW 17APR2024

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JH 11JUN2024

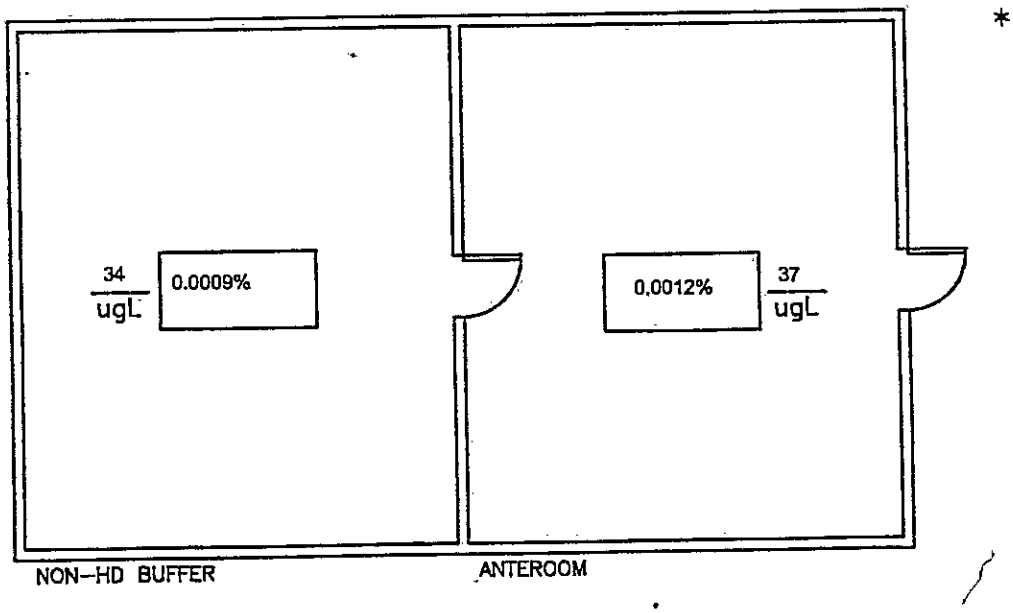
TEST REPORT NO. 301170334

CLIENT: HEARTLAND APOTHECARY
ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE, NON-HD BUFFER RM
OTHER: MCI# KK0113

TEST EQUIPMENT – Photometer: Mfg. ATI Model 2I S/N 71723
CAL DUE 23JUL2024

ALL UG/L CALCULATED
SCANNED BY JR



AEROSOL CHALLENGE INSTALLATION LEAK TEST

A MINIMUM OF 10 ug/L COLD SMOKE PAO WAS INTRODUCED FROM RETURN OUTSIDE OF CLEANROOM*. A 100% SCAN OF THE FILTER MEDIA AND SURROUNDING FRAME / SEAL WAS CONDUCTED. RESULTS INDICATED ON DIAGRAM.

BR=BEFORE REPAIR, AR=AFTER REPAIR (REPAIRS MADE WITH RTV SILICONE), //=MEDIA LEAKAGE, XX=FRAME LEAKAGE

SMOKE DETECTORS: NO
CHALLENGE RECORDED IN MICRO-GRAMS PER LITER (ugL)

BRW 17APR2024

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KK0113-REV-230412.DWG

QA REVIEWED
17 JUN 2024

FILTER MEDIA REPAIR TRACKING

TEST REPORT NO. 301170334

CLIENT: HEARTLAND APOTHECARY

ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED

MFG: CLEANROOM

IDENTIFYING NO.: NA

LOCATION: PHARMACY

ROOM: ANTE, NON-HD BUFFER RM

OTHER: MCI# KK0113

FILTER #	FILTER MEDIA AREA (dimensions in inches)	PATCH SIZE (dimensions in inches)	UP/DOWN STREAM	DATE OF REPAIR	% AREA	TOTAL REPAIR %
A	0.00 x 0.00 = 0.00 SQ IN	0.00 x 0.00 = 0.00 SQ IN	NA	NA	0.00	0.00
B	0.00 x 0.00 = 0.00 SQ IN	0.00 x 0.00 = 0.00 SQ IN	NA	NA	0.00	0.00

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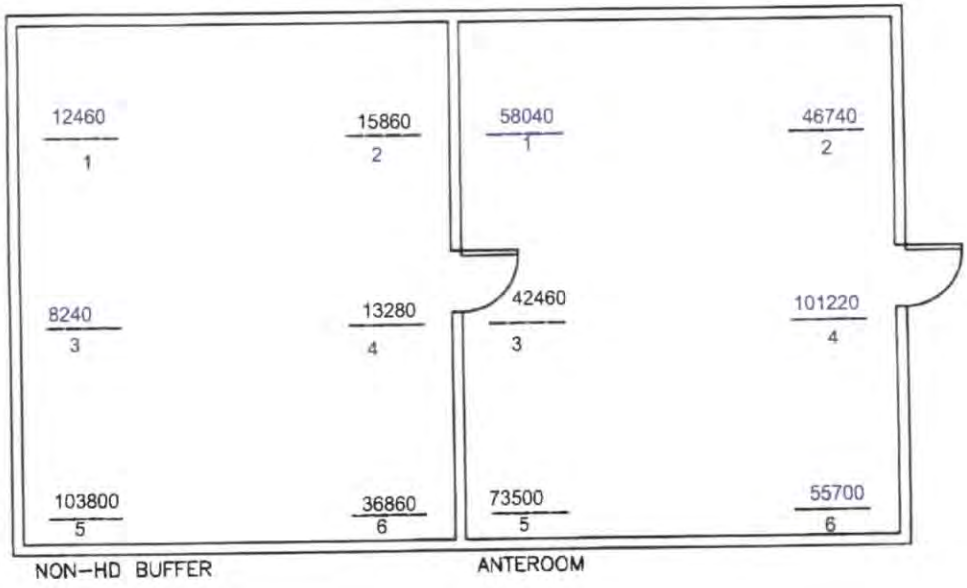
QA REVIEWED
JH 11JUN2024

TEST REPORT NO. 301170334

CLIENT: HEARTLAND APOTHECARY
ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE, NON-HD BUFFER RM
OTHER: MCI# KK0113

TEST EQUIPMENT – Particle Counter: Mfg. TSI Model 9350-02 S/N 93501723004
CAL DUE 15MAY2024



AIRBORNE PARTICLE COUNT SURVEY

TAKEN AT 42" WORK SURFACE ELEVATION. ROOM IN OPERATIONAL CONDITIONS WITH 2 PERSON(S) IN ROOM.

GOWNING LEVEL = ASEPTIC

ISO CLASS 7 & 8
MINIMUM SAMPLE VOLUME 2 LITERS @ 50 LPM FOR 1 MINUTE(S)

SURVEY TO BE READ AS FOLLOWS:
0.5 MICRON & LARGER PARTICLES PER CUBIC METER (PPCM)

BRW 17APR2024

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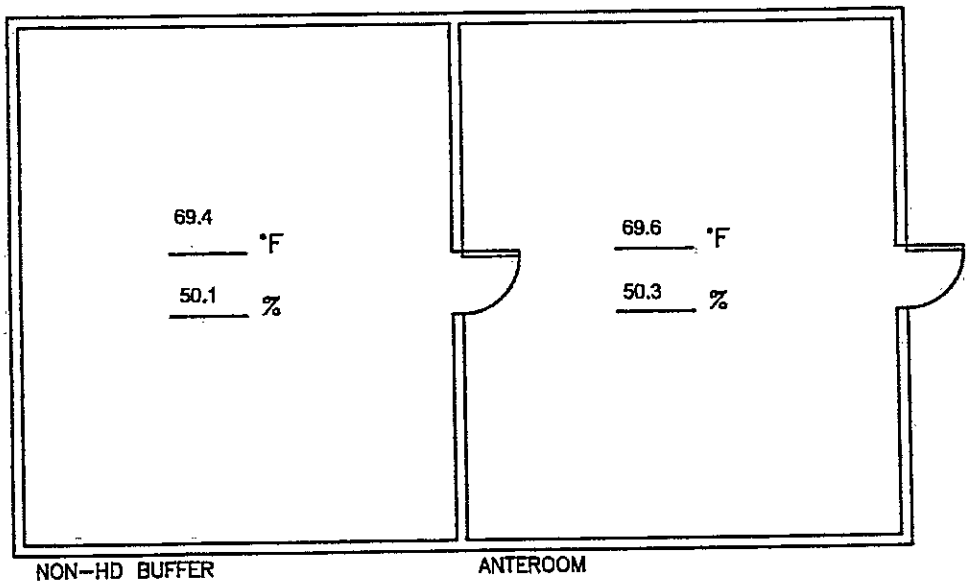
QA REVIEWED
JH 11JUN2024

TEST REPORT NO. 301170334

CLIENT: HEARTLAND APOTHECARY
ADDRESS: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922

TYPE OF EQUIPMENT BEING TESTED
MFG.: CLEANROOM
IDENTIFYING NO.: NA
LOCATION: PHARMACY
ROOM: ANTE, NON-HD BUFFER RM
OTHER: MCI# KK0113

TEST EQUIPMENT – Temp/Humidity Probe: Mfg. TSI Model 966 S/N P23360079
CAL DUE 14MAY2024



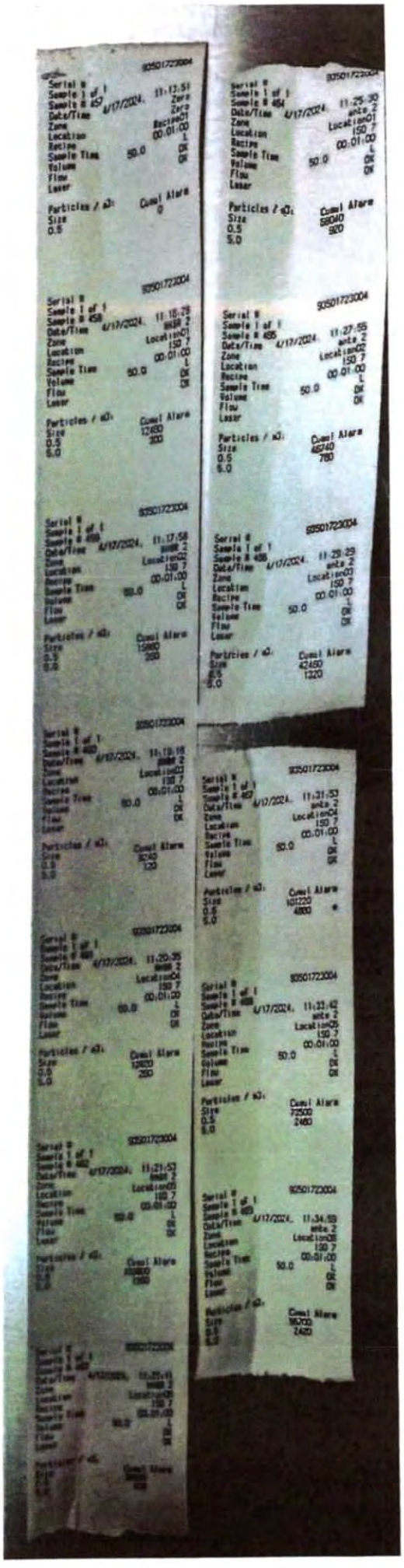
TEMPERATURE / RELATIVE HUMIDITY
TEMPERATURE - DEGREES FAHRENHEIT (°F)
RELATIVE HUMIDITY - RELATIVE HUMIDITY (%)

BRW 17APR2024

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KK0113-REV-230412.DWG

QA REVIEWED
JH 11JUN2024



QA REVIEWED
JH 11/20/2024

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Bethlehem, PA 18017

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Fax: 610-954-7803
email: cecs_info@steris.com
www.sterislifesciences.com

CERTIFICATE OF CALIBRATION

MANUFACTURER TSI **MODEL** 9565-P

SERIAL NUMBER 9565P2334031 **DESCRIPTION** VelociCalc Thermoanemometer (Meter)

Controlled Environment Certification Services, Inc. does hereby certify that all performance and acceptance tests required were successfully conducted according to required specifications. All calibration data and test instrumentation used have been obtained using standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST), have been derived from accepted values of natural physical constants, or by the use of ratio type of self calibration. The calibration system complies with ISO/IEC 17025:2017.

February 15, 2024
Date of Calibration

May 14, 2024
Next Calibration is Due

Todd Stevens 15 FEB 2024
Authorized Name/Signature/Date

138096
MCI#

301062875
REPORT#

CECS, Inc.
Client Name

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email: cecs_info@steris.com
www.sterislifesciences.com

CERTIFICATE OF CALIBRATION

MANUFACTURER TSI / Alnor **MODEL** EBT731

SERIAL NUMBER EBT732012001 **DESCRIPTION** Micromanometer / Balometer

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February 28, 2025
Next Calibration is Due

Thomas Dahl 04 MAR 2024
Authorized Name/Signature/Date

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MCI#

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CERTIFICATE OF CALIBRATION

MANUFACTURER *Air Techniques International* **MODEL** *2i*

SERIAL NUMBER *71723* **DESCRIPTION** *Aerosol Photometer*

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January 24, 2024
Date of Calibration

July 23, 2024
Next Calibration is Due

Kelly Sahanic Kelly Sahanic 26Jan2024
Authorized Name/Signature/Date

138084
MCI#

301060468
REPORT#

CECS, Inc.
Client Name

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www.sterislifesciences.com

CERTIFICATE OF CALIBRATION

MANUFACTURER TSI **MODEL** 9350-02

SERIAL NUMBER 93501723004 **DESCRIPTION** Laser Particle Counter

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November 16, 2023
Date of Calibration

May 15, 2024
Next Calibration is Due

Dave Matos 20 NOV 2023
Authorized Name/Signature/Date

127863
MCN#

301069072
REPORT#

CECS, Inc.
Client Name

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CERTIFICATE OF CALIBRATION

MANUFACTURER TSI **MODEL** 966

SERIAL NUMBER P23360079 **DESCRIPTION** VelociCalc Thermoanemometer(Probe)

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February 15, 2024
Date of Calibration

May 14, 2024
Next Calibration is Due

Todd Stevens 15 FEB 2024
Authorized Name/Signature/Date

138097
MCI#

301062790
REPORT#

CECS, Inc.
Client Name

Standard Operating Procedure (SOP) for Handling Pharmacy Complaints

1. Purpose

The purpose of this SOP is to establish a clear and effective procedure for handling and resolving complaints within the pharmacy to ensure customer satisfaction and compliance with regulatory requirements.

2. Scope

This SOP applies to all employees of the pharmacy, including pharmacists, pharmacy technicians, and support staff.

3. Responsibilities

- **Pharmacy Staff**: First point of contact for receiving complaints and initiating the documentation process.
- **Pharmacy Manager**: Responsible for reviewing, investigating, and resolving complaints. Ensures that corrective actions are implemented and documented.
- **Quality Assurance (QA) Team**: Monitors the complaint management process and ensures compliance with regulatory standards.

4. Procedure

4.1 Receiving Complaints

1. **Direct Complaints**: When a customer presents a complaint in person, listen attentively and acknowledge their concern.
2. **Telephone Complaints**: For complaints received over the phone, listen carefully, take detailed notes, and confirm the information with the customer.
3. **Written Complaints**: For complaints received via email or written communication, print out and acknowledge receipt within one business day.

4.2 Documenting Complaints

1. **Complaint Form**: Complete a Complaint Form, including:
    - Date and time of complaint
    - Customer's name and contact information
    - Detailed description of the complaint
    - Name of the staff member receiving the complaint
2. **Complaint Log**: Enter the details of the complaint into the Complaint Log for tracking and reference.

4.3 Initial Assessment

1. **Severity Assessment**: Assess the severity and potential impact of the complaint (e.g., medication error, service issue).
2. **Immediate Actions**: If the complaint involves an urgent issue (e.g., potential harm to a patient), take immediate corrective action and escalate to the Pharmacy Manager.

4.4 Investigation

1. **Gather Information**: Collect all relevant information and documentation related to the complaint.
2. **Interview Involved Parties**: Interview staff members involved to understand the situation from all perspectives.
3. **Root Cause Analysis**: Identify the root cause of the issue

4.5 Resolution

1. **Develop Action Plan**: Create an action plan to address and resolve the complaint, including corrective and preventive actions.
2. **Implement Actions**: Implement the corrective actions and ensure they are effective.
3. **Communicate with Customer**: Inform the customer of the resolution and actions taken. Apologize for any inconvenience caused and thank them for their feedback.

4.6 Follow-up

1. **Monitor Effectiveness**: Monitor the effectiveness of the implemented actions to prevent recurrence.
2. **Customer Satisfaction**: Follow up with the customer to ensure they are satisfied with the resolution.

4.7 Documentation and Reporting

1. **Update Records**: Ensure all documentation related to the complaint is complete and stored in the Complaint Log.
2. **Regular Review**: Conduct regular reviews of the Complaint Log to identify trends and areas for improvement.
3. **Regulatory Reporting**: Report any serious complaints to the appropriate regulatory authorities as required.

5. Training

- All pharmacy staff must receive training on the complaint handling process and this SOP.
- Regular refresher training sessions should be conducted to ensure ongoing compliance.

6. Review and Revision

- This SOP should be reviewed annually or whenever there are significant changes in the complaint handling process.

- Any revisions must be approved by the Pharmacy Manager and communicated to all staff.

By following this SOP, the pharmacy ensures a consistent, fair, and efficient approach to handling customer complaints, ultimately leading to improved customer satisfaction and service quality.

End of Day Report 2024: Pharmacist verifies that all prescriptions Dispensed have been checked for Accuracy.

	January	February	March	April	May	June	July	August	September	October	November	December
1												
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4												
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Customer	Heartland Apothecary	**Sample Date**	10Jun2024
Facility Address	9947 Kingston Pike Knoxville, TN 37922	**Issue Date**	21Jun2024
Contact Name	Randy Martin	**MCI #**	KK0114
E-Mail Address	randymartinpharmd@gmail.com	**SOA #**	17470486
Report ID	24CE0908	**Test Report #**	102406502

USP <797> Single Plate Environmental Monitoring Final Report Summary Sheet

Viable Environmental Monitoring (VEM) is utilized to determine the microbial growth within a controlled environment. USP <797> "Pharmaceutical Compounding – Sterile Preparations" is used as a reference.

Media:

	Lot #	Expiration Date	Controls	Growth Promotion Testing
TSA w/ Lec+P80	1010432470	12Jul2024	Pass	Pass

Incubation (transferred):

Temperature	Duration	Incubation Dates
30-35°C (Bacterial)	48 hours-5 days	11Jun2024 to 13Jun2024
20-25°C (Fungal)	5-7 days	13Jun2024 to 18Jun2024

Equipment:

Type	Serial #	Calibration Due Date
SAS (Surface Air Sampler)	20-D-15224	04Aug2024
SAS (Surface Air Sampler)	18-D-12891	04Aug2024
SAS (Surface Air Sampler)	16-D-10530	18Oct2024

Acceptance Criteria:

Acceptance criteria is determined by the action levels provided in USP <797> (2022) for the number of viable organisms present. If levels measured during viable sampling exceed the action levels, an attempt must be made to identify any microorganisms recovered to the genus level.

ISO Classification	Viable Air (Impaction) Sampling	Viable Surface Sampling
ISO 5	≤ 1 CFU/m^3	≤ 3 CFU/plate
ISO 7	≤ 10 CFU/m^3	≤ 5 CFU/plate
ISO 8	≤ 100 CFU/m^3	≤ 50 CFU/plate

Results:

☒ VEM sample(s) meet the acceptance criteria: No exceeding counts observed.

☐ VEM sample(s) do not meet acceptance criteria: There were exceeded counts observed on one or more sample – genus level identification provided.

Reported by/ Date: TMS 21Jun2024 Reviewed by/ Date: TMM 21Jun2024

These results relate only to the items tested

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Enumeration Report Sheet - Final Report

Customer: Heartland Apothecary
Facility: NA
Address: 9947 Kingston Pike Knoxville, TN 37922
Guideline: USP <797>
Laboratory Method: MRPT-XXXX EM
Deviations: None

Sample Date: 10Jun2024
Received Date: 11Jun2024
Report ID: 24CE0908
Type of Sampler: SAS
Laboratory Test Dates: 11Jun2024 to 18Jun2024

MCI # KK0114
SOA # 17470486
Test Report # 102406502
33°C: 11Jun2024 to 13Jun2024
23°C: 13Jun2024 to 18Jun2024

Total Bacterial Count incudes: GNR - Gram negative rod, GPC - Gram positive cocci, GPSFR- Gram positive spore forming rod, GPNSFR - Gram positive non spore forming rod, CPS- Coagulase positive Staphylococcus

Media	Lot Number	Expiration Date	Controls: Pass/Fail
TSAw/Lec+P80	1010432470	12Jul2024	Pass

Sample code: Location #	Sample Description	ISO Class (area) 5,7 or 8	Volume (L) or Area (cm²)	Sample Standing: Pass/ Action	Action Level: > CFU	Alert Level >	Total Bacterial Count	Total Fungal Count: Yeast / Mold	Total Microbial (Bac/ Mold) Count	Total Calculated Microbial Count (TCMC)*1
AV1	PEC #1 Germfree BSC S/N: 5224490001	5	1000	Pass	1	NE	0	0	0	<1
AV2	**PEC #2 Germfree BSC S/N: 2S-15-BR-6700**	**5**	**1000**	**TNR**	**1**	**NE**	**NA**	**NA**	**NA**	**NA**
AV3	PEC #3 Germfree BSC S/N: 5224490002	5	1000	Pass	1	NE	0	0	NA	<1
AV4	Non-HD Buffer	7	1000	Pass	10	NE	0	0	0	<1
AV5	**Anteroom**	**8**	**1000**	**TNR**	**100**	**NE**	**NA**	**NA**	**NA**	**NA**
SV1	PEC #1 Germfree BSC S/N: 5224490001	5	25	Pass	3	NE	0	0	0	<1
SV2	**PEC #2 Germfree BSC S/N: 2S-15-BR-6700**	**5**	**25**	**TNR**	**3**	**NE**	**NA**	**NA**	**NA**	**NA**
SV3	PEC #3 Germfree BSC S/N: 5224490002	5	25	Pass	3	NE	0	0	NA	<1
SV4	**Non-HD Buffer, Table**	**7**	**25**	**TNR**	**6**	**NE**	**NA**	**NA**	**NA**	**NA**
SV5	**Anteroom, Cart**	**6**	**25**	**TNR**	**50**	**NE**	**NA**	**NA**	**NA**	**NA**

*1TCMC Expressed as: AV# : CFU/m³ if the SAS is used, any TMC over 15 is adjusted as required. SV#: CFU/plate

Reported by/ Date: TMS 21JUN2024
Reviewed by/ Date: TMM 21JUN2024
Total Samples: 5 Single Plate

Prepared by CECS, Inc.

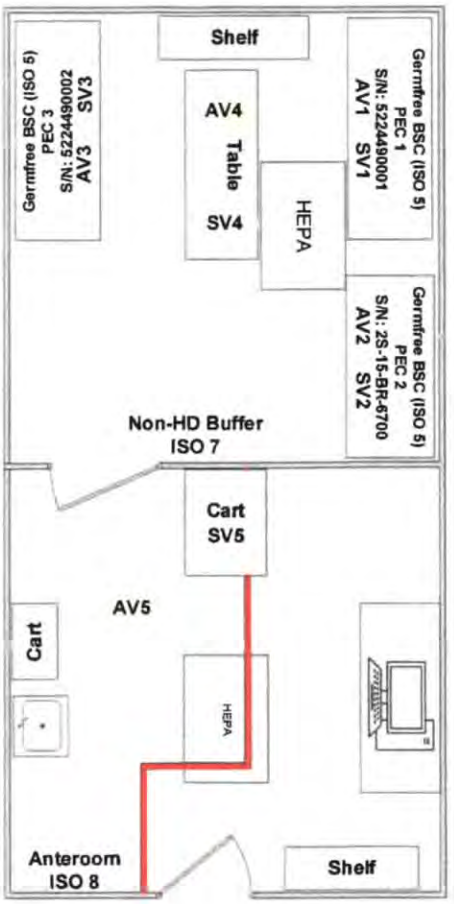
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USP <797> ENVIRONMENTAL MONITORING PLAN FOR VIABLE PARTICLES

KK0114 Heartland Apothecary



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Customer MCI #/Name: KK0114 Heartland Apothecary

PEC #	**1**	**Manufacturer/Model/ SN**	Germfree	BSC	5224490001
PEC #	**2**	**Manufacturer/Model/ SN**	Germfree	BSC	2S-15-BR-6700
PEC #	**3**	**Manufacturer/Model/ SN**	Germfree	BSC	5224490002

Sample date	10Jun2024	**Technician name**	Cayla Walton	**Activity**	☐As built ☒Static ☐Dynamic
Sample time	11:25 AM				
No. of people in rooms	_1_ / recorded in space	**Media lot #**	TSA 1010432470	**Expiration date**	12Jul2024
Sampler SN	20-D-15224	**Sampler cal due date**	04Aug2024		
Sampler SN	16-D-10530	**Sampler cal due date**	18Oct2024		
Sampler SN	18-D-12891	**Sampler cal due date**	04Aug2024		
SOA #	17470486	**Test Report #**	102406502	**Sterile 70% IPA (Lot #/Exp)**	CONTEC 1000699-0-0-1 07/2028
Gowning	☒ Bouffant ☒Shoe covers ☒Gloves ☐Safety glasses ☒Mask ☐Jumpsuit ☒Gown				

Observations/Additional Notes:
Sampling of AV1, AV3, AV4, SV1, and SV3

Acceptance levels:
ISO 5 Air = ≤ 1 CFU/m^3 / ISO 5 Surface = ≤ 3 CFU/plate
ISO 7 Air = ≤ 10 CFU/m^3 / ISO 7 Surface = ≤ 5 CFU/plate
ISO 8 Air = ≤ 100 CFU/m^3 / ISO 8 Surface = ≤ 50 CFU/plate

SAS sample volumes:
All air samples: 1000L

Prepared By : Isabella Mercado 18Jun2024

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USP <797> Footnotes and Additional Report Information

Result Interpretation	USP Requirements	Test Methods	Abbreviations
All recoveries analyzed in this report are directly correlated to the SOA associated with this project and is intended as such only. Dual Plate Method Calculation: Bacterial and Fungal (mold/yeast) counts are added from the corresponding plates for each location. Viable samples considered "For Information Only" have no action limits associated with the testing. One cubic meter is equal to 1000 liters. TNTC is equivalent to >219 CFU/plate. Reporting values for USP <797> (2022): Air = CFU/m^3 Surface = $CFU/25cm^2$	Acceptance criteria is determined by the action levels provided in USP <797> (2022) for the number of viable organisms present for Active Air, Surface, and Fingertip testing. If levels measured during viable sampling exceed the action levels, an attempt must be made to identify any microorganisms recovered to the genus level. Microbiological air and/or surface monitoring must be conducted in all classified areas during dynamic operating conditions. The condition of the area and number of personnel present is documented on the STERIS sample plan. This number includes the STERIS technician collecting the samples if applicable.	For active air sampling via SAS, the positive hole correction factor is a statistical tool which calculates a probable count from the total raw count, considering that multiple particles can impact on the same sample hole. Therefore, the sum of the raw counts may be less than the positive corrected total. All USP active air sampling is performed using an impaction device per USP <797> (2022). For media, plates contain Polysorbate 80 and Lecithin to neutralize residues of cleaning and disinfecting agents to aid in prevention of false negative results. Media Controls: An unexposed media plate from each sampling event/project is submitted for quality control purposes to ensure any recoveries are true and actual and that samples were not compromised during shipping to the laboratory. A positive/negative control is submitted by the sampling technician and the lot and expiration shall be the same as the sample plates being submitted to the lab for analysis.	**AV** - Air Viable **CFU** - Colony Forming Unit **C-SCA** - Containment Segregated Compounding Area **CSP** - Compounded Sterile Preparation **DCA** - Direct Compounding Area **EC** - Exceeded Counts **FIO** - For Information Only **HD** - Hazardous **ISO** - International Standards Organization **MCI** – STERIS internal tracking number **MEA** - Malt Extract Agar **NA** - Not Applicable **NE** - Not Established **NG** - Not Given **OC** - Organism of Concern **PEC** - Primary Engineering Control **RABS** – Restricted Access barrier System **SAS** - Surface Air Sampler **SCA** - Segregated Compounding Area **SDA** - Sabouraud Dextrose Agar **SEC** - Secondary Engineering Control **SNR** - Sample Not Received **SOA** - Sales Order Acknowledgment **SV** - Surface Viable **SW** - Swab **TNR** - Test Not Requested **TNTC** - Too Numerous to Count **TSA** - Tryptic Soy Agar **USP** - United States Pharmacopeia

CECS References: WI VEM-XXXX EM, WI MRPT-XXXX EM

This page is for informational purposes only

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email: cecs_info@steris.com

CLASS II, TYPE A2 BIOLOGICAL SAFETY CABINET

Test Report No.: 102395479
Date: June 7, 2024
Client: HEARTLAND APOTHECARY
Address: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922
Attn: RANDY MARTIN

Mfg./Model: Germfree BBF-4SSRX
Identifying No.: 5224490001
Location: PHARMACY
Room: NON HD BUFFER
Other:
MCI#: DCIC508642

SUMMARY OF TEST RESULTS

AIRFLOW VELOCITY RESULTS

Test Results on Page 2

FINAL - DOWNFLOW VELOCITY TEST ☑ PASS ☐ FAIL AVG ☐ PASS AVG/FAIL UNIFORMITY
INFLOW VELOCITY TEST ☑ PASS ☐ FAIL

SITE INSTALLATION ASSESSMENT TESTS

Test Results on Page 2

SASH ALARM TEST	☐ PASS	☐ FAIL	☑ NA
AIRFLOW OR PRESSURE ALARM TEST	☐ PASS	☐ FAIL	☑ NA
TYPE B SUPPLY BLOWER INTERLOCK TEST	☐ PASS	☐ FAIL	☑ NA
EXHAUST SYSTEM PERFORMANCE TEST	☐ PASS	☐ FAIL	☑ NA

AEROSOL CHALLENGE INSTALLATION LEAK TEST

Test Results on Page 3

AS FOUND - SUPPLY FILTER	☑ PASS	☐ FAIL	☐ NO TEST	NA
AS FOUND - EXHAUST FILTER	☑ PASS	☐ FAIL	☐ NO TEST	NA
FINAL - SUPPLY FILTER	☑ PASS	☐ FAIL	☐ NO TEST	NA
FINAL - EXHAUST FILTER	☑ PASS	☐ FAIL	☐ NO TEST	NA

AIRBORNE PARTICLE COUNT TEST ☑ PASS ☐ FAIL ☐ NO TEST

Test Results on Page 3

AIRFLOW SMOKE PATTERN TESTS

Test Results on Page 4

DOWNFLOW TEST	☑ PASS	☐ FAIL	
VIEW SCREEN RETENTION TEST	☑ PASS	☐ FAIL	☐ MEETS MFR. SPECS
WORK OPENING EDGE RETENTION TEST	☑ PASS	☐ FAIL	
SASH/WINDOW SEAL TEST	☑ PASS	☐ FAIL	

Note: Noise Level Test and Lighting Intensity Test results are for information only.

Testing Performed In Accordance with CECS, Inc. **WI #**BSC-1018 CERT

Certified In Accordance with NSF 49, Annex F & CETA CAG-003-2006-13

Retest Date: OCTOBER, 2024

Remarks: NA

Above Testing Work Performed By Matt Lawrence **Date** 07-Jun-2024

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Test Report No.: 102395479

FINAL AIRFLOW VELOCITY TESTS

Anemometer: Mfg. TSI **Model** 966 **S/N** P20080067 **Cal Due** July 23, 2024

DOWNFLOW VELOCITY AND UNIFORMITY PROFILE

☑ **Pass Average Velocity & Airflow Uniformity**

Number of Supply Readings Taken	21				All readings within the larger of ±25% of Avg. or ±16 FPM.	
Maximum Supply Velocity Allowable/Actual	99	/	92	fpm		
Minimum Supply Velocity Allowable/Actual	59	/	70	fpm	*Acceptance Criteria*	☐ **Fail Average Velocity**
Average Supply Velocity	79	fpm	67	- 82 fpm		☐ **Pass Average Velocity Fail Airflow Uniformity**

Diagram of Supply Velocity Profile Taken at 8 **inch(es)** sash height

73	77	75	74	73	72	73
79	78	75	71	70	71	72
87	87	89	89	90	91	92

Exhaust Filter

No. of Exhaust Readings Taken	9			*Acceptance Criteria*			
Average Intake Velocity	105	fpm	102	- 112	fpm	☑ **Pass**	☐ **Fail**

155	139	142
154	136	146
140	125	119

Average Exhaust Velocity (Ve)	139.56	**fpm**
Exhaust Area (Ae)	1.58	**sq ft**
(Ve x Ae = Qe) Exhaust Volume (Qe)	220.50	**cfm**
Intake Area (Ai)	2.11	**sq ft**
(Qe / Ai = Vi) Intake Velocity (calculated) (Vi)	105	**fpm**

Velocity Conforms to: Manufacturer's Specs. & Manufacturer's Specs **Motor Parameters:** NA

Blower Speed Required: Increasing **Internal Damper:** NA

Exhaust Configuration: Internal **Exhaust Damper:** NA

SITE INSTALLATION ASSESSMENT TESTS

Sash Alarm Test	☐ **PASS**	☐ **FAIL**	☑ **NA**	No alarm designed by Mfr.
Airflow or Pressure Alarm Test	☐ **PASS**	☐ **FAIL**	☑ **NA**	NA-No Alarm Installed
Type B Supply Blower Interlock Test	☐ **PASS**	☐ **FAIL**	☑ **NA**	
Exhaust System Performance Test	☐ **PASS**	☐ **FAIL**	☑ **NA**	NA

Differential Pressure: Hood 0.45 **"W.C.** **Exhaust Duct:** NA **"W.C.**

(cannot be greater than 8 fpm below the minimum intake velocity range) Canopy Performance Impact

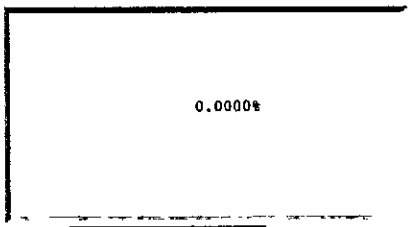
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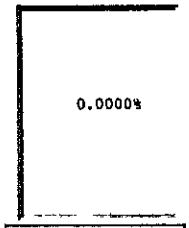
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AEROSOL CHALLENGE INSTALLATION LEAK TEST

Photometer: Mfg. TEC Services, I **Model** PH-5 **S/N** 1622 **Cal Due** August 21, 2024

Diagram of repairable filter leaks with challenge concentration of A minimum of 10 ug/Liter PAO CAS# 68649-12-7





Leak Concentrations as shown:

Filters marked "100% Scan" were scan tested over the filter media and separate passes made on the surrounding frame/seal. Filter acceptance is 0.01% of the upstream concentration. Filters marked "Probe Tested" were tested using the Total Leakage Test Method. Filter acceptance is 0.005% of the upstream concentration.

Comments Below:

NA

/-media leakage
x-frame leakage
BR-before repair
AR-after repair

Leaks Repaired: NA

Supply Filter Results:

As Found ☑ **Pass** ☐ **Fail** ☐ **No Test**

NA

Final ☑ **Pass** ☐ **Fail** ☐ **No Test**

NA

100% Scan **Leaks Repaired:** NA

Exhaust Filter Results:

As Found ☑ **Pass** ☐ **Fail** ☐ **No Test**

NA

Final ☑ **Pass** ☐ **Fail** ☐ **No Test**

NA

AIRBORNE PARTICLE COUNT

Particle Counter: Mfg. TSI **Model** 9350-02 **S/N** 93501605003 **Cal Due** June 12, 2024

Note: All particles 0.5 **micron and larger were counted.**

Readings shown are in particles per cubic meter of air.

Ambient room particle count = 6560 ppcm (Room Ambient)

Sample Locations are taken at 12 **Inches above the work surface.**

Particle Count locations are identified with numbers (1) through (5).

Room ambient count is identified as (Room Ambient)

(1) 0		0 (2)
	(3) 0	
(4) 0		0 (5)

Specification: ISO Class 5 0.5 um & larger (At-Rest) ISO 14644-1:2015 ☑ **Pass** ☐ **Fail** ☐ **No Test**

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Test Report No.: 102395479

AIRFLOW SMOKE PATTERN TESTS

1. DOWNFLOW TEST:

A smoke source shall be passed from one end of the cabinet to the other, along the centerline of the work surface at a height of 4 inches (10 cm) above the top of the access opening. The smoke shall show smooth downward flow with no dead spots or reflux (upward flow). No smoke shall escape from the cabinet.

☑ **PASS** ☐ **FAIL**

Comments: NA

2. VIEW SCREEN RETENTION TEST:

A smoke source shall be passed from one end of the cabinet to the other, 1 inch (2.5 cm) behind the viewscreen, at a height of 6 inches (15 cm) above the top of the access opening. The smoke shall show smooth downward flow with no dead spots or reflux. No smoke shall escape from the cabinet.

☑ **PASS** ☐ **FAIL** ☐ **MEETS MANUFACTURER'S SPECIFICATIONS**

Comments: NA

3. WORK OPENING EDGE RETENTION TEST:

A smoke source shall be passed along the entire perimeter of the work opening edges, approximately 1.5" (3.8 cm) outside the cabinet. Particular attention should be paid to corners and vertical edges. No smoke shall reflux out of the cabinet once drawn in, nor shall smoke billow over the work surface or penetrate onto it.

☑ **PASS** ☐ **FAIL**

Comments: NA

4. SASH/WINDOW SEAL TEST:

A smoke source shall be passed up the inside of the window 2" (5 cm) from the sides and along the top of the cabinet interior work area. No smoke shall escape out of the cabinet.

☑ **PASS** ☐ **FAIL**

Comments: NA

REMARKS

Supply HEPA Filter(s) Size: 1-20 x 46 x 6 MK375100600

Exhaust HEPA Filter(s) Size: 1-16 x 18 x 6 MK375100500

Pre Filter(s) Size: NA

HEPA Filter(s) Replaced: No

Prefilter(s) Replaced: No

U.V. Lamp(s) Replaced: NA

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email: cecs_info@steris.com

OPERATIONAL NON-VIABLE PARTICLE COUNT USP<797>

Test Report No.: 102395479
Date: June 07, 2024
Client: HEARTLAND APOTHECARY
Address: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922
Attn: RANDY MARTIN

Mfg./Model: Germfree BBF-4SSRX
Identifying No.: 5224490001
Location: PHARMACY
Room: NON HD BUFFER
Other:
MCI#: DCIC508642

NON-VIABLE PARTICLE COUNT CONDITIONS OF TEST

Type of Clean Zone: Unidirectional
Cleanroom or zone Cleanliness Classification: ISO Class 5
Particle Class Limit In Particles Per Cubic Meter: 3520
Measures Particle Size in Microns (and larger): 0.5
Number of Particle Count Sample locations: (L) 1

Occupancy State of Test: Operational
Type of Test: Verification
Sample Time: 1 **in Minutes**
Sample Volume: 28.3 **Liters Per Minute**
Total Sample Volume: 84.9 **Liters**

PARTICLE COUNT VALUES - REPORTED IN PARTICLES PER CUBIC METER

Particle Counter: Mfg. TSI **Model** 9350-02 **S/N** 93501605003 **Cal Due** June 12, 2024

OPERATIONAL PARTICLE COUNTS: The particle counter isokinetic probe is positioned within six inches upstream of the product manipulation point.

For unidirectional flow applications the particle counter isokinetic probe shall be pointed into the airstream.

For nonunidirectional flow applications the particle counter isokinetic probe shall be pointed vertically towards the ceiling.

This sampling point is positioned near the arm convergence point, but not interfering with operator hand and arm movement. The isolator operator shall simulate compounding operations during the three (3) 1-minute sampling periods. Testing performed in Accordance with ISO Std 14644-1: 2015.

EACH READING must not exceed the particle count class limit.

sample 1 (ppcm)	sample 2 (ppcm)	sample 3 (ppcm)
0	0	0

Particle Count Specification: ISO Class 5 (3520ppcm @ 0.5um & larger) Operational per ISO Std 14644-1: 2015 ☑ **Pass** ☐ **Fail** ☐ **No Test**

Remarks: NA

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Test Report No.: 102395479

AIRFLOW VISUALIZATION TEST - USP <797>

Dynamic airflow smoke pattern testing is performed to ensure that this device provides adequate unidirectional airflow to support aseptic operations as required for the intended tasks under "dynamic operating conditions". A visual smoke/fog tracer shall be conveniently deployed within the unidirectional flow zone to visualize airflow without disrupting the airflow patterns. A video recording device shall document the airflow patterns and operator aseptic process. A tripod may be needed to support and aim the video recording device.

A dynamic airflow smoke pattern test shall be performed to ensure that the device adequately supports the actual process and that compounding staff are using the device properly. The dynamic airflow smoke pattern test shall use the actual compounding staff performing simulations of the compounding facility's MOST-COMPLICATED sterile compounding processes in which critical sites are potentially exposed.

Dynamic airflow smoke pattern testing shall prove the device provides unidirectional airflow with no dead spots or refluxing at the Direct Compounding Area (DCA) for the operating velocity at which the unit was certified. A dynamic airflow smoke pattern test shall (must) be performed at every certification.

A visible source of smoke, such as a neutrally-buoyant, glycol-based fog generator, or ventilation smoke tube, is used to observe air patterns within the unidirectional space. Smoke is generated directly downstream of the HEPA filter diffuser screen and then observed as it flows across the critical site and the DCA and to a return or out of the critical area. The smoke source shall be moved to introduce a smoke stream through the user/operator's hand/arm movements throughout the aseptic manipulation process. Smoke exiting the critical area should not re-enter.

It is therefore required that a dynamic airflow smoke pattern test be performed at every certification to:

- Determine the optimum layout within the DCA.
- Demonstrate with the compounding staff how to establish optimal "FIRST AIR" based on the compounding facility's aseptic technique procedures.
- Indicate suitability of the unidirectional airflow device for the intended purpose.

The result of the dynamic airflow smoke pattern testing should be witnessed or reviewed by the compounding facility supervisor(s) or designated person(s) to determine acceptability of current aseptic technique SOPs or otherwise improve optimal operating set-ups based on airflow patterns within the space.

The intentions of unidirectional airflow are clearly stated in the FDA guidance document for industry "Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice." "In situ air pattern analysis should be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions".

This written report details the airflow patterns with a definitive statement of acceptability for the intended purpose. Any findings, comments, or recommendations may be recorded in the "Remarks" section. The video recording should clearly identify the DCA along with the appropriate aseptic technique performed by compounding personnel.

Disclaimer: The compounding staff is fully responsible for the organization's aseptic techniques and procedures, if found unacceptable by inspectors and / or regulatory agencies. This video is used to help establish optimal use of "FIRST AIR" BASED ON THEIR CHOSEN TECHNIQUE. This testing organization does not claim to be experts in aseptic technique procedures but can identify improper blocking of "FIRST AIR" based on the user's techniques and offer improvements.

The video recording of this airflow visualization smoke pattern test is provided on an external flash drive for instant user access for supervisory review, internal audits, compliance purposes, regulatory agency inspections, and training purposes.

☑ **Pass - Airflow Visualization Test** ☐ **Fail - Airflow Visualization Test** ☐ **No Test**

Under operational conditions, airflow smoke patterns should demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic (operational) conditions within the unidirectional flow device. The smoke illustrates the importance of proper use of "First Air" in the Direct Compounding Area (DCA).

Remarks: NA

Testing Performed In Accordance with CECS, Inc. **WI #** BSC-1018 CERT & CETA CAG-003-2006-13

Above Testing Work Performed By Matt Lawrence **Date:** 07-Jun-2024

Retest Date: OCTOBER, 2024

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email: cecs_info@steris.com

CLASS II, TYPE A2 BIOLOGICAL SAFETY CABINET

Test Report No.: 102395462
Date: June 7, 2024
Client: HEARTLAND APOTHECARY
Address: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922
Attn: RANDY MARTIN

Mfg./Model: Germfree BBF-4SSRX
Identifying No.: 5224490002
Location: PHARMACY
Room: NON HD BUFFER
Other:
MCI#: DCIC508200

SUMMARY OF TEST RESULTS

AIRFLOW VELOCITY RESULTS

Test Results on Page 2

FINAL - DOWNFLOW VELOCITY TEST ☑ PASS ☐ FAIL AVG ☐ PASS AVG/FAIL UNIFORMITY
INFLOW VELOCITY TEST ☑ PASS ☐ FAIL

SITE INSTALLATION ASSESSMENT TESTS

Test Results on Page 2

SASH ALARM TEST	☐ PASS	☐ FAIL	☑ NA
AIRFLOW OR PRESSURE ALARM TEST	☐ PASS	☐ FAIL	☑ NA
TYPE B SUPPLY BLOWER INTERLOCK TEST	☐ PASS	☐ FAIL	☑ NA
EXHAUST SYSTEM PERFORMANCE TEST	☐ PASS	☐ FAIL	☑ NA

AEROSOL CHALLENGE INSTALLATION LEAK TEST

Test Results on Page 3

AS FOUND - SUPPLY FILTER	☑ PASS	☐ FAIL	☐ NO TEST	NA
AS FOUND - EXHAUST FILTER	☑ PASS	☐ FAIL	☐ NO TEST	NA
FINAL - SUPPLY FILTER	☑ PASS	☐ FAIL	☐ NO TEST	NA
FINAL - EXHAUST FILTER	☑ PASS	☐ FAIL	☐ NO TEST	NA

AIRBORNE PARTICLE COUNT TEST ☑ PASS ☐ FAIL ☐ NO TEST

Test Results on Page 3

AIRFLOW SMOKE PATTERN TESTS

Test Results on Page 4

DOWNFLOW TEST	☑ PASS	☐ FAIL	
VIEW SCREEN RETENTION TEST	☑ PASS	☐ FAIL	☐ MEETS MFR. SPECS
WORK OPENING EDGE RETENTION TEST	☑ PASS	☐ FAIL	
SASH/WINDOW SEAL TEST	☑ PASS	☐ FAIL	

Note: Noise Level Test and Lighting Intensity Test results are for information only.

Testing Performed In Accordance with CECS, Inc. **WI #**BSC-1018 CERT

Certified In Accordance with NSF 49, Annex F & CETA CAG-003-2006-13

Retest Date: OCTOBER, 2024

Remarks: NA

Above Testing Work Performed By Matt Lawrence **Date** 07-Jun-2024

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Test Report No.: 102395462

FINAL AIRFLOW VELOCITY TESTS

Anemometer: Mfg. TSI Model 966 S/N P20080067 Cal Due July 23, 2024

DOWNFLOW VELOCITY AND UNIFORMITY PROFILE

☑ Pass Average Velocity & Airflow Uniformity

Number of Supply Readings Taken	21						All readings within the larger of ±25% of Avg. or ±16 FPM.
Maximum Supply Velocity Allowable/Actual	93	/	84	fpm			
Minimum Supply Velocity Allowable/Actual	56	/	56	fpm	*Acceptance Criteria*		☐ Fail Average Velocity
Average Supply Velocity	74	fpm	67	-	82	fpm	☐ Pass Average Velocity Fail Airflow Uniformity

Diagram of Supply Velocity Profile Taken at 8 inch(es) sash height

78	78	79	79	78	82	84
58	56	64	63	60	70	72
79	79	80	81	80	82	82

Exhaust Filter

No. of Exhaust Readings Taken	9			*Acceptance Criteria*				
Average Intake Velocity	105	fpm		102	-	112	fpm	☑ Pass ☐ Fail

123	131	172
125	133	130
150	143	160

Average Exhaust Velocity (Ve)	140.78	fpm
Exhaust Area (Ae)	1.58	sq ft
(Ve x Ae = Qe) Exhaust Volume (Qe)	222.43	cfm
Intake Area (Ai)	2.11	sq ft
(Qe / Ai = Vi) Intake Velocity (calculated) (Vi)	105	fpm

Velocity Conforms to: Manufacturer's Specs. & Manufacturer's Specs Motor Parameters: NA

Blower Speed Required: No Change Internal Damper: NA

Exhaust Configuration: Internal Exhaust Damper: NA

SITE INSTALLATION ASSESSMENT TESTS

Sash Alarm Test	☐ PASS	☐ FAIL	☑ NA	No alarm designed by Mfr.
Airflow or Pressure Alarm Test	☐ PASS	☐ FAIL	☑ NA	NA-No Alarm Installed
Type B Supply Blower Interlock Test	☐ PASS	☐ FAIL	☑ NA	
Exhaust System Performance Test	☐ PASS	☐ FAIL	☑ NA	NA

Differential Pressure: Hood 0.40 "W.C. Exhaust Duct: NA "W.C.

(cannot be greater than 8 fpm below the minimum intake velocity range) Canopy Performance Impact

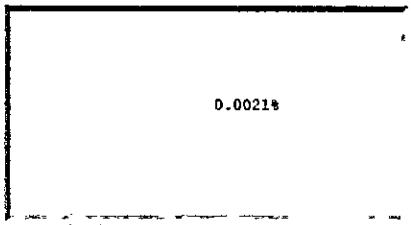
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Test Report No.: 102395462

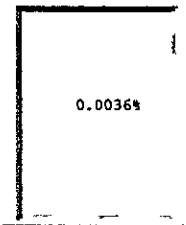
AEROSOL CHALLENGE INSTALLATION LEAK TEST

Photometer: Mfg. TEC Services, I **Model** PH-5 **S/N** 1622 **Cal Due** August 21, 2024

Diagram of repairable filter leaks with challenge concentration of A minimum of 10 ug/Liter PAO CAS# 68649-12-7



Supply Filter 100% SCAN



Exhaust Filter

Leak Concentrations as shown:

Filters marked "100% Scan" were scan tested over the filter media and separate passes made on the surrounding frame/seal. Filter acceptance is 0.01% of the upstream concentration. Filters marked "Probe Tested" were tested using the Total Leakage Test Method. Filter acceptance is 0.005% of the upstream concentration.

Comments Below:

NA

/-media leakage
x-frame leakage
BR-before repair
AR-after repair

Leaks Repaired: NA

Supply Filter Results:

As Found ☑ Pass ☐ Fail ☐ No Test

NA

Final ☑ Pass ☐ Fail ☐ No Test

NA

100% Scan **Leaks Repaired:** NA

Exhaust Filter Results:

As Found ☑ Pass ☐ Fail ☐ No Test

NA

Final ☑ Pass ☐ Fail ☐ No Test

NA

AIRBORNE PARTICLE COUNT

Particle Counter: Mfg. TSI **Model** 9350-02 **S/N** 93501605003 **Cal Due** June 12, 2024

Note: All particles 0.5 **micron and larger were counted.**

Readings shown are in particles per cubic **meter** **of air.**

Ambient room particle count = 6560 ppcm (Room Ambient)

Sample Locations are taken at 12 **Inches above the work surface.**

Particle Count locations are identified with numbers (1) through (5).

Room ambient count is identified as (Room Ambient)

(1) 0		0 (2)
	(3) 0	
(4) 0		0 (5)

Specification: ISO Class 5 0.5 um & larger (At-Rest) ISO 14644-1:2015 ☑ Pass ☐ Fail ☐ No Test

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Test Report No.: 102395462

AIRFLOW SMOKE PATTERN TESTS

1. DOWNFLOW TEST:

A smoke source shall be passed from one end of the cabinet to the other, along the centerline of the work surface at a height of 4 inches (10 cm) above the top of the access opening. The smoke shall show smooth downward flow with no dead spots or reflux (upward flow). No smoke shall escape from the cabinet.

☑ **PASS** ☐ **FAIL**

Comments: NA

2. VIEW SCREEN RETENTION TEST:

A smoke source shall be passed from one end of the cabinet to the other, 1 inch (2.5 cm) behind the viewscreen, at a height of 6 inches (15 cm) above the top of the access opening. The smoke shall show smooth downward flow with no dead spots or reflux. No smoke shall escape from the cabinet.

☑ **PASS** ☐ **FAIL** ☐ **MEETS MANUFACTURER'S SPECIFICATIONS**

Comments: NA

3. WORK OPENING EDGE RETENTION TEST:

A smoke source shall be passed along the entire perimeter of the work opening edges, approximately 1.5" (3.8 cm) outside the cabinet. Particular attention should be paid to corners and vertical edges. No smoke shall reflux out of the cabinet once drawn in, nor shall smoke billow over the work surface or penetrate onto it.

☑ **PASS** ☐ **FAIL**

Comments: NA

4. SASH/WINDOW SEAL TEST:

A smoke source shall be passed up the inside of the window 2" (5 cm) from the sides and along the top of the cabinet interior work area. No smoke shall escape out of the cabinet.

☑ **PASS** ☐ **FAIL**

Comments: NA

REMARKS

Supply HEPA Filter(s) Size: 1-20 x 46 x 6 MK375100600

Exhaust HEPA Filter(s) Size: 1-16 x 18 x 6 MK375100500

Pre Filter(s) Size: NA

HEPA Filter(s) Replaced: No

Prefilter(s) Replaced: No

U.V. Lamp(s) Replaced: NA

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email: cecs_info@steris.com

OPERATIONAL NON-VIABLE PARTICLE COUNT USP<797>

Test Report No.: 102395462
Date: June 07, 2024
Client: HEARTLAND APOTHECARY
Address: 9947 KINGSTON PIKE
KNOXVILLE, TN 37922
Attn: RANDY MARTIN

Mfg./Model: Germfree BBF-4SSRX
Identifying No.: 5224490002
Location: PHARMACY
Room: NON HD BUFFER
Other:
MCI#: DCIC508200

NON-VIABLE PARTICLE COUNT CONDITIONS OF TEST

Type of Clean Zone: Unidirectional
Cleanroom or zone Cleanliness Classification: ISO Class 5
Particle Class Limit In Particles Per Cubic Meter: 3520
Measures Particle Size in Microns (and larger): 0.5
Number of Particle Count Sample locations: (L) 1

Occupancy State of Test: Operational
Type of Test: Verification
Sample Time: 1 **in Minutes**
Sample Volume: 28.3 **Liters Per Minute**
Total Sample Volume: 84.9 **Liters**

PARTICLE COUNT VALUES - REPORTED IN PARTICLES PER CUBIC METER

Particle Counter: Mfg. TSI **Model** 9350-02 **S/N** 93501605003 **Cal Due** June 12, 2024

OPERATIONAL PARTICLE COUNTS: The particle counter isokinetic probe is positioned within six inches upstream of the product manipulation point.

For unidirectional flow applications the particle counter isokinetic probe shall be pointed into the airstream.

For nonunidirectional flow applications the particle counter isokinetic probe shall be pointed vertically towards the ceiling.

This sampling point is positioned near the arm convergence point, but not interfering with operator hand and arm movement. The isolator operator shall simulate compounding operations during the three (3) 1-minute sampling periods. Testing performed in Accordance with ISO Std 14644-1: 2015.

EACH READING must not exceed the particle count class limit.

sample 1 (ppcm)	sample 2 (ppcm)	sample 3 (ppcm)
0	0	0

Particle Count Specification: ISO Class 5 (3520ppcm @ 0.5um & larger) Operational per ISO Std 14644-1: 2015 ☑ **Pass** ☐ **Fail** ☐ **No Test**

Remarks: NA

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Test Report No.: 102395462

AIRFLOW VISUALIZATION TEST - USP <797>

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☑ **Pass - Airflow Visualization Test** ☐ **Fail - Airflow Visualization Test** ☐ **No Test**

Under operational conditions, airflow smoke patterns should demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic (operational) conditions within the unidirectional flow device. The smoke illustrates the importance of proper use of "First Air" in the Direct Compounding Area (DCA).

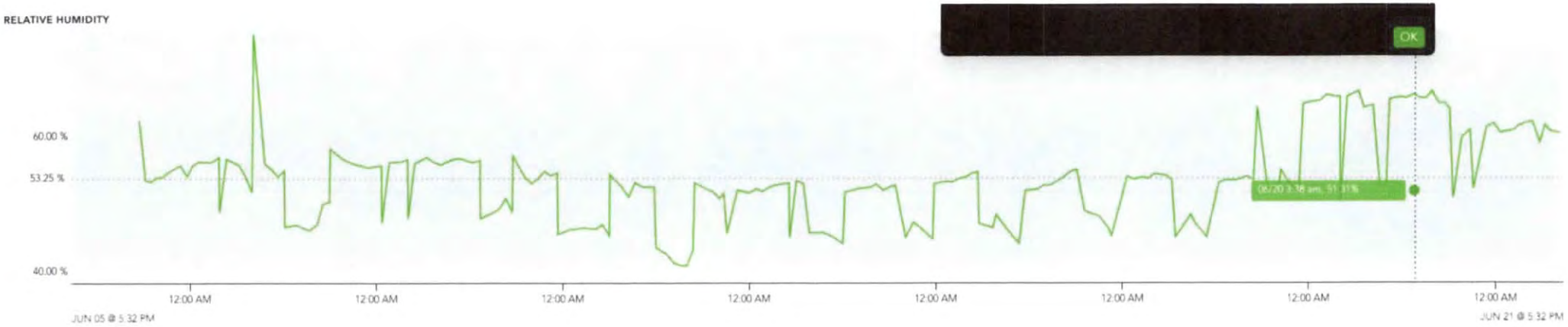
Remarks: NA

Testing Performed In Accordance with CECS, Inc. **WI #** BSC-1018 CERT & CETA CAG-003-2006-13

Above Testing Work Performed By Matt Lawrence **Date:** 07-Jun-2024

Retest Date: OCTOBER, 2024

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RELATIVE HUMIDITY
OK
60.00 %
53.25 %
40.00 %
12:00 AM
12:00 AM
12:00 AM
12:00 AM
12:00 AM
12:00 AM
12:00 AM
12:00 AM
JUN 05 @ 5:32 PM
JUN 21 @ 5:32 PM

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800-523-9952 (Customer Service)
Ph: 610-867-5302 Fax: 610-954-7903
Email: CECS_micro@steris.com

PRELIMINARY NOTIFICATION OF RESULTS: VIABLE ENVIRONMENTAL MONITORING

Customer	Heartland Apothecary	**Sales Order #**	17470486
Facility Address	9947 Kingston Pike Knoxville, TN 37922	**Report ID #**	24CE0908
Contact Name	Randy Martin	**Sample Date**	10Jun2024
E-Mail Address	randymartinpharmd@gmail.com	**Issue Date**	18Jun2024

Please be advised of the following results:

☒ The initial read showed no growth on any samples.

☐ The initial read showed some growth, but no exceeded alert or action levels on any samples.

☐ The initial read showed either an exceeded alert or action level on at least one sample (see notes section below).

☐ The final read showed either an exceeded alert or action level on at least one sample (see notes section below).

Notes *(in the event of EC, locations will be noted below):*

Sampling of AV1, SV1, AV3, SV3 and AV4 only.

Acronyms/ Definitions:

SV = Surface Viable	AV = Active Air Viable	CFU = Colony Forming Unit	SP = Settle Plate	EC = Exceeded CFU
CG = Compressed Gas	SW = Swab	GFT = Gloved Fingertip	FIO = For Information Only	
Action Level: *an established microbial level, when exceeded trigger appropriate investigation and corrective action*				
Alert Level: *an established microbial level providing a warning of potential drift from normal operating conditions*				

Reported by/ Date: IMM 18JUN2024

Reviewed by/ Date: TMS 18JUN2024

These results relate only to the items tested

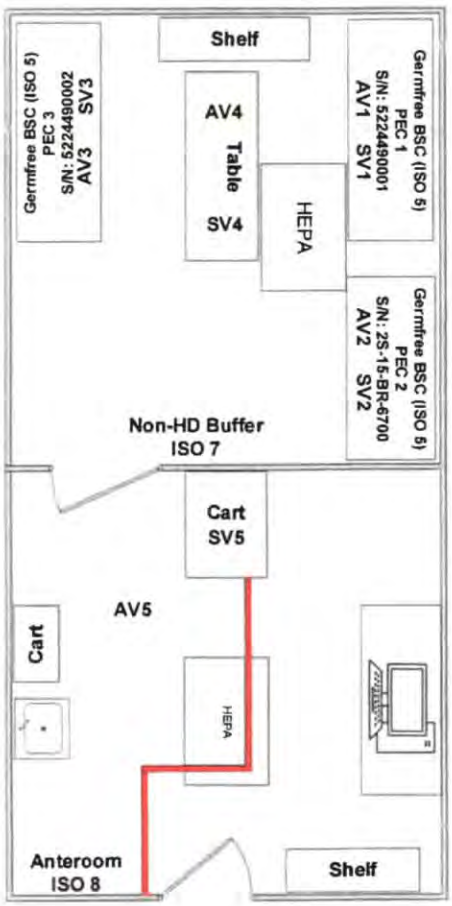
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5960 Heisley Rd. Mentor, OH 44060

800-523-9952 (Customer Service)
Ph: 610-867-5302 Fax: 610-954-7903
Email: CECS_micro@steris.com

USP <797> ENVIRONMENTAL MONITORING PLAN FOR VIABLE PARTICLES

KK0114 Heartland Apothecary



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Controlled Environment Certification Services, Inc.
A Subsidiary of STERIS Corporation
5960 Heisley Rd. Mentor, OH 44060

800-523-9952 (Customer Service)
Ph: 610-867-5302 Fax: 610-954-7903
Email: CECS_micro@steris.com

Customer MCI #/Name: KK0114 Heartland Apothecary

PEC #	**1**	**Manufacturer/Model/ SN**	Germfree	BSC	5224490001
PEC #	**2**	**Manufacturer/Model/ SN**	Germfree	BSC	2S-15-BR-6700
PEC #	**3**	**Manufacturer/Model/ SN**	Germfree	BSC	5224490002

Sample date	10Jun2024	**Technician name**	Cayla Walton	**Activity**	☐As built ☒Static ☐Dynamic
Sample time	11:25 AM				
No. of people in rooms	_1_ / recorded in space	**Media lot #**	TSA 1010432470	**Expiration date**	12Jul2024
Sampler SN	20-D-15224	**Sampler cal due date**	04Aug2024		
Sampler SN	16-D-10530	**Sampler cal due date**	18Oct2024		
Sampler SN	18-D-12891	**Sampler cal due date**	04Aug2024		
SOA #	17470486	**Test Report #**	102406502	**Sterile 70% IPA (Lot #/Exp)**	CONTEC 1000699-0-0-1 07/2028
Gowning	☒ Bouffant ☒Shoe covers ☒Gloves ☐Safety glasses ☒Mask ☐Jumpsuit ☒Gown				

Observations/Additional Notes:
Sampling of AV1, AV3, AV4, SV1, and SV3

Acceptance levels:
ISO 5 Air = ≤ 1 CFU/m^3 / ISO 5 Surface = ≤ 3 CFU/plate
ISO 7 Air = ≤ 10 CFU/m^3 / ISO 7 Surface = ≤ 5 CFU/plate
ISO 8 Air = ≤ 100 CFU/m^3 / ISO 8 Surface = ≤ 50 CFU/plate

SAS sample volumes:
All air samples: 1000L

Prepared By : Isabella Mercado 18Jun2024

Staff Meeting June 12 2024

Todays meeting is to cover points that need to be addressed following our inspection

- Complaint handling: Please inform Randy of any complaints from patients. We will have a new process for documenting complaints to help us better learn from our mistakes and offer better care for our patients. More on this to come over the next week or two
- All control substance inventory must be completed on the same day for all areas either before the open of business or after closing
- If certified technician or pharmacist takes a verbal prescription their initials have to be noted on the prescription
- Control substances cannot have stamped or electronic signatures. If it does have either of these then the office must be called to have them either resend with hand signature or notate verbal order was given
- All pharmacist that check prescriptions must sign signature log for that day
- If office calls in for refills for a patient and makes changes all changes must be notated on the hard copy
- All control prescriptions must have physical address of patient on hard copy: no doctors office addresses, no PO Boxes.

Standard Operating Procedure (SOP) for Controlled Substance Inventory

1. Purpose

To establish procedures for the proper management, record-keeping, and security of controlled substances to ensure compliance with the Drug Enforcement Administration (DEA) regulations and the Tennessee Board of Pharmacy regulations.

2. Scope

This SOP applies to all personnel involved in the handling, storage, and inventory management of controlled substances at Heartland Apothecary.

3. Definitions

- **Controlled Substance:** A drug or chemical whose manufacture, possession, or use is regulated by the government.
- **DEA:** Drug Enforcement Administration, the federal agency responsible for enforcing the controlled substances laws and regulations of the United States.
- **Inventory:** A complete and accurate list of all controlled substances on hand.

4. Responsibilities

- **Pharmacist-in-Charge (PIC):** Responsible for the overall management of controlled substances, ensuring compliance with all regulations.
- **Designated Staff:** Individuals authorized to handle controlled substances under the supervision of the PIC.

5. Procedures

5.1. Initial Inventory

- Conduct an initial inventory of all controlled substances on the date the pharmacy or healthcare facility first engages in dispensing controlled substances.
- Record the inventory details, including the date, time, substance name, form, quantity, and the signature of the person conducting the inventory.

5.2. Biennial Inventory

- Perform a biennial inventory (every two years) on any date within two years of the previous inventory date.
- Record the same details as the initial inventory.
- Ensure the inventory is conducted at the beginning or end of the business day (entire pharmacy all at same time).

5.3. New Stock Inventory

- Upon receiving new stock, immediately update the inventory records.
- Verify the received quantity against the supplier's invoice and the order placed.
- Store the new stock in the designated secure area.

5.4. Inventory Records

- Maintain records of all controlled substance inventories for a minimum of two years.
- Store records in a secure location with restricted access.
- Use either a bound logbook or an electronic record-keeping system that complies with DEA regulations.

5.5. Storage and Security

- Store all controlled substances in a securely locked, substantially constructed cabinet.
- Limit access to authorized personnel only.
- Implement security measures such as surveillance cameras and alarm systems.

5.6. Dispensing and Usage Records

- Maintain detailed records of all dispensing and usage of controlled substances.
- Include patient information, prescribing practitioner details, substance name, dosage, and quantity dispensed.
- Ensure that records are updated in real-time and reviewed regularly for accuracy.

5.7. Disposal of Controlled Substances

- Dispose of expired or unused controlled substances in accordance with DEA and Tennessee Board of Pharmacy guidelines.
- Use authorized disposal methods, such as reverse distributors or DEA-approved take-back programs.
- Record the disposal details, including the date, substance name, quantity, and method of disposal.

5.8. Inventory Discrepancies

- Immediately investigate any discrepancies between the physical inventory and recorded quantities.
- Report significant losses or thefts to the DEA and Tennessee Board of Pharmacy within one business day.
- Document the findings of the investigation and any corrective actions taken.

5.9. Periodic Audits

- Conduct periodic audits of controlled substance inventory to ensure compliance with this SOP.

- Randomly select a sample of controlled substances for audit and compare physical counts with inventory records.
- Document the audit findings and address any discrepancies.

6. Compliance and Training

- Provide training to all staff involved in the handling of controlled substances on this SOP and relevant regulations.
- Ensure ongoing compliance through regular review and updates of this SOP as necessary.

7. Review and Revision

- This SOP shall be reviewed annually and revised as needed to ensure compliance with current regulations.
- Revisions shall be documented, and the updated SOP shall be distributed to all relevant personnel.

Document Control

- **Version:** 1.0
- **Effective Date:** 6.25.24
- **Review Date:**
- **Approved By:** Randy Martin
- **Signature:** _____

Standard Operating Procedure (SOP) for Two-Temperature Testing with Incubator in Sterile Lab

1. Purpose

To establish standardized procedures for performing two-temperature testing using an incubator to ensure the accuracy and reliability of test results in a sterile lab environment.

2. Scope

This SOP applies to all personnel involved in two-temperature testing in the sterile lab at Heartland Apothecary

3. Definitions

- **Incubator:** A device used to maintain controlled environmental conditions for the growth of microbiological cultures or the storage of samples.
- **Two-Temperature Testing:** The process of incubating samples at two different temperatures to evaluate the growth or stability of microorganisms or other biological samples.

4. Responsibilities

- **Lab Manager:** Responsible for overseeing the testing process and ensuring compliance with this SOP.
- **Lab Technicians:** Responsible for performing the testing procedures as outlined in this SOP.

5. Materials and Equipment

- Incubator capable of maintaining the required temperatures
- Sterile sample containers
- Temperature log sheets or electronic monitoring system
- Personal protective equipment (PPE)
- Sterile lab environment
- Calibration equipment (e.g., thermometer, datalogger)

6. Procedures

6.1. Preparation

- Verify that the incubator is clean, calibrated, and in proper working condition.
- Ensure the sterile lab environment is maintained, and all personnel are wearing appropriate PPE.
- Prepare and label sterile sample containers with relevant information (e.g., sample ID, date, temperature).

6.2. Initial Setup

- Set the incubator to the first required temperature _____
- Allow the incubator to stabilize at the set temperature before placing any samples inside.
- Document the incubator settings and the time the incubator reached the desired temperature.

6.3. Sample Incubation at First Temperature

- Place the samples in the incubator, ensuring they are evenly spaced and not touching each other or the incubator walls.
- Record the time the samples are placed in the incubator.
- Maintain the incubator at the first temperature for the specified duration _____

6.4. Transition to Second Temperature

- After the specified incubation period at the first temperature, remove the samples from the incubator.
- Adjust the incubator to the second required temperature _____
- Allow the incubator to stabilize at the second temperature.
- Once stabilized, place the samples back into the incubator.

6.5. Sample Incubation at Second Temperature

- Record the time the samples are placed in the incubator at the second temperature.
- Maintain the incubator at the second temperature for the specified duration _____

6.6. Monitoring and Documentation

- Regularly monitor the incubator temperature to ensure it remains within the specified range.
- Document the temperature readings at regular intervals (_____) using temperature log sheets or an electronic monitoring system.
- Note any deviations from the set temperatures and the corrective actions taken.

6.7. Completion of Testing

- After the specified incubation periods at both temperatures, remove the samples from the incubator.
- Record the time the samples are removed and any observations about the samples' appearance or condition.

6.8. Data Analysis and Reporting

- Analyze the results of the two-temperature testing as per the lab's standard analysis procedures.

- Document the findings and prepare a report detailing the test results, including any deviations and corrective actions.
- Submit the report to the Lab Manager for review and approval.

7. Maintenance and Calibration

- Perform regular maintenance and calibration of the incubator as per the manufacturer's instructions and lab protocols.
- Document all maintenance and calibration activities in the equipment log.

8. Compliance and Training

- Provide training to all lab personnel on this SOP and ensure they understand the procedures and importance of compliance.
- Conduct regular reviews and updates of this SOP to ensure it remains current with regulatory and industry standards.

9. Review and Revision

- This SOP shall be reviewed annually and revised as necessary to reflect changes in procedures, equipment, or regulations.
- Revisions shall be documented, and the updated SOP shall be distributed to all relevant personnel.

Document Control

- **Version:** 1.0
- **Effective Date:** 6.25.2024
- **Review Date:**
- **Approved By:** Randy Martin
- **Signature:** _____

4EEE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FO3326596 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Optimal Balance Pharmacy LLC

Physical Address: 2204 Cypress Creek Parkway Suite F

City: Houston State: TX Zip: 77090

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 281-919-2964 Toll Free # (NAC 639.708, NRS 639.23286): 844-879-6784

Fax: 833-702-1164 Contact Email: chris@obprx.com

Website: obprx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Jordan Navalle

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23914

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jordan Navalle	NV Pharmacist Registration #: 23914
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): _____

Corporation/Organization Name: Optimal Balance Pharmacy LLC

Mailing Address: 2204 Cypress Creek Parkway Suite F

City: Houston State: TX Zip: 77090

Telephone: 281-919-2964 Email: chris@obprx.com

Contact Person Name: Christopher Quintana

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO/ Owner (title) for Optimal Balance Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Christopher Quintana

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

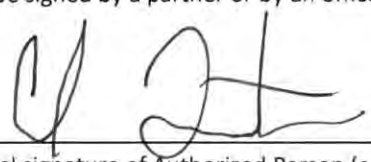
02/24/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Quintana - CEO / Owner

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

02/24/25

Date

Board Use Only	Date Received: 4/2/25	Amount: $500-261117

OPTIMAL BALANCE PHARMACY LLC

EIN: 92-1119382

2204 Cypress Creek Pkwy, Suite F
Houston, TX 77090
P:281-919-2964

OWNERSHIP ORGANIZATIONAL CHART

Name: Christopher Quintana
Title: Owner
Percentage owned: 100%

[redacted]

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for OPTIMAL BALANCE PHARMACY LLC (file number 804811021), a Domestic Limited Liability Company (LLC), was filed in this office on November 16, 2022.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on May 05, 2025.

Jane Nelson
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Optimal Balance Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable): _____

Physical Address: 2204 Cypress Creek Parkway Suite F

City: Houston State: TX Zip: 77090

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 281-919-2964 Website: OBPRX.COM

Licensing Company Email: chris@obprx.com

Section 2: Personal Information

First: Jordan Middle: _____ Last: Navalle

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Optum Rx				From - To (MM/YY – MM/YY): 11/2022 - present
Business Address: 5627 University Hts	City: San Antonio		State: TX	Zip: 78249
Phone:	Title: Home Delivery Pharmacist			Number of Employed Hours: 40 hrs weekly
Description of Duties:				

Business Name: CVS Health				From - To (MM/YY – MM/YY): 10/2021 - 11/2023
Business Address: 14900 Jones Maltsberger	City: San Antonio		State: TX	Zip: 78247
Phone:	Title: Overnight Pharmacist			Number of Employed Hours: 40 hrs weekly
Description of Duties:				

Business Name: Davila Pharmacy				From - To (MM/YY – MM/YY): 11/2023 - present
Business Address: 1423 Guadalupe St	City: San Antonio		State: TX	Zip: 78207
Phone:	Title: Staff Pharmacist			Number of Employed Hours: 10hrs weekly
Description of Duties:				

Business Name: PharMerica				From - To (MM/YY – MM/YY): 9/2022 - 11/2022
Business Address: 3019 Interstate Dr	City: San Antonio		State: TX	Zip: 78219
Phone:	Title: Staff Pharmacist			Number of Employed Hours: 40hrs weekly
Description of Duties:				

Business Name: Unlimited Pharmacy				From - To (MM/YY – MM/YY): 7/2022 - 8/2022
Business Address: 12801 Wetmore Rd	City: San Antonio		State: TX	Zip: 78247
Phone:	Title: Per Diem Pharmacist			Number of Employed Hours: 10hrs weekly
Description of Duties:				

Continue on next page if additional space is needed.

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Presbyterian College School of Pharmacy		2016-2020	
Address	**City**	**State**	**Zip**
307 N Broad St	Clinton	SC	29325
Diploma/Degree obtained, if any			
Doctor of Pharmacy Candidate			
School Name		From - To (MM/YY – MM/YY)	
Bob Jones University		2006-2011	
Address	**City**	**State**	**Zip**
1700 Wade Hampton Blvd.	Greenville	SC	29614
Diploma/Degree obtained, if any			
Bachelors of Science, Graphic Design, Biology minor			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012 - 2021	[redacted]			
1990 – 2012				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jordan Navalle

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/26/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Bexar

I, Jordan Navalle, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/26/2024

Date

Subscribed and Sworn to before me this 26th day of August 2024.

Notary Public Signature

MARIO TREVINO JR
NOTARY PUBLIC
STATE OF TEXAS
NOTARY ID 128072547
MY COMM. EXP. 09-28-2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Optimal Balance Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 2204 Cypress Creek Parkway Suite F

City: Houston State: TX Zip: 77090

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 281-919-2964 Website: OBPRX.COM

Licensing Company Email: chris@obprx.com

Section 2: Personal Information

First: Christopher Middle: Last: Quintana

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF HOUSTON		09/2000 - 05/2006	
Address	**City**	**State**	**Zip**
4302 UNIVERSITY DR	HOUSTON	TX	77004
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE IN FINANCE			

School Name		From - To (MM/YY – MM/YY)	
EISENHOWER HIGH SCHOOL		09/1992 - 05/1996	
Address	**City**	**State**	**Zip**
7922 ANTOINE DR	HOUSTON	TX	77088
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/20 - PRESENT	[redacted]			
01/2014 - 3/20	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or in a related capacity within the last 10 years.

Business Name: OPTIMAL BALANCE PHARMACY			From - To (MM/YY – MM/YY): 11/22 - PRESENT
Business Address: 2204 CYPRESS CREEK PKWY STE F	City: HOUSTON	State: TX	Zip: 77090
Phone: 281.919.2964	Title: OWNER		
Description of Duties: I OVERSEE ALL ASPECTS OF BUSINESS OPERATIONS, ENSURING HIGH-QUALITY PATIENT CARE AND REGULATORY COMPLIANCE.			

Business Name: PROMED PHARMACY			From - To (MM/YY – MM/YY): 9/2018 - PRESENT
Business Address: 2421 ALDINE MAIL ROUTE RD, STE B	City: HOUSTON	State: TX	Zip: 77039
Phone: 281.372.8522	Title: OWNER		
Description of Duties: I OVERSEE ALL ASPECTS OF BUSINESS OPERATIONS FOR AN INDEPENDENT RETAIL PHARMACY.			

Business Name: TRAVA HEALTH			From - To (MM/YY – MM/YY): 1/2023 - PRESENT
Business Address: 21175 STATE HIGHWAY 249 #239	City: HOUSTON	State: TX	Zip: 77070
Phone: 281.241.9005	Title: CO-FOUNDER		
Description of Duties: I OVERSEE THE HEALTHCARE ASPECT OF THIS NATIONWIDE TELEMEDICINE COMPANY.			

Business Name: GENESIS REFERENCE LABORATORIES			From - To (MM/YY – MM/YY): 2/2018 - 4/2022
Business Address: 7924 FOREST CITY RD. STE 210	City: ORLANDO	State: FL	Zip: 32810
Phone: 844.510.0194	Title: CHIEF BUSINESS DEVELOPMENT OFFICER		
Description of Duties: I WAS IN CHARGE OF OVERSEEING THE NATIONWIDE SALESTEAM FOR THIS NATIONWIDE DIAGNOSTIC LABORATORY			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Quintana

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/24/25

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Harris

I, CHRISTOPHER QUINTANA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/24/25

Date

Subscribed and Sworn to before me this 24TH day of February, 2025

Notary Public Signature

JOSE ZAMARRIPA
Notary Public, State of Texas
Comm. Expires 10-24-2027
Notary ID 134618403

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Optimal Balance Pharmacy LLC

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 2204 Cypress Creek Parkway Suite F

City: Houston State: TX Zip: 77090

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 281-919-2964 Toll Free # (NAC 639.708, NRS 639.23286): 844-879-6784

Fax: 833-705-1164 Contact Email: chris@obprx.com

Website: OBPRX.COM

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Jordan Navalle

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23914

Name of Person with direct knowledge of compounding procedures: Jordan Navalle

Email of Person with direct knowledge of compounding procedures: chris@obprx.com

Telephone of Person with direct knowledge of compounding procedures: 281-919-2964

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ■ Low ■ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
See attached for compounded products list
- Testosterone Cypionate / Enanthate / Propionate Injections
- Nandrolone Injections

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ■ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?
Name: Eagle Analatyical Labs
Address: 11111 S. Wilcrest Drive, Suite 1000
City: Houston State: TX Zip: 77099
Telephone: 1-800-745-8916

7. What is your procedure for visual inspection of compounded sterile products?
Visual Vial Inspections for particulate Matter, container integrity, clarity & color observation. & check for label Accuracy.

8. How often do you perform glove fingertip and medial fill testing?
(GFT) High risk → Every 3 months for Active compounders.
(media fill Testing → Every 6 months

9. What is your policy if an employee fails a glove fingertip or media-fill test?
- removal from compounding duties
- Investigate root cause & correct it.
- retraining.
- requalification & Documentation.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
- Didactic Training (USP 797- 800)
- Hands on training.
- competency Exam.
- Competency Evaluation (Media fill, garbing, GFT etc.-)
- Documention of procedures per employee.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
① PECs: - wear appropriate PPE., use sterile, lint-free wipes
- clean from cleanest to dirtiest areas
- use germicidal detergent followed by sterile isopropyl alcohol & allow to air dry.
frequency: at beginning of each shift, before each batch, after spills, at the end of shift.
Similar practice for secondary controls.
frequency is daily & monthly. agents used: Prompt Rtu, for Peridox Rtu, both.

12. Who performs the sterile compounding process at your facility?
Lead compounding Technician.

13. Who is responsible and accountable for the sterile compounding process at your facility?
Pharmacist-Incharge & Lead Technician (sterile compounding) Division.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
all Temp defendent (cold) products are shipped over nite/Next day delivery.
In Temp protected Packaging. with ice paks (sealed).
With label "Refrigrate upon Arrival" cold.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?

① Laminar airflow Workbench

② BSC class II — ③ Air science PS-36 for Non-sterile

2. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☑ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☒ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☒ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☒ No

7. If yes, list the name of the device:

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

① Safe Handling Instructions.
- Do not crush, split open.
- Disposal Instructions
- usually contained on Aux Labels on the vial container
- Labeling & written material

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

- Didactic (Knowledge based training)
  - USP 800 & USP 797 requirements
  - Risks of HD Exposures
  - HD Handeling & containment
  - Proper donning & doffing PPE
- Hands on demonstration & practice
- competency Testing of HD
- observation Period
- Documentation

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

- GLP-1's
- NAD+
- Methycobalamin
- Lipoc, Lipo-B
- Vit. B-complex.
- Ascorbic Acid

2. What sterilization methods are utilized at your facility?

- Filtration (sterile Filtration) use of 0.22 micron filter. In an ISO class 5 PEC. - Bubble point testing.
- Aspetic processing: combining sterile components Ex. Sterile powder & sterile diluent In Iso 5 conditions.

3. Does your facility utilize biological indicators? ☐ Yes ☒ No

4. If yes, describe how they are utilized:

- We use third party testing.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Quintana

Name of Person who Completed the Form

CEO/Owner

Title

Signature (copies or stamps not accepted)

02/24/25

Date

Board Use Only	Date Received: 4/2/25	Date Approved:	Approved By:

DocuSign Envelope ID: E143849E-0766-456F-8C21-343398C8275B

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *OPTIMAL BALANCE PHARMACY, LLC*

License Number:

Address: *2204 CYPRESS CREEK PARKWAY, SUITE F, HOUSTON, TX 77090*

Phone: *281-919-2964*

Email:

Class of License: *AS*

License Expiration:

DEA #:

DEA Expiration:

Inspection Information

Type: *Compliance*

Purpose: *Other*

Purpose Other: *Follow-up to Pre-Inspection*

Date: *07/26/2023*

Arrival Time: *9:45 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Laura Smith Williams *PIC* *51511*

Witness

Madison Davis

DocuSign Envelope ID: E143849E-0766-456F-8C21-343398C8275B

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *OPTIMAL BALANCE PHARMACY, LLC* License Number:

Class of License: *AS*

Inspection Information

Type: *Compliance* Purpose: *Other* Purpose Other: *Follow-up to Pre-Inspection*

Date: *07/26/2023* Arrival Time: *9:45 AM* Departure Time: *10:15 AM*

Action Taken: *Pre-Inspection*

General Comments: *Pharmacy has demonstrated that the clean room is maintained at a temperature of 20 degrees Celsius or cooler and provided passing environmental sampling results.*

Pre-Inspection Checklist

Verify Owner/Owner's Representative ID	*Yes*
Name: *Christopher Quintana* Title: *Owner*	
Verify PIC ID	*Yes*
Name: *Laura Smith Williams* Title: *PIC*	
1. The prescription department has adequate space for the size and scope of the pharmaceutical services provided by the pharmacy.	*Yes*
2. Fixtures (i.e. shelving, countertops, etc.) for the storage of drugs, equipment, and supplies necessary to operate a pharmacy are installed.	*Yes*
3. Electrical supply exists.	*Yes*
4. A sink with hot and cold running water available exclusive of the restroom facilities.	*Yes*
5. Pharmacy arranged in an orderly fashion and kept clean.	*Yes*
6. The prescription department is complete and contains the following required equipment and supplies including, but not limited to:	*Yes*
6a. data processing system including a printer or comparable equipment;	*Yes*
6b. refrigerator to be maintained within a range compatible with the proper storage of drugs requiring refrigeration;	*Yes*
6c. adequate supply of child-resistant, light-resistant, tight, and, if applicable, glass containers;	*Yes*

OPTIMAL BALANCE PHARMACY, LLC

6d. adequate supply of prescription labels with name, address, and telephone number of the pharmacy;	Yes
6e. appropriate equipment necessary for the proper preparation of prescription drug orders;	Yes
6f. metric-apothecary weight and measure conversion charts;	Yes
6g. If the pharmacy serves the public, the word "pharmacy" or similar word or symbol, as determined by the board, is displayed in a prominent place on the front of the pharmacy.	Yes
7. A reference library is on site and current:	Yes
7a. Texas Pharmacy Laws and Regulations (publication year: _____)	Yes
Publication Year : *Online*	
7b. Drug Interactions Reference (publication year: _____)	Yes
Publication Year : *Online*	
7c. General Information Reference (publication year: _____)	Yes
Publication Year : *Online*	
7d. Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations (If the pharmacy is compounding non-sterile preparations)	Yes
7e. General reference text on veterinary drugs (if the pharmacy dispenses veterinary prescriptions)	Not Applicable
7f. Basic Antidote Information and telephone number of the nearest Regional Poison Control Center.	Yes
8.If the pharmacy is compounding sterile preparations, the following references are also required:	Yes
8a. United States Pharmacopeia/National Formulary or USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding Sterile Preparations	Yes
8b. Chapter 71 of the USP/NF concerning Sterility Tests.	Yes
8c. Chapter 85 of the USP/NF concerning Bacterial Endotoxins Test	Yes
8d. Chapter 1163 of the USP/NF concerning Quality Assurance in Pharmaceutical Compounding	Yes
8e. Handbook on Injectable Drugs (publication year: _____)	Yes
Publication Year : *Online*	
8f. Specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy (e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs)	Yes

OPTIMAL BALANCE PHARMACY, LLC

9. Security Requirements can be met to assure the pharmacy will be locked by key, combination, or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site.	Yes
10. Pharmacy has basic alarm system with the off-site monitoring and perimeter and motion sensors. (Alarm must be activated). *If your city requires an alarm permit, provide a copy of the permit.	Yes
11. Written policies and procedures/SOPs for the pharmacy's security system that meet the requirements of Rule 291.33(b)(2)(E)	Yes
12. An area suitable for confidential patient counseling, if the pharmacy serves the general public	Yes
13. If compounding sterile preparations, the pharmacy has controlled area that meets the requirements in Rule 291.133 (d)(6)(A) if the pharmacy is compounding low-risk and medium-risk preparations or Rule291.133(d)(6)(B) if high-risk preparations are being compounded.	Yes
14. Certified primary engineering control device (e.g., laminar airflow work benches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators).	Yes
15. Certified clean room(s) (e.g. ante area, buffer area).	Yes

Discussion Items:

The requirements of TSBP Rule 291.11 and Section 565.0591 of the Pharmacy Act regarding the operation of a pharmacy within 6 months of becoming licensed.	Yes
Corresponding Responsibility and the Red Flags checklist using references from the DEA RPh Manual, the Texas Controlled Substances Act, and TSBP Rules 291.29 and 291.34 (b).	Yes
Pharmacy will need to conduct an opening inventory on the first day of business.	Yes
Pharmacy will need to report all controlled substances to the PMP as required.	Yes

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).

Laura Smith Williams

Madison Davis

Description	Route of Admin	Dosage Form
ACNE KETO CREAM	Topical	Cream
ALPROSADIL 100MCG/ML WATER FOR INJECTION SOLUTION	Injection	Solution
ALPROSTADIL 500MCG /ML ALCOHOL STOCK SOLUTION	Injection	Solution
ANASTROZOLE 0.25MG CAP	Oral	Capsule
ANASTROZOLE 0.5MG CAP	Oral	Capsule
ANASTROZOLE 1MG CAP	Oral	Capsule
ASCORBIC ACID 500MG/ML INJ.	Injection	Liquid
ATROPINE 0.1% STOCK SOLUTION	Injection	Solution
AZELAIC ACID/VITAMIN E/NIACINAMIDE 17%-1%-2%/GM TOPICAL CREAM	Topical	Cream
BENZOCAINE 20%-LIDOCAINE 10%-TETRACAINE 10%- TOPICAL CREAM	Topical	Cream
BI-EST 1.25MG (80/20) CAPSULE	Oral	Capsule
BI-EST 2.5MG (80/20) CAPSULE	Oral	Capsule
BI-EST 5MG (80/20) CAPSULE	Oral	Capsule
BI-EST 6MG (80/20) CAPSULE	Oral	Capsule
BI-MIX 30MG-1MG/ML	Injection	Solution
GLUTATHIONE 200MG/ML SOLN	Injection	Liquid
HAIR RESTORE ULTRA SCALP SOLUTION	Topical	Solution
IBUTAMOREN 12.5MG CAPS	Oral	Capsule
IBUTAMOREN 25MG CAPS	Oral	Capsule
LIDOCAINE 23%, TETRACAINE 10% TOPICAL CREAM	Topical	Cream
LIDOCAINE 23%-TETRACAINE 7%-PRILOCAINE 2% TOPICAL CREAM	Topical	Cream
LIPO-B (B-12/MIC)	Injection	Solution
LIPO-C	Injection	Solution
LIPO-DEN	Injection	Solution
LIVER SUPPORT CAP	Oral	Capsule
METHYLCOBALAMIN 1MG/ML SOLN	Injection	Solution
MINOXIDIL/FINASTERIDE 5%-0.1%/ML SOLN	Topical	Solution
MYER'S COCKTAIL (1)	Injection	Solution
MYER'S COCKTAIL SOLN	Injection	Solution
NAD+ 100MG/ML SOLN	Injection	Solution
NanDec/TestCyp/TestEna 60mg-7mg-70mg/ml	Injection	Solution
NANDROLONE 200MG/ML SOLN (GRAPE SEED OIL)	Injection	Powder
NANDROLONE 200MG/ML SOLN (MCT)	Injection	Powder
OXYTOCIN 10 IU/MG/ MANNITOL TRITURATION	Nasal	Solution
OXYTOCIN NASAL SPRAY 100 IU/ML	Nasal	Solution
OXYTOCIN TROCHE 120 IU	Buccal	Lozenge
PHENTERMINE HCL 45MG CAPS	Oral	Capsule
PHENTERMINE SR 37.5MG CAPS	Oral	Capsule
PHENTOLAMINE/MANNITOL TRITURATION	Injection	Powder

PHENYLEPHRINE INJ 0.1% SOLN	Injection	Solution
PRESERVED WATER (PARABENS)	Oral	Solution
PROGESTERONE 100MG SR CAPS	Oral	Capsule
PROGESTERONE 125MG CAP	Oral	Capsule
PROGESTERONE 150MG CAP	Oral	Capsule
PROGESTERONE 200MG SR CAPS	Oral	Capsule
PROGESTERONE 50MG CAP	Oral	Capsule
PROGESTERONE 75MG CAP	Oral	Capsule
PYRIDOXINE 100MG/ML SOLN	Injection	Solution
QUADMIX	Injection	Solution
SEMAGLUTIDE 2.5MG/ML SOLN (1ML)	Injection	Solution
SEMAGLUTIDE 2.5MG/ML SOLN (2ML)	Injection	Solution
SEMAGLUTIDE 2.5MG/ML SOLN (3ML)	Injection	Solution
SEMAGLUTIDE 2.5MG/ML SOLN (4ML)	Injection	Solution
SEMAGLUTIDE 2MG/ML SOLN (4ML)	Injection	Solution
SEMAGLUTIDE/B12 2.5MG-500MCG/ML SOLN (3ML)	Injection	Solution
SEMAGLUTIDE/B12 2.5MG-500MCG/ML SOLN (5ML)	Injection	Solution
SEMAGLUTIDE/B12 10MG-100MCG/ML SOLN (1ML)	Injection	Solution
SEMAGLUTIDE/B12 10MG-500MCG/ML SOLN (1ML)	Injection	Solution
SEMAGLUTIDE/B12 10MG-500MCG/ML SOLN (2ML)	Injection	Solution
SEMAGLUTIDE/B12 1MG-500MCG/ML SOLN (1ML)	Injection	Solution
SEMAGLUTIDE/B12 1MG-500MCG/ML SOLN (3ML)	Injection	Solution
SEMAGLUTIDE/B12 1MG-500MCG/ML SOLN (4ML)	Injection	Solution
SEMAGLUTIDE/B12 1MG-500MCG/ML SOLN (7ML)	Injection	Solution
SEMAGLUTIDE/B12 2MG-500MCG/ML SOLN (1ML)	Injection	Solution
SEMAGLUTIDE/B12 2MG-500MCG/ML SOLN (3ML)	Injection	Solution
SEMAGLUTIDE/B12 4MG-100MCG SOLN (1ML)	Injection	Solution
SEMAGLUTIDE/B12 4MG-500MCGML SOLN (1ML)	Injection	Solution
SEMAGLUTIDE/B12 4MG-500MCGML SOLN (2ML)	Injection	Solution
SEMAGLUTIDE/B12 4MG-500MCGML SOLN (3ML)	Injection	Solution
SEMAGLUTIDE/B12 5MG-500MCG/ML SOLN (1ML)	Injection	Solution
SEMAGLUTIDE/B12 5MG-500MCG/ML SOLN (2.5ML)	Injection	Solution
SEMAGLUTIDE/B12 5MG-500MCG/ML SOLN (2ML)	Injection	Solution
SEMAGLUTIDE/B12 5MG-500MCG/ML SOLN (3ML)	Injection	Solution
SEMAGLUTIDE/B12 5MG-500MCG/ML SOLN (4ML)	Injection	Solution
SEMAGLUTIDE/B12 6MG-500MCG/ML SOLN (1ML)	Injection	Solution
SEMAGLUTIDE/B12 6MG-500MCG/ML SOLN (2ML)	Injection	Solution
SEMAGLUTIDE/B12 8MG-500MCG/ML SOLN (1ML)	Injection	Solution
SEMAGLUTIDE/B12 8MG-500MCG/ML SOLN (2ML)	Injection	Solution
SEMAGLUTIDE/B6 5MG-25MG/ML SOLN (2ML)	Injection	Solution

SILDENAFIL 110MG CAPS	Oral	Capsule
SILDENAFIL 125MG ODT	Oral	Tablet, Rapid Dissolve
SILDENAFIL 1MG, TEST 1MG/GM CREAM	Topical	Cream
SILDENAFIL 55MG CAP	Oral	Capsule
SILDENAFIL SR 110MG CAPS	Oral	Capsule
SILDENAFIL SR 36MG CAPSULE	Oral	Capsule
SILDENAFIL SR 75MG CAPS	Oral	Capsule
SILDENAFIL TROCHE 100MG (ODT)	Buccal	Lozenge
SILDENAFIL/TADALAFIL 50MG-10MG CAPSULE	Oral	Capsule
SILDENAFIL/TADALAFIL 50MG-10MG RDT	Oral	Capsule
SILDENAFIL/TADALAFIL 55MG-12MG CAPSULE	Oral	Capsule
SULFURIC ACID 20%(W/V) AQUEOUS SOLUTION	Misc.(Non-Drug; Combo Route)	Solution
SUPER BI-MIX	Injection	Solution
SUPER QUAD-MIX	Injection	Solution
SUPER TRI-MIX	Injection	Solution
TADALAFIL 12MG CAPS	Oral	Capsule
TADALAFIL 12MG MINT CHEWABLE	Oral	Tablet
TADALAFIL 24MG CAP	Oral	Capsule
TADALAFIL 24MG MINT CHEWABLE	Oral	Tablet
TADALAFIL 25MG ODT	Oral	Tablet, Rapid Dissolve
TADALAFIL 6MG MINT CHEWABLE	Oral	Tablet
TADALAFIL SR 12MG CAPS	Oral	Capsule
TADALAFIL SR 18MG CAPS	Oral	Capsule
TADALAFIL SR 24MG CAPS	Oral	Capsule
TADALAFIL SR 3MG CAPS	Oral	Capsule
TADALAFIL SR 6MG CAPS	Oral	Capsule
TADALAFIL SR 7MG CAPS	Oral	Capsule
TADALAFIL TROCHE 12.5MG	Buccal	Lozenge
TADALAFIL TROCHE 20MG	Buccal	Lozenge
TADALAFIL TROCHE 25MG	Buccal	Lozenge
TEST CYP/TEST PRO 15MG-5MG/ML SOLN	Injection	Solution
TEST CYP/TEST PRO 160MG-40MG/ML SOLN	Injection	Solution
TEST CYP/TEST PRO 200MG-50MG/ML SOLN	Injection	Solution
TESTOSTERONE 100MG/GM CREAM	Topical	Cream
TESTOSTERONE 10MG/GM TOPICAL CREAM	Topical	Cream
TESTOSTERONE 200MG/GM TOPICAL CREAM	Topical	Cream
TESTOSTERONE 30MG/GM TOPICAL CREAM	Topical	Cream
TESTOSTERONE 4MG/GM TOPICAL CREAM	Topical	Cream
TESTOSTERONE 50MG/GM TOPICAL CREAM	Topical	Cream
TESTOSTERONE 5MG/GM TOPICAL CREAM	Topical	Cream

TESTOSTERONE CYP 200MG/ML SOLN	Injection	Solution
TESTOSTERONE CYP 200MG/ML SOLN (GRAPE SEED OIL)	Injection	Solution
TESTOSTERONE CYP 20MG/ML SOLN	Injection	Solution
TESTOSTERONE CYP 20MG/ML SOLN (GRAPE SEED OIL)	Injection	Solution
TESTOSTERONE CYP 50MG/ML SOLN	Injection	Solution
TESTOSTERONE CYP 50MG/ML SOLN (2.5ML)	Injection	Solution
TESTOSTERONE CYP 50MG/ML SOLN (GRAPE SEED OIL)	Injection	Solution
TESTOSTERONE CYP/ANASTROZOLE 200MG-1MG/ML SOLN	Injection	Solution
TESTOSTERONE ENT 200MG/ML SOLN	Injection	Solution
TESTOSTERONE ENT 200MG/ML SOLN (GRAPE SEED OIL)	Injection	Solution
TESTOSTERONE PRO 100MG/ML SOLN	Injection	Solution
TESTOSTERONE/ESTRADIOL 1%-0.01%/GM VAGINAL CREAM	Vaginal	Cream
TIRZEPATIDE 10MG/ML SOLN (2ML)	Injection	Solution
TIRZEPATIDE 5MG/0.5ML SOLN (1ML)	Injection	Solution
TIRZEPATIDE 5MG/0.5ML SOLN (2ML)	Injection	Solution
TIRZEPATIDE 5MG/0.5ML SOLN (3ML)	Injection	Solution
TIRZEPATIDE 5MG/0.5ML SOLN (4ML)	Injection	Solution
TIRZEPATIDE 5MG/0.5ML SOLN (5ML)	Injection	Solution
TIRZEPATIDE 5MG/0.5ML SOLN (6ML)	Injection	Solution
TIRZEPATIDE/B12 10MG-500MCG/ML SOLN (2ML)	Injection	Solution
TIRZEPATIDE/B12 10MG-500MCG/ML SOLN (3ML)	Injection	Solution
TIRZEPATIDE/B12 15MG-500MCG/ML SOLN (2ML)	Injection	Solution
TIRZEPATIDE/B12 15MG-500MCG/ML SOLN (6ML)	Injection	Solution
TIRZEPATIDE/B12 17MG-500MCG/2ML SLON (4ML)	Injection	Solution
TIRZEPATIDE/B12 20MG-500MCG/ML SOLN (2ML)	Injection	Solution
TIRZEPATIDE/B12 20MG-500MCG/ML SOLN (3ML)	Injection	Solution
TIRZEPATIDE/B12 25MG-500MCG/ML SLON (2.4ML)	Injection	Solution
TIRZEPATIDE/B12 25MG-500MCG/ML SLON (2ML)	Injection	Solution
TIRZEPATIDE/B12 30MG-500MCG/ML SLON (2ML)	Injection	Solution
TIRZEPATIDE/B12 30MG-500MCG/ML SOLN (6ML)	Injection	Solution
TIRZEPATIDE/B12 34MG-500MCG/ML SLON (8ML)	Injection	Solution
TIRZEPATIDE/B12 5MG-500MCG/0.5ML SOLN (3ML)	Injection	Solution
TIRZEPATIDE/B12 5MG-500MCG/ML SOLN (2ML)	Injection	Solution
TIRZEPATIDE/B12 7.5MG-500MCG/ML SOLN (2ML)	Injection	Solution
TIRZEPATIDE/B6 20MG-8MG/ML SOLN (1ML)	Injection	Solution
TIRZEPATIDE/METHYLCOBALAMIN 10MG-1MG/ML SOLN	Injection	Solution
TIRZEPATIDE/METHYLCOBALAMIN 10MG-500MCG/ML SOLN (2ML)	Injection	Solution
TIRZEPATIDE/METHYLCOBALAMIN 20MG-500MCG/ML SOLN (2ML)	Injection	Solution
TOREMIFENE 80MG CAP	Oral	Capsule
TRIMIX	Injection	Solution

TRIMIX XL	Injection	Solution
VARDENAFIL TROCHE 20MG ODT	Buccal	Lozenge
VITAMIN B-COMPLEX SOLN	Injection	Solution
XSEED	Oral	Capsule

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This certifies that the pharmacy named below is hereby licensed to operate as a Class **AS** pharmacy.

License No. **34829** Expiration Date: **8/31/2025**

Balances: 4

OPTIMAL BALANCE PHARMACY LLC
2204 CYPRESS CREEK PKWY STE F
HOUSTON TX 77090

Julie R. Spier, R.Ph.
President

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 34829

OPTIMAL BALANCE PHARMACY LLC

License Information

License Status Active
License # 34829
Expiration Date 08/31/2025
Date License Issued 08/03/2023

Address

2204 CYPRESS CREEK PKWY STE F
HOUSTON, TX 77090
County HARRIS
Phone (281) 919-2964

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy
Community Sterile Compounding
Type of Ownership LLC
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
AMIRZADEH, REZA

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	No

Translating services (Listed Below If Available)

Spanish

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 3292224 34829 OPTIMALBALANCEPHARMACYLLC 2023-07 07-2028-1 (002).pdf
- 3292224 34829 OPTIMALBALANCEPHARMACYLLC 2023-07 07-2028-2 (002).pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	Yes
Ship Prescription Out of State	Yes

Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	Yes
Compounding Sterile-Risk Level Med	Yes
Compounding Sterile-Risk Level High	Yes
Compounding Non-Sterile	Yes
24 Hour Service	Yes
Closed Door	No
Compounding, Office Use	No
Home Delivery	Yes
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
AMIRZADEH, REZA	39992	07/17/2001	01/31/2026	PIC	Active
ARORA, MADHURIMA	58125	03/31/2016	10/31/2025	Staff	Active
TELLMAN, BENJAMIN DAVID	25790	09/08/1981	09/30/2026	Staff	Active

Page 1 of 1 20 View 1 - 3 of 3

Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
BUTLER, BRANDON	217504	03/18/2013	03/31/2027	Staff	Active
CORDOVA, MONICA	194664	01/28/2011	03/31/2026	Staff	Active
CRUZ, LAKYIA NICOLE	370529	05/06/2024	05/31/2026	Staff	Active
EKSTROM, TINA	195488	03/02/2011	10/31/2026	Staff	Active
FABIAN, YANERIC E	358773	08/15/2023	08/31/2025	Staff	Active
FERGUSON, ASJAH QUIMEIAH RIERRE	319877	04/01/2021	05/31/2027	Staff	Active
FLORES, REBECA	365005	12/19/2023	06/30/2027	Staff	Active
HERNANDEZ, JORGE ARMANDO	243197	05/18/2015	01/31/2027	Staff	Active
LUNA, ELEUTERIO	146266	01/18/2008	07/31/2026	Staff	Active
PENA BARRUETO, DAILYN	272211	07/14/2017	05/31/2026	Staff	Active
PENA, SAVANAH	376668	09/10/2024	09/30/2026	Staff	Active
RIVERA, MICHELLE	105252	04/29/2004	10/31/2025	Staff	Active
SCIFERS, ELIZABETH	378217	10/07/2024	10/31/2026	Staff	Active
STANLEY, EZRA LYNN	368425	03/12/2024	03/31/2026	Staff	Active
THORNTON, SHAWNTIA	363301	11/08/2023	11/30/2025	Staff	Active
WHITSON, KRISTINA LYNN	384469	03/11/2025	03/31/2027	Staff	Active

Page 1 of 1 20 View 1 - 16 of 16

Texas Remote Pharmacy Information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner Information

Owner Name	Owner Title	Address	City	State	Zipcode
OPTIMAL BALANCE PHARMACY, LLC	OWNER	,			
QUINTANA, CHRISTOPHER	OFFICER	,			

Page 1 of 1 20 View 1 - 2 of 2

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

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DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FO3326596	12-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-18-2023

OPTIMAL BALANCE PHARMACY, LLC
2204 CYPRESS CREEK PKWY STE F
HOUSTON, TX 770903108

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
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2204 CYPRESS CREEK PKWY STE F
HOUSTON, TX 770903108

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Form DEA-223 (9/2016)

4FFF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☒ Nuclear	DEA #: N/A
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☒ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: RLS (USA) Inc

Physical Address: 1516 Kimberly Avenue

City: Fullerton State: CA Zip: 92831

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 714-278-4701 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 714-278-4702 Contact Email: Licensing@rls.bio

Website: www.rls.bio

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Dung Nguyen

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21778

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Dung Nguyen, Pharm. D.	NV Pharmacist Registration #: 21778
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Darren Patti	Credentials: see attached list	%: 0
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Darren Patti
Registered Pharmacist Licenses

License Type	License Number	State	Status
Registered Pharmacist	051290696	IL	Active
Registered Pharmacist	2007031818	MO	Active
Registered Pharmacist	5502043469	MI	Active

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Telix Pharmaceuticals (US) Inc

Corporation/Organization Name: RLS (USA) Inc

Mailing Address: 255 Primera Boulevard, Suite 440

City: Lake Mary State: FL Zip: 32746

Telephone: 813-285-3065 Email: licensing@rls.bio

Contact Person Name: David Miller

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Group Chief Operating Officer (title) for RLS (USA) Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Darren Patti

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

30 APR 25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Darren Patti

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

30 APR 25

Date

Board Use Only	Date Received: 5/20/25	Amount: $500 - CK 2304

Disciplinary Summary
RLS (USA) Inc. Pharmacies

RLS (USA) Inc., f/k/a Amersham Health Nuclear, Medical Pharmacy, 1 Naylon Place, Livingston, NJ 07039

March 8, 2004: New Jersey Board of Pharmacy issued a $225.00 penalty and requested a letter of corrective action as a result of violations of N.J.A.C 13:39-12.2(e) (Prescription label does not have the chemical form of the radioactive drug) and N.J.A.C 13:39-12.4(c) (Missing a current text in the category of "General Practice of Pharmacy") found during an inspection conducted on 12/19/2003. RLS (USA) Inc. satisfied all requirements of the corrective action, paid the fine, and remains in good standing with the New Jersey Board of Pharmacy.

RLS (USA) Inc., f/k/a/ Med-Physics, Inc., d/b/a/ GE Healthcare, 1 Naylon Place, Livingston, NJ 07039

May 19, 2017: New Jersey Board of Pharmacy issued a $5,500.00 penalty and requested a letter of corrective action as a result of violations of N.J.A.C 13:39-11.24(a)6 (Adequate efforts were not made to ensure the pharmacy's quality assurance program) and N.J.A.C 13:39-11.24(a)10 (When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards) found during an inspection conducted on 8/10/2016. The pharmacy paid the fine and met all requirements of the corrective action, and remains in good standing with the New Jersey Board of Pharmacy.

RLS (USA) Inc., 1283 Mountain View Alviso Road Ste. A - B, Sunnyvale, CA 94089

February 14, 2024: RLS (USA) Inc. failed to follow its written policies and procedures when, on dates ranging from 12/30/2022 to 6/26/2023, it failed to remove pharmacy equipment from use following microbial contamination. This resulted in a violation of California pharmacy law for which the Board issued a Citation. No fine was assessed and the pharmacy took corrective action to address the violations. The pharmacy remains in good standing with the California Board of Pharmacy.

RLS (USA) Inc., 16259 Stagg Street, Ste A, Van Nuys, CA 91406

October 11, 2024: RLS (USA) Inc. failed to timely notify the California Board of Pharmacy upon a change in the Pharmacist-in-Charge. RLS (USA) Inc. operated without an approved PIC for the pharmacy and was fined a total of $1500. RLS complied with all requirements of the citation and the pharmacy remains in good standing with the California Board of Pharmacy.

State of New Jersey

OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

JAMES E. MCGREEVEY
Governor

PETER C. HARVEY
Attorney General
RENI ERDOS
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 8, 2004

John Marzocca, RPIC
Amersham Health Nuclear
Medical Pharmacy
1 Naylon Place
Livingston, NJ 07039

Re: Inspection Report #8-1066.6
Inspection Date: 12/19/03

Dear Mr. Marzocca:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated:

N.J.A.C. 13:39-12.2(e)
Prescription label does not have the chemical form of the radioactive drug.
$25.00

N.J.A.C. 13:39-12.4(c)
Missing a current text in the category of "General Practice of Pharmacy".
$200.00

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the attached acknowledgment and agree to the following:

1. Pay a penalty in the amount of **$225.00** and provide to the Board a Letter of Corrective Action. (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively, you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, directing you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973).504-6450.

The enclosed certification should be completed and returned to the Board **within fifteen (15) days following your receipt of this letter.** In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained here in shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: Joanne Boyer
Joanne Boyer
Executive Director

JB/mw

cc: Marianne Greenwald, Deputy Attorney General
[redacted]

5/26/04 Exec 10E (6)

CERTIFICATION

I, JOHN MARZOCCA, hereby acknowledge that I have read and reviewed the Board's letter dated March 8, 2004 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

☐ I acknowledge the conduct which has been charged and agree to:

1. Cease and desist in engaging in the conduct alleged and pay a penalty in the amount of **$225.00** (to be paid upon signing of this certification).

2. Send a **Letter of Corrective Action**, as requested by the Board, with this certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this certification are public documents.

☑ I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before the rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the certifications are public documents.

☐ I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board, testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this certification are public documents.

(Signature)

Dated: 3/31/04

JOHN MARZOCCA
(Print Name)

Ref: John Marzocca, RPIC
Amersham Health Nuclear
Medical Pharmacy
1 Naylon Place
Livingston, NJ 07039

Amersham Health
1 Naylpn Place
Livingston New Jersey 07039

March 31, 2004

Joanne Boyer
Executive Director
Division of Consumer Affairs
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Ms. Boyer:

We are in receipt of your letter dated 8 March 2004 concerning the alleged deficiencies sited during an inspection of our Livingston, New Jersey facility conducted 19 December 2003. The alleged deficiencies as stated in your letter are listed below for ease of reference:

N.J.A.C.13:39-12.4(c)
Missing a current edition of a text in the category of "General Practice of Pharmacy".

We at Amersham Health believe that in the spirit of, and pursuant to, New Jersey State Board of Pharmacy Regulations, current texts via computer access, pertaining to the General Practice of Pharmacy meet these requirements of N.J.A.C.13:39-12.4(c). The two texts are USP/NF via internet access, and Pass Assured, a computer text used by our pharmacy technicians to prepare for the PTCB certification test. This computer text covers the following items in the general practice of pharmacy:

Pharmacy Law
Terminology
Calculations
Metric Conversions
Dosage Forms
Aseptic Techniques
Pharmacy Operations
Third Party Reimbursements.

The above notwithstanding, Amersham Health has also purchased a current edition of Remington's "The Science and Practice of Pharmacy" on 11 March 2004.

N.J.A.C.13:39-12.2(e)
Prescription label does not have the chemical form of the radioactive drug.

Amersham Health was unable to locate the definition of chemical form within New Jersey Board of Pharmacy Regulations so we reverted to the DOT interpretation. The Chemical form of a radioactive drug is required on all DOT Bills-of-Lading for radioactive deliveries and is addressed by the U.S D.O.T. under 49 CFR 172.203, and is defined as "**a generic chemical description is acceptable for chemical form**". Under these conditions Amersham Health can only interpret "chemical form" in NJAC 13:39-12.2(e) to be the name of the radiopharmaceutical drug. Attachment 1 contains an actual prescription label listing the name of the radionuclide (i.e., Tc-99m, In-111, etc...) along with the actual generic chemical (radiopharmaceutical/brand) name of the drug (i.e., Myoview, MAA, MDP, etc...). Amersham Health believes that if one interpreted "chemical form", as "inorganic salt", then all radioactive prescriptions have the potential of being "mislabeled". For example, Tc99mMyoview, Tc99mMDP, Tc99mMag 3, and Tc99mDTPA are "different" radiopharmaceutical drugs used to diagnose different organs within the body. Following the current board of pharmacy labeling

guidelines, and interpreting chemical form as inorganic salt, then all five prescription labels would read "Tc99m Inorganic Salt". The actual drug(brand) name would not have to appear on the label pursuant to regulation, which would cause all five prescriptions to be identical which in turn could be described as "mislabeled". Therefore the only way to assure that a radioactive prescription is not "mislabeled" is to interpret chemical form to be the name of the radiopharmaceutical. The name of the radiopharmaceutical currently appears on all Amersham Health prescriptions.

Based on this understanding Amersham Health respectfully requests that the both "deficiencies" be rescinded, and would like to request an informal meeting to discuss the matter with the board.

If you have any questions or require any additional information, please contact me at (973) 533-9109, or Richard Hughes, Corporate Radiation Safety Officer at (609) 514-6647.

Sincerely,

John Marzocca R.Ph
Pharmacist in charge

Amersham Health New Jersey
1 Naylon Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-011
[redacted]
Nuclear Medicine

Order #2450929 Date 03/31/04

Tc-99m MAA
4.0000 mCi
0.5234 ml
9:30 On 03/31/04 Calibration Time

ACT DISP: 4.0000 mCi 148.0000 MBq (+/- 10%)
LOT NO. 35-03/31/04 RX-2416608
ASSAY: 7.6423 mCi/ml MFGR: In-House Prep
EXP TIME: 15:05 EXP DATE: 03/31/04
LIC. NO. 29-14017-01 P.O. NO.: SO3000184
PIC: John Marzocca, R.Ph.

ADDRESS: 600 RIVER AVE., LAKEWOOD, NJ, 087
DOCTOR: Patel, Bharat
PATIENT: Per Physician's Order
PROCEDURE: Pulmonary Perfusion

SPECIAL INSTRUCTIONS:
Mo-99 content < 0.15 uCi/mCi at expiration time Agitate Syringe Prior to Injection -- Don't Use If Particles Visible.

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

Amersham Health New Jersey
1 Naylon Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-015
[redacted]
Nuclear Medicine

Order #2447823 Date 03/31/04

Tc-99m MDP
25.0000 mCi
0.8236 ml
10:00 On 03/31/04 Calibration Time

ACT DISP: 25.0000 mCi 925.0000 MBq (+/- 10%)
LOT NO. 18-03/31/04 RX-2413566
ASSAY: 30.3545 mCi/ml MFGR: In-House Prep
EXP TIME: 13:35 EXP DATE: 03/31/04
LIC. NO.: 29-07213-03 P.O. NO: C-0382
PIC: John Marzocca, R.Ph.

ADDRESS: 495 NORTH 13TH STREET, NEWARK,
DOCTOR: Freyne,J
PATIENT: Per Physician's Order
PROCEDURE: Skeletal Imaging

SPECIAL INSTRUCTIONS:
Mo-99 content < 0.15 uCi/mCi at expiration time Hydrate Patient Prior to Imaging.

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

Amersham Health New Jersey
1 Naylon Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-015
[redacted]
Nuclear Medicine

Order #2450742 Date 03/31/04

Tc-99m DTPA
25.0000 mCi
0.8970 ml
14:00 On 03/31/04 Calibration Time

ACT DISP: 25.0000 mCi 925.0000 MBq (+/- 10%)
LOT NO. 30-03/31/04 RX-2416421
ASSAY: 27.8707 mCi/ml MFGR: In-House Prep
EXP TIME: 20:35 EXP DATE: 03/31/04
LIC. NO.: 29-07213-03 P.O. NO.
PIC: John Marzocca, R.Ph.

ADDRESS: 495 NORTH 13TH STREET, NEWARK,
DOCTOR: Freyne,J
PATIENT: Per Physician's Order
PROCEDURE: Renal Imaging

SPECIAL INSTRUCTIONS
Mo-99 content < 0.15 uCi/mCi at expiration time

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

Amersham Health New Jersey
1 Naylon Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-296
[redacted]
18

Order #2448221 Date 03/31/04

Tc-99m Myoview
25.0000 mCi
0.7774 ml
13:30 On 03/31/04 Calibration Time

ACT DISP: 25.0000 mCi 925.0000 MBq (+/- 10%)
LOT NO. 99-03/31/04 RX-2413984
ASSAY: 32.1585 mCi/ml MFGR: In-House Prep
EXP TIME: 20:05 EXP DATE: 03/31/04
LIC. NO.: 29-30100-01 P.O. NO.:
PIC: John Marzocca, R.Ph.

ADDRESS: 585 NEW BRUNSWICK AVE, FORDS,
DOCTOR: SODHI,A
PATIENT: Per Physician's Order
PROCEDURE: Myocardial Perfusion

SPECIAL INSTRUCTIONS
Mo-99 content < 0.15 uCi/mCi at expiration time

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

State of New Jersey

OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

JAMES E. MCGREEVEY
Governor

PETER C. HARVEY
Attorney General
RENI ERDOS
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

July 22, 2004

John Marzocca, RPIC
Amersham Health Nuclear
1 Naylon Place
Livingston NJ 07039

GE
4403

RE: Inspection Report #8-1066.6

Dear Mr. Marzocca:

The Board reviewed your letter of March 31, 2004 in which you offered mitigation concerning the above referenced Inspection Report.

It was the decision of the Board at the May 26, 2004 meeting, to mitigate the following violation(s):

N.J.A.C.13:39-12.2(e) for $25.00 and deny the mitigation for N.J.A.C.13:39-12.4(c)for $200.00

Please submit the remaining balance in the amount of $200.00 along with a letter of corrective action.

Yours truly,

Joanne Boyer

Joanne Boyer, RPh
Executive Director

JB/sm

YHM-2017-03364

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

CHRISTOPHER S. PORRINO
Attorney General

STEVE C. LEE
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 19, 2017

John Marzocca, RPIC
Med-Physics, Inc., d/b/a GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039

Re: Inspection #8-1066-16-X
Date of Inspection: August 10, 2016

Dear Mr. Marzocca:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on Attachment A.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you **MUST SIGN THE ATTACHED CERTIFICATION** and agree to the following:

PAY A PENALTY IN THE AMOUNT OF $5,500.00 and **PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION.** (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record. Please take notice that if the Board determines that the initial inspection findings require a reinspection to ensure that cited deficiencies have been properly addressed, you may be subject to any costs associated with the reinspection.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit

determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification MUST be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, RPh
Executive Director

AR/rh
(1/17)

CERTIFICATION

I, JOHN MARZOCCA, hereby acknowledge that I have read and reviewed the Board's letter dated May 19, 2017 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

[✓] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $5,500.00** (to be paid upon signing of this Certification).

2. **Send a Letter of Corrective Action,** as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[ ] I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

[ ] I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board, testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this Certification are public documents.

(Signature)

Dated: 6/12/17

JOHN MARZOCCA
(Print Name)

Ref: John Marzocca, RPIC
Med-Physics, Inc., d/b/a GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039
(28RS00446300)
Inspection #8-1066-16-X
AR/rh
(1/17)

ATTACHMENT A

36. **Med-Physics, Inc., d/b/a GE Healthcare** - 1 Naylon Place, Livingston, New Jersey 07039
Pharmacist-In-Charge: John Marzocca
Bureau File #8-1066-16-X, **Period:** 8/10/16
Reference: Board of Pharmacy inspection conducted per N.J.S.A.45:1-18, N.J.S.A.45:14-48(a)11&12 and a request from the Board to inspect all pharmacies that engage in compounding sterile preparations.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-11.24(a)6	Adequate efforts were not made to ensure the pharmacy's quality assurance program. Specifically, on June 17, 2015, the pharmacy's internal surface sampling detected a total of twenty-two (22) Colony Forming Units (CFUs) from various locations, including support table used in sterile compounding, the prep room and the pass through. On January 11, 2016, internal surface sampling detected one (1) CFU from the ISO 5 hood, one (1) CFU from Tech Hood 2 and one (1) CFU from Biologic Safety Cabinet (BSC) 6. Sixty-nine (69) CFUs were detected at various testing sites, including support tables, support cars and the dispensing room. On June 27, 2016, according to the pharmacy's internal surface sampling, four (4) CFUs were detected at BSC support table 1, four (4) CFUs were detected at BSC support table 6, one (1) CFU at cart 2 and three (3) CFUs at a general support table. Additionally, a total of twenty-one (21) CFUs were found in the gowning room. On all of these occasions, the pharmacy failed to analyze the species to the genus level in order to exclude the possibility of the existence of highly pathogenic species. By reviewing the cleaning log for the month of June 2016, the pharmacy failed to specify the details of cleaning in the event of CFU detection.	**$3,000.00**

N.J.A.C.13:39-11.24(a)10	When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards. Specifically, on September 28, 2015, during the environmental monitoring tsts conducted by ENV Services, a laboratory equipment certification company, air sampling detected multiple CFUs in the dispensing room, the gowning room, the prep room, the White Blood Cell (WBC) anteroom and the WBC prep room. The nature of the CFUs detected in these areas was deemed non-highly pathogenic. The quantities of CFUs were below action level. Air Sample number 10 detected one (1) CFU in the center of the WBC Room and the species was identified as fungal in nature. This finding was deemed as Out-of-Compliance (OOC). On the following day, September 29, 2015, ENV Services detected one (1) CFU in the dispensing room, classified as ISO Class 7. The species was identified as fungal in nature. This finding was again deemed as OOC. John Marzocca, RPIC acknowledged that upon learning the test results on October 9, 2015, the pharmacy failed to cease using the affected equipment. The cleaning log for the month of October 2015 failed to indicate that the pharmacy performed triple cleaning in order to address these findings. On October 19, 2016, during a follow-up visit by Inv. Qi to the pharmacy, Mr. Marzocca stated that during the most recent environmental monitoring test performed by ENV Services, the maximum CFU count for two (2) ISO classified areas was exceeded. Air sampling detected one (1) CFU of genus in fungi nature from one of the BSC units, ISO Class 5, as well as thirteen (13) CFUs from one of the support tables. The CFUs detected were a highly pathogenic species. Mr. Marzocca stated that the pharmacy followed the N.J.A.C. regulation this time and ceased using the affected equipment.	**$2,500.00**

	Daily and weekly cleaning procedures were reviewed in detail. Upon review, it appeared that the pharmacy updated the cleaning frequency, cleaning methods and cleaning materials since my August 2016 visit.	
TOTAL: $5,500.00		

2/17

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

June 12, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

In response to NJ Board of Pharmacy letter Dated May 19, 2017 concerning inspection #8-1066-16-X, please find the enclosed signed certification letter with a check for $5500. Below are the corrective actions:

1. Contact plate surface samples are currently conducted in-house biannually. Any microbial recovery will be analyzed by an independent third party company, such as Nelson Labs 6280 South Redwood Road, Salt Lake City Utah. This is in addition to our cleanroom certification company (ENV) collecting and analyzing environmental air and surface samples biannually and identifying all recovered microbes to the genus level.
2. In 2016, we and our third-party certification vendor (ENV) enacted more stringent garbing, cleaning, and clean room entry procedures. Prior to these new protocols ENV would wheel in testing equipment from the street into our clean room without thoroughly cleaning the equipment and transportation carts. ENV now requires and supplies their technicians with clean room coveralls to wear during certification procedures. ENV technicians also thoroughly clean their testing equipment which is properly maintained for clean room entry and transfer all necessary equipment to GE clean room carts prior to certification testing.
3. In 2016 we have also changed our protocols to a more aggressive daily "cleaning and disinfection" of our primary and secondary engineering controls. We now use germicidal cleaning and disinfecting agents daily in addition to using sterile 70% isopropyl alcohol in the primary engineering controls. Prior to this change we used germicidal agents weekly and 70% isopropyl alcohol daily. We have also started a rotation of a sporicidal agent in our cleaning and disinfecting procedures.

If you have any questions, please do not hesitate to contact me at 973-533 9109

Sincerely,

John Marzocca R.Ph

APR 04 2017

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

March 28, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

In response to NJ Board of Pharmacy letter Dated march 9, 2017 concerning the observations identified during an inspection of our Livingston New Jersey Nuclear Pharmacy conducted August 10, 2016. The observations stated in your letter are listed below for ease of reference:

[N.J.A.C.13:39-1124(a)6]- Adequate efforts were not made to ensure the pharmacy's quality assurance program.

Although this regulation does not make any reference to internal sampling to be analyzed for species to the genus to exclude the possibility of the existence of highly pathogenic species, Medi-Physics, Inc. d/b/a/ GE Healthcare Livingston NJ, has added this to our environmental monitoring protocols. Contact plate samples incubated on site which show organism growth will be analyzed by an independent certified third party laboratory for ID'ing to genus level. Additionally, our cleanroom certification company (ENV) shall continue to take environmental samples for air and surface contamination biannually during re-certification procedures. All growth recovered from third party vendor sampling shall also be ID'd to genus level.

[N.J.A.C.13:39-24(a)10]-When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the primary engineering controls or cleanroom that was out of compliance until such time that the cleanroom met the requisite standards.

The Livingston Pharmacy did not take action to immediately cease using secondary engineering controls on September 28, 2015, as a result of the environmental monitoring tests, due to the fact the we were unaware of this requirement per 13:39-24(a)10 until the **January 2016** New Jersey Board of Pharmacy newsletter article titled- Regulation Regarding Out-of-Compliance Cleanrooms and Primary Engineering. Our Standard Operating Procedures, at the time required us to immediately deep clean the area of concern, perform an investigation to determine action necessary to eliminate recurrence of the contamination, and retest prior to reuse. After further review of the information in that newsletter, the Livingston Pharmacy is in the process of updated

protocols to include 13:39-24(a)10. At this time, we are in compliance with this regulation as evidenced by our SOP's as well as Mr. Qi's follow up visit on October 19, 2016 stating that ENV services monitoring found a maximum CFU count exceeded in a BSC hood which was taken out of service until an EVN re-test was performed.

If you any questions or require any additional information, please contact me at (973) 533-9009.

Sincerely,

John Marzocca R.Ph

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

CHRISTOPHER S. PORRINO
Acting Attorney General

STEVE C. LEE
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

March 9 , 2017

Medi-Physics, Inc. dba GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039
Attn: Jon Marzocca, RPIC

RE: Inspection Report #8-1066-16X for the period:08/10/2016

Dear Mr. Marzocca:

The New Jersey Board of Pharmacy (the "Board") has received the above mentioned inspection report, a copy of which is included with this letter, and has requested that you respond to the following items within **ten (10) days** of receipt of this letter:

1) Please provide a detailed response to the inspector's observations and any "areas of concern" noted for each citation in the "Report of Inspection" on pages #1 through #5. Your response should include an explanation for each issue noted, as well as what steps you have taken (or are planning to take) to address each item.

2) Please provide a detailed response for each citation and any "areas of concern" noted on page #1 of "Exhibit #15". You do not need to respond to items a second time, if you addressed a citation as part of your response to the "Report of Inspection" section. Again, your response should include an explanation for each issue noted, as well as what steps you have taken (or are planning to take) to address each item.

Feel free to include any additional supporting documentation you feel the Board should consider when reviewing your response. The Board will review this report and your response to this letter at the next available Board meeting.

Failure to respond and provide this information within ten (10) days from receipt of this letter will constitute a failure of a duty to cooperate pursuant to N.J.A.C. 13:45C-1.3 and may result in disciplinary action by the Board, including suspension of your permit to operate a pharmacy and/or to engage in sterile compounding.

Sincerely,

Anthony Rubmaccio, RPh
Executive Director
New Jersey Board of Pharmacy

MEDI physics

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

March 28, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

Please see the enclosed Biological Sampling Report that was requested with regards to inspection report #8-1066-16-X. Should you have any questions please do not hesitate to contact me at 973- 533 9109.

Sincerely

John Marzocca R.Ph

MAY 24 2017

2880 Bergey Road, Ste. K
Hatfield, PA 19440
www.envservices.com
800 - 345 - 6094

Presents:

Biological Sampling Report

Control ID #: 802-136385-2114V

Prepared for:

GE HEALTHCARE - LIVINGSTON
ONE NAYLON PLACE
LIVINGSTON, NJ 07039

CLEANROOM

Attention:

MIKE AGNELLO
1-973-533-9109
MICHAEL.AGNELLO@GE.COM

Date(s) Tested:

21 MARCH 2017

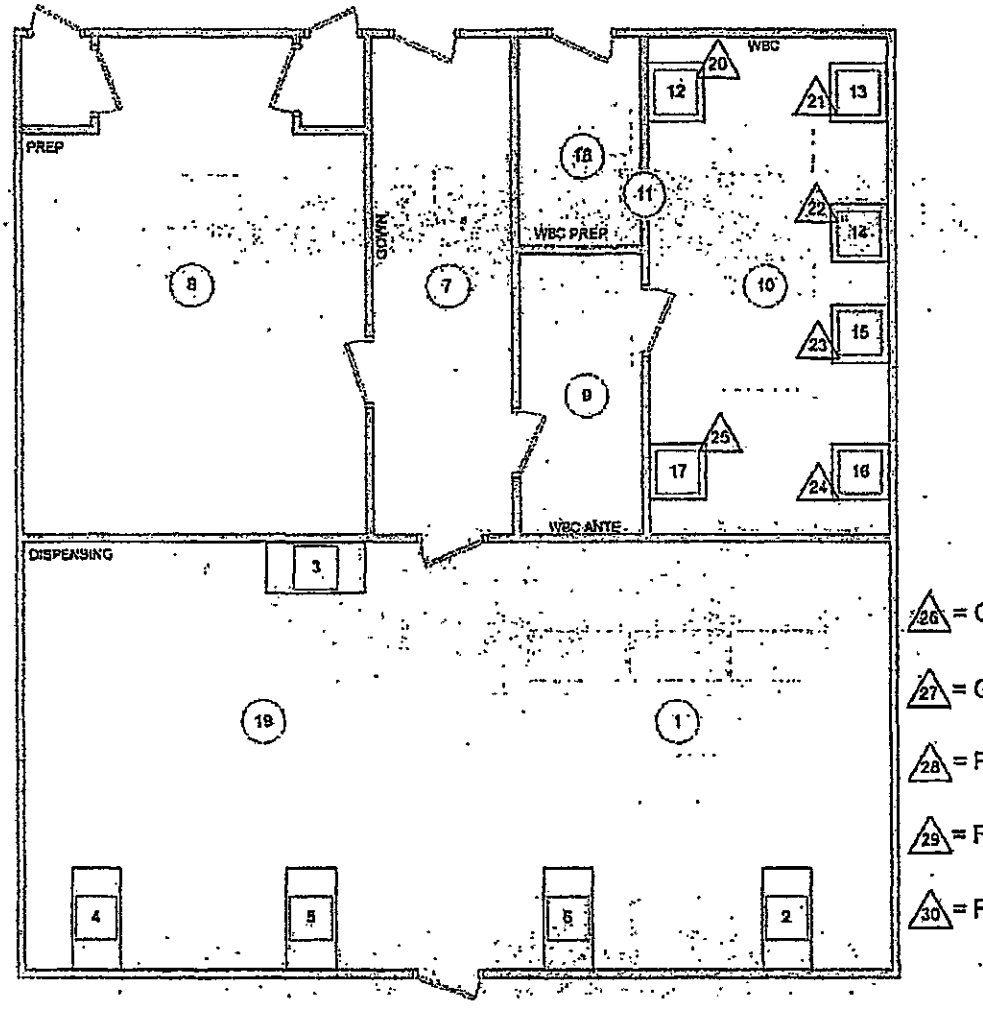
Field Service Technician(s):

JONATHAN STETTLER

BIOLOGICAL SAMPLING LOCATIONS

OPERATIONAL / DYNAMIC

CLEANROOM



Simple Location Key

- Air and Surface, Bacteria and Fungal
- Surface Only, Bacteria and Fungal
- Air Only, Bacteria and Fungal

MAY 24 2017

Test Result
For Reference Only

ENV SERVICES, Inc. PROVIDING NATIONWIDE SOLUTIONS, CERTIFICATION, CALIBRATION, VALIDATION, CLEANROOMS	Project: GE HEALTHCARE - LIVINGSTON ONE NAYLON PLACE LIVINGSTON, NJ 07039
	Control ID #: 802-136385-2114V

TEST EQUIPMENT

GE HEALTHCARE - LIVINGSTON
LIVINGSTON, NJ 07039
CLEANROOM

Equipment Name	Manufacturer	Model	Serial	Calibration Due Date
AIR SAMPLER	PBI	SAS SUPER 360	16-D-11262	21 NOV 17

Test equipment calibration certificates available upon request.
Company ID: NJ0795-024 Unique ID: 350931

RP17032718

M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

USP <797>Viable Sample Report

Client Project ID:

802-136385 NJ0795-024 GE LIVNGSTON

Reported To:
Client Name: ENV Services, Inc.
Client Address: 2880 Bergey Rd, Suite K
City, State, Zip: Hatfield, PA 19940
Attn: REPORTS DEPT
Sample(s) Condition: Acceptable

Sampling Date: 03/21/2017
Date Received: 03/22/2017
Final Analyzation: 03/27/2017
Report Generation: 03/27/2017
Job ID: 17032214

Failed Sample Summary

COC No.	Location of Sample	Test Method	ISO Class	Result (Total CFUs)	Comments

* Microorganisms above the action levels per USP <797> or CAG-009-00 or deemed highly pathogenic.
Overall Comments: Growth Found On Client Samples

USP <797> Recommended Action Levels for Microbial Contamination

ISO Class	Particulate Size ($0.5m/m^3$)	Air (400-1000L) (CFU/m^3/plate)	Surface CFU/Plate	Post Media-Fill Gloved Fingertip (CFU/plate, combined hands, all risk levels)	Gloved Fingertip (CFU/plate, combined hands, all risk levels)	Media-Fill Test
5	3,520	>1	>3	>3	0	+ or -
7	352,000	>10	>5	N/A	N/A	N/A
8 or worse	3,520,000	>100	>100	N/A	N/A	N/A

Approved By:
Jerritt Nunneley, M.S., CNBT
Laboratory Director

Approved Date: 03/27/2017

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RP17032718

M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

Pass: Less than the limit of detection.

Acceptable: Microorganisms under the action levels per USP <797> or CAG-009-00.

Fail: Microorganisms above the action levels per USP <797> or CAG-009-00 or deemed highly pathogenic.

Unclassified: (non-HEPA filtered area).

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
1	Accept	1 (CFU/m³)	7	DISPENSING ROOM	BACTERIA - AIR USP	1000 (L)	17032214.01	1
				Raw CFU	CFU/m³		Origin	
Micrococcus luteus				1	1		Human	

Comments :

1		No Growth (CFU/m³)	7	DISPENSING ROOM	FUNGAL - AIR USP	1000 (L)	17032214.02	1

Comments :

2		No Growth (CFU/m³)	5	LFU S/N:20012084	BACTERIA - AIR USP	1000 (L)	17032214.03	1

Comments :

2		No Growth (CFU/m³)	5	LFU S/N:20012084	FUNGAL - AIR USP	1000 (L)	17032214.04	1

Comments :

2		No Growth (25cm²)	5	LFU S/N:20012084	BACTERIA - SURFACE USP	25cm²	17032214.05	1

Comments :

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COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
3		No Growth (CFU/m³)	5	LFU S/N:20012083	BACTERIA - AIR USP	1000 (L)	17032214.06	1

Comments :

3		No Growth (CFU/m³)	5	LFU S/N:20012083	FUNGAL - AIR USP	1000 (L)	17032214.07	1

Comments :

3		No Growth (25cm²)	5	LFU S/N:20012083	BACTERIA - SURFACE USP	25cm²	17032214.08	1

Comments :

4		No Growth (CFU/m³)	5	LFU S/N:206000075	BACTERIA - AIR USP	1000 (L)	17032214.09	1

Comments :

4		No Growth (CFU/m³)	5	LFU S/N:206000075	FUNGAL - AIR USP	1000 (L)	17032214.10	1

Comments :

4		No Growth (25cm²)	5	LFU S/N:206000075	BACTERIA - SURFACE USP	25cm²	17032214.11	1

Comments :

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COC#	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
5		No Growth (CFU/m³)	5	LFU S/N:20012082	BACTERIA - AIR USP	1000 (L)	17032214.12	1

Comments :

5		No Growth (CFU/m³)	5	LFU S/N:20012082	FUNGAL - AIR USP	1000 (L)	17032214.13	1

Comments :

5		No Growth (25cm²)	5	LFU S/N:20012082	BACTERIA - SURFACE USP	25cm²	17032214.14	1

Comments :

6		No Growth (CFU/m³)	5	LFU S/N:20207024	BACTERIA - AIR USP	1000 (L)	17032214.15	1

Comments :

6		No Growth (CFU/m³)	5	LFU S/N:20207024	FUNGAL - AIR USP	1000 (L)	17032214.16	1

Comments :

6		No Growth (25cm²)	5	LFU S/N:20207024	BACTERIA - SURFACE USP	25cm²	17032214.17	1

Comments :

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COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
7		No Growth (CFU/m³)	8	GOWN ROOM	BACTERIA - AIR USP	1000 (L)	17032214.18	1

Comments :

8		No Growth (CFU/m³)	8	PREP ROOM	BACTERIA - AIR USP	1000 (L)	17032214.19	1

Comments :

9	Accept	2 (CFU/m³)	7	WBC ANTE ROOM	BACTERIA - AIR USP	1000 (L)	17032214.20	1

	Raw CFU	CFU/m³	Origin
Staphylococcus epidermidis	2	2	Human

Comments :

10		No Growth (CFU/m³)	7	CENTER OF WBC ROOM	BACTERIA - AIR USP	1000 (L)	17032214.21	1

Comments :

10		No Growth (CFU/m³)	7	CENTER OF WBC ROOM	FUNGAL - AIR USP	1000 (L)	17032214.22	1

Comments :

11		No Growth (CFU/m³)	7	HEPA PASS THRU	BACTERIA - AIR USP	1000 (L)	17032214.23	1

Comments :

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COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
12		No Growth (CFU/m³)	5	BSC S/N:2515CH10052	BACTERIA - AIR USP	1000 (L)	17032214.24	1

Comments :

12		No Growth (CFU/m³)	5	BSC S/N:2515CH10052	FUNGAL - AIR USP	1000 (L)	17032214.25	1

Comments :

12		No Growth (25cm²)	5	BSC S/N:2515CH10052	BACTERIA - SURFACE USP	25cm²	17032214.26	1

Comments :

13		No Growth (CFU/m³)	5	BSC S/N:2515CH10053	BACTERIA - AIR USP	1000 (L)	17032214.27	1

Comments :

13		No Growth (CFU/m³)	5	BSC S/N:2515CH10053	FUNGAL - AIR USP	1000 (L)	17032214.28	1

Comments :

13		No Growth (25cm²)	5	BSC S/N:2515CH10053	BACTERIA - SURFACE USP	25cm²	17032214.29	1

Comments :

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COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
14		No Growth (CFU/m³)	5	BSC S/N:2515CH10054	BACTERIA - AIR USP	1000 (L)	17032214.30	1

Comments :

14		No Growth (CFU/m³)	5	BSC S/N:2515CH10054	FUNGAL - AIR USP	1000 (L)	17032214.31	1

Comments :

14		No Growth (25cm²)	5	BSC S/N:2515CH10054	BACTERIA - SURFACE USP	25cm²	17032214.32	1

Comments :

15		No Growth (CFU/m³)	5	BSC S/N:2515CH10384	BACTERIA - AIR USP	1000 (L)	17032214.33	1

Comments :

15		No Growth (CFU/m³)	5	BSC S/N:2515CH10384	FUNGAL - AIR USP	1000 (L)	17032214.34	1

Comments :

15		No Growth (25cm²)	5	BSC S/N:2515CH10384	BACTERIA - SURFACE USP	25cm²	17032214.35	1

Comments :

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COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRU
16	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10055	BACTERIA - AIR USP	1000 (L)	17032214.36	1

Comments :

16	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10055	FUNGAL - AIR USP	1000 (L)	17032214.37	1

Comments :

16	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10055	BACTERIA - SURFACE USP	25cm²	17032214.38	1

Comments :

17	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10619	BACTERIA - AIR USP	1000 (L)	17032214.39	1

Comments :

17	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10619	FUNGAL - AIR USP	1000 (L)	17032214.40	1

Comments :

17	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10619	BACTERIA - SURFACE USP	25cm²	17032214.41	1

Comments :

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COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
18	Accept..	1 (CFU/m³)	8	WBC PREP ROOM	BACTERIA - AIR USP	1000 (L)	17032214.42	1

	Raw CFU	CFU/m³	Origin
Staphylococcus epidermidis	1	1	Human

Comments :

19	[redacted]	No Growth (CFU/m³)	7	DISPENSING ROOM #2	BACTERIA - AIR USP	1000 (L)	17032214.43	1

Comments :

20	[redacted]	No Growth (25cm²)	7	2515CH10052 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.44	1

Comments :

21	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10053 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.45	1

Comments :

22	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10054 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.46	1

Comments :

23	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10384 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.47	1

Comments :

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COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
24	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10055 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.48	1

Comments :

25	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10619 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.49	1

Comments :

26	[redacted]	No Growth (25cm²)	7	GENERATOR LID HANDLE	BACTERIA - SURFACE USP	25cm²	17032214.50	1

Comments :

27	[redacted]	No Growth (25cm²)	7	GENERATOR SUPPORT TABLE	BACTERIA - SURFACE USP	25cm²	17032214.51	1

Comments :

28	[redacted]	No Growth (25cm²)	7	PHARMACISTS COMPOUNDING TABLE	BACTERIA - SURFACE USP	25cm²	17032214.52	1

Comments :

29	Accept	1 (25cm²)	7	RANDOM CART	BACTERIA - SURFACE USP	25cm²	17032214.53	1

	Raw CFU	CFU/25cm²	Origin
Bacillus infantis	1	1	Environment

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COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
30	[redacted]	No Growth (25cm²)	7	RANDOM CART	BACTERIA - SURFACE USP	25cm²	17032214.54	1

Comments :

	[redacted]	Growth (CFU/m³)	N/A	(+) Controls	(+) BACTERIA CNTL- AIR/SURF. USP	0 (L)	17032214.55	1

Comments :

	[redacted]	Growth (CFU/m³)	N/A	(+) Controls	(+) FUNGAL CNTL - AIR/SURF. USP	0 (L)	17032214.56	1

Comments :

	[redacted]	No Growth (CFU/m³)	N/A	(-) Controls	(-) BACTERIA CNTL- AIR/SURF. USP	0 (L)	17032214.57	1

Comments :

	[redacted]	No Growth (CFU/m³)	N/A	(-) Controls	(-) FUNGAL CNTL - AIR/SURF. USP	0 (L)	17032214.58	1

Comments :

Control Media

Test	Type	Media	Manufacturer	Lot#	Exp. Date
(+) BACTERIA CNTL	AIR/SURF.	TSA	Remel	990985	05/08/2017
(-) BACTERIA CNTL	AIR/SURF.	TSA	Remel	990985	05/08/2017
(+) FUNGAL CNTL	AIR/SURF.	SabDex	Remel	993957	04/13/2017
(-) FUNGAL CNTL	AIR/SURF.	SabDex	Remel	993957	04/13/2017

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GLOSSARY

OrganismName	Description
Bacillus infantis	
Micrococcus luteus	Can be found in many places such as the human skin, water, dust, and soil. Generally thought of as harmless bacterium, but there have been rare cases of Micrococcus infections in people with compromised immune systems.
Staphylococcus epidermidis	A coagulase-negative Staphylococcus that is part of the normal human flora, typically the skin flora, and less commonly the mucosal flora. Although S. epidermidis is not usually pathogenic, patients with compromised immune systems are at risk of developing infection. These infections are generally hospital-acquired. S. epidermidis is a particular concern for people with catheters or other surgical implants because it is known to form biofilms that grow on these devices.

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USP <797>Supplemental Information

1. Growth Media
   - 1.1. A general microbiological growth medium such as Soybean-Casein Digest Medium (also known as Tryptic ase Soy Broth (TSB) or agar (TSA) shall be used to support the growth of bacteria.
   - 1.2. Malt Extract Agar (MEA) or suitable substitute shall be used to support the growth of fungi.
   - 1.3. Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with Lethicin and Polysorbate 80).
   - 1.4. Incubate inverted bacterial media for 2-3 days at 33-37°C and fungal for 5-7 days at 26-30°C.

2. Viable Sampling
   - 2.1. Air:
     - 2.1.1. Shall be performed dynamically at least semiannually (i.e. every 6 months) in ALL ISO Class environments.
     - 2.1.2. Impact shall be the preferred method volumetric sampling, settling plates are not sufficient.
     - 2.1.3. 400-1000 litersof air shall be tested at each location and reported as CFU/m^3 of air.
   - 2.2. Surface:
     - 2.2.1. Shall be performed dynamically in ALL ISO classified areas on a periodic basis (contact plates and/or swabs) and shall be done at the conclusion of compounding.
     - 2.2.2. Results are reported as CFU per sampled unit area.

3. Gloved Fingertip Testing
   - 3.1. Shall be performed for all CSP risk level compounding.
   - 3.2. Immediately after gowning, the evaluator shall collect a gloved fingertip and thumb sample from both hands on a general microbiological media (TSA).
   - 3.3. Initial gloved fingertip/thumb sampling procedure requires (0 CFU) no less than 3 times before initially being allowed to compound CSPs for human use.
   - 3.4. Re-evaluation of all compounding personnel shall occur at least annually for low- and medium-risk level CSPs and semiannually for high-risk.
   - 3.5. CFU action level shall be based on the total number of CFU on both gloves and not per hand.
   - 3.6. Should be reported separately as number of CFU per employee per hand (left hand, right hand).

4. Media-Fill Testing
   - 4.1. Shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level; and semiannually for high-risk.
   - 4.2. Shall be evaluated using sterile fluid bacterial (TSA) culture media-fill verification.
   - 4.3. Media-filled vials shall be incubated with a range of 33-37° C for 14 days.

5. Reporting Information
   - 5.1. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds, and yeasts) must be immediately remedied, regardless of CFU count. Any CFU count that exceeds its respective action level shall have an investigation into the source of contamination, shall be eliminated, the affected area cleaned, and resampling performed.
   - 5.2. Positive controls are unopened samples submitted for growth promotion testing (inoculation) which eliminates false negatives. Negative controls are unopenedsamples submitted for incubation solely which eliminates false positives.
     - 5.2.1. There should be a positive and negative control for each lot number of every media type used.
   - 5.3. MRL is the minimum reporting limit for a sample.
   - 5.4. Results found in this report are solely tied to the project above and the samples therein.

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2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 14, 2024

DATED MATERIAL ENCLOSED

RLS USA INC
ATTN: WERNER GRUNER, PRS
1283 MOUNTAIN VIEW ALVISO RD STE A-B
SUNNYVALE, CA 94089

RE: CI 2023 103137
RLS USA INC
PHY 57865

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

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- February 28, 2024: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- March 15, 2024: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

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If you have any questions regarding this Citation please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Anne Sodergren
EXECUTIVE OFFICER

By: 

Joshua Monforte
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

Unless contested, Citations are final 30 days from the date of service. Acceptance of a Citations is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than February 28, 2024 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than March 15, 2024 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any enclosed documents please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2023 103137	RLS USA INC, PHY 57865

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1751.3 subd. (a)	Sterile Compounding Policies and Procedures; Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding...
CCR, Title 16, § 1751.4(a)	Facility and Equipment Standards for Sterile Compounding; No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations

CONDUCT:

Failure to follow policies and procedures: CCR 1751.3(a) states in pertinent part, any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. RLS USA Inc. located at 1283 Mountain View, Alviso Rd Ste A-B, Sunnyvale, CA 94089 was not compliant. Specifically, on at least 12/30/22 and 6/26/23 RLS USA Inc. failed to immediately remove its ISO Class 5 PEC from use following air microbial contamination action level exceedance as required in RLS USA Inc.'s Standard Operating Procedure "6.3.1 Certification of ISO Classified Environments." This was a violation of pharmacy law.

Unsafe compounding of sterile drug preparations: CCR 1751.4(a) states, no sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations. RLS USA Inc. located at 1283 Mountain View, Alviso Rd Ste A-B, Sunnyvale, CA 94089 was not compliant. Between at least 12/30/22 and 1/11/23, and between at least 6/26/23 and 7/14/23, RLS USA Inc. compounded sterile preparations in a laminar flow work bench which was identified as having microbial growth exceeding the action level defined in the pharmacy's written policies and procedures. This was a violation of pharmacy law.

CITATION ISSUED ON: February 14, 2024

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number **Name, License No**
CI 2023 103137 **RLS USA INC, PHY 57865**

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
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CONDUCT:

Failure to follow policies and procedures: CCR 1751.3(a) states in pertinent part, any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. RLS USA Inc. located at 1283 Mountain View, Alviso Rd Ste A-B, Sunnyvale, CA 94089 was not compliant. Specifically, on at least 12/30/22 and 6/26/23 RLS USA Inc. failed to immediately remove its ISO Class 5 PEC from use following air microbial contamination action level exceedance as required in RLS USA Inc.'s Standard Operating Procedure "6.3.1 Certification of ISO Classified Environments." This was a violation of pharmacy law.

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CITATION ISSUED ON: February 14, 2024

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: RLS USA INC

License No: PHY 57865

Citation Number : CI 2023 103137

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check I contest the Citation and request an Office Conference.

Check One:

I contest the entire Citation or

specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name:

Signature: Dated:

Address of Service:

City: State: Zip:

Daytime Number: ( ) Email Address: ( )

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:
RLS USA INC
PHY 57865

Respondent

Citation Case No : CI 2023 103137
NOTICE OF APPEAL
(Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATE

(Respondent)

Mailing Address of Respondent:

(Street Address)

(City (State) (Zip) ( ) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

(Attorney's Name

(Street Address)

(City (State) (Zip) ( ) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: RLS USA INC, PHY 57865
Citation and Fine CI 2023 103137

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On February 14, 2024, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California.

NAME	CERTIFIED MAIL NO
RLS USA INC ATTN: WERNER GRUNER, PRS 1283 MOUNTAIN VIEW ALVISO RD STE A-B SUNNYVALE, CA 94089	7019 2970 0002 2051 5965

I declare under penalty of perjury that the forgoing is true and correct.

Executed on February 14, 2024, at Sacramento, California.

DECLARANT
Joshua Monforte
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

October 11, 2024

DATED MATERIAL ENCLOSED

RLS USA INC
ATTN: MANNON BANKSON, COO
16259 STAGG ST STE A
VAN NUYS, CA 91406

RE: CI 2024 105586
RLS USA INC
PHY 57866

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

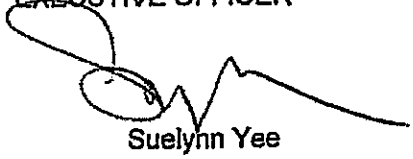
- November 10, 2024: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 25, 2024: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 10, 2024: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By: 

Suelynn Yee
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 10, 2024.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

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If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 25, 2024 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 10, 2024 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2024 105586	RLS USA INC, PHY 57866

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4113(F)	Pharmacist-in-Charge: Notification to Board; if a pharmacy is unable, in the exercise of a reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer or administrator of the pharmacy...	$500.00
Bus. & Prof. Code § 4305 subd. (b)	Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action	$1,000.00

CONDUCT:

Business and Professions Code section 4113(f) requires a licensee to, when unable to identify a permanent pharmacist-in-charge within 30 days of the date when a pharmacist-in-charge (PIC) ceases to act, provide the name of a pharmacist, owner, or manager to act as an interim pharmacist-in-charge for a period not to exceed 120 days. Specifically, on March 13, 2024, the Board received an Application for Change of Pharmacist-In-Charge from RLS USA Inc, which had been signed under penalty of perjury by a corporate officer, the disassociated PIC, and the newly designated PIC. The form indicated that the prior interim PIC, Anahita Malekakhlagh (RPH 73484), had disassociated on March 11, 2024 and that Scott Hudek (RPH 49826) took over as the permanent PIC on the same date. However, Anahita Malekakhlagh's (RPH 73484) interim period, which had begun on August 25, 2023, had previously expired on December 22, 2023. Anahita Malekakhlagh (RPH 73484) acted as the interim PIC from August 25, 2023 to March 11, 2024, 199 days.

Business and Professions Code section 4305(b) authorizes the Board to take disciplinary action against a licensee for operation of a pharmacy for more than 30 days without the supervision or management of a pharmacist-in-charge (PIC). Specifically, on March 13, 2024, the Board received an Application for Change of Pharmacist-In-Charge from RLS USA Inc, which had been signed under penalty of perjury by a corporate officer, the disassociated PIC, and the newly designated PIC. The application declared that Scott Hudek (RPH 49826) had taken over as the permanent PIC on March 11, 2024. However, as RLS USA Inc failed to pay their Application for Change of Pharmacist-In-Charge's application fee until July 11, 2024, the Board was unable to approve Scott Hudek (RPH 49826) as the permanent PIC until July 11, 2024. RLS USA Inc operated without a Board approved PIC from March 11, 2024 through July 10, 2024, 121 days.

CITATION ISSUED ON: October 11, 2024	TOTAL AMOUNT OF FINE(S): $1,500.00

PAYMENT OF FINE(S) DUE BY: November 10, 2024

A

RLS (USA) Inc

Officers and Ownership Information

Name	Title	Percent Ownership
Telix Pharmaceuticals (US)	Owner	100%
Darren Patti	Group Chief Operating Officer	0%
Darren Smith	Group Chief Financial Officer	0%
Oliver Newman	Company Secretary	**0%**

B

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	RLS (USA) INC.
Entity No.:	4312518
Registration Date:	08/28/2019
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of April 23, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 320430826

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RLS (USA) Inc
Pharmacy/Wholesaler License # (if applicable) N/A Pending
Physical Address 1516 Kimberly Ave
City Fullerton State CA Zip 92831
Mailing Address (if different from physical address) same as above
City _____ State _____ Zip _____
Telephone 714-278-4701 Website www.rls.bio
Licensing Company Email Licensing@rls.bio

Section 2: Personal Information

First Dung Middle Tran Last Nguyen
Alias(es, nicknames, name changes, etc.) Don

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of the Pacific: Thomas J Long School of Pharmacy		09/93-06/96	
Address	**City**	**State**	**Zip**
751 Brookside Rd	Stockton	CA	95211
Diploma/Degree obtained, if any			
Pharm.D.			

School Name		From - To (MM/YY – MM/YY)	
University of the Pacific		09/91-05/95	
Address	**City**	**State**	**Zip**
3601 Pacific Ave	Stockton	Ca	95211
Diploma/Degree obtained, if any			
B.S. Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Bolsa Grande High School		09/89-06/91	
Address	**City**	**State**	**Zip**
9401 Westminster Blvd	Garden Grove	CA	92844
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Leuzinger High School		09/87-06/89	
Address	**City**	**State**	**Zip**
4118 Rosecrans Ave	Lawndale	CA	90260
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/97-current				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
RLS (USA) Inc.			09/20-current	
Business Address		**City**	**State**	**Zip**
1516 Kimberly Ave		Fullerton	CA	92831
Phone	**Title**		**Number of Employed Hours**	
714-278-4701	Pharmacy Manager		9440	
Description of Duties				
Oversee the operation of the nuclear pharmacy at Fullerton location including the compounding, dispensing and distribution of, and record keeping related to prescription drugs.				

Business Name			From - To (MM/YY – MM/YY)	
GE Healthcare			04/04-08/20	
Business Address		**City**	**State**	**Zip**
1516 Kimberly Ave		Fullerton	CA	92831
Phone	**Title**		**Number of Employed Hours**	
714-278-4701	Pharmacist in Charge		16640	
Description of Duties				
Oversee the operation of the nuclear pharmacy at Fullerton location including the compounding, dispensing and distribution of, and record keeping related to prescription drugs.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Dung Tran Nguyen, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DN I am at least 21 years of age;
3. DN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dung Tran Nguyen
Print Name (First, Last)

Dung Nguyen
Original Signature (electronic, copies or stamps not accepted)

5/8/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dung Tran Nguyen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/12/25

Date

Please have this section completed in the presence of a Notary Public.

State of NJ, ss. County of Essex

I, Dung Tran Nguyen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/12/25

Date

Subscribed and Sworn to before me this 12 day of May.

Notary Public Signature

KAREN PEIST
Notary Public, State of New Jersey
Comm. # 50222459
My Commission Expires 6/5/2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: RLS (USA) Inc.

NV Pharmacy or Outsourcing facility license # (if applicable): N/A Pending

Physical Address: 1516 Kimberly Ave

City: Fullerton State: CA Zip: 92831

Mailing Address (if different from physical address): Same as physical address

City: N/A State: N/A Zip: N/A

Telephone: 714-278-4701 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 714-278-4702 Contact Email: licensing@rls.bio

Website: https://rls.bio/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Phuc Nguyen, Pharm D.

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21778

Name of Designated Person(s) as defined by revised USP 797 guidelines: Phuc Nguyen

Email of Designated Person(s): chris.nguyen@rls.bio

Telephone of Designated Person(s): 714-278-4701

Physical Address: 1516 Kimberly Ave

City: Fullerton

Mailing Address (if different from physical address):

City: N/A

Telephone: 714-278-4701

Fax: 714-278-4702

Website: https://rls.bio/

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220):

Supervising/Managing Pharmacist NV Pharmacist Registration #:

Name of Designated Person(s) as defined by revised USP 797 guidelines:

Email of Designated Person(s):

Telephone of Designated Person(s): 714-278-4701

City:

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 01/16/25

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Ga-68 Illucix, Ga Gozellix

12. What laboratory performs your sterility or endotoxin testing?

Name: N/A all starting components are sterile

Address:

City: State: Zip:

Telephone:

13. What is your procedure for visual inspection of compounded sterile products?
Visual inspection of radiopharmaceuticals through leaded glass

14. How often do you perform glove fingertip and medial fill testing?
Every 12 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
Self paced computer based training with competency exams. Direct instruction with demonstration for specific tasks.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Primary engineering controls cleaned daily (DeconQuat 200 plus and Sterile IPA) and prior to each production run (Sterile IPA).
Cleaned monthly with DeconSpore 200 plus.

Secondary controls cleaned daily with DeconQuat 200 plus and Sterile IPA. Monthly cleaning with DeconSpore 200 plus.

17. Who performs the sterile compounding process at your facility?
Pharmacists only

18. Who is responsible and accountable for the sterile compounding process at your facility?
The PIC and staff Pharmacists

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Use of in-house couriers and shipped directly to end user in tested Type A packaging.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?
N/A

2. Are you complying with all USP 800 guidelines?	☐ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	☐ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No

9. If yes, list the name of the device:
N/A

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Annually

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☒ Yes ☐ No

4. What is the frequency for completing volumetric-active air sampling?

Every 6 months

5. What is the frequency for completing surface sampling? Monthly		
6. What is the frequency for using sporicidal agents? Monthly		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	☐ Yes	■ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	☐ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dung Nguyen

Name of Person who Completed the Form

PIC/Pharmacy Manager

Title

D Nguyen

Signature (copies or stamps not accepted)

5/8/25

Date

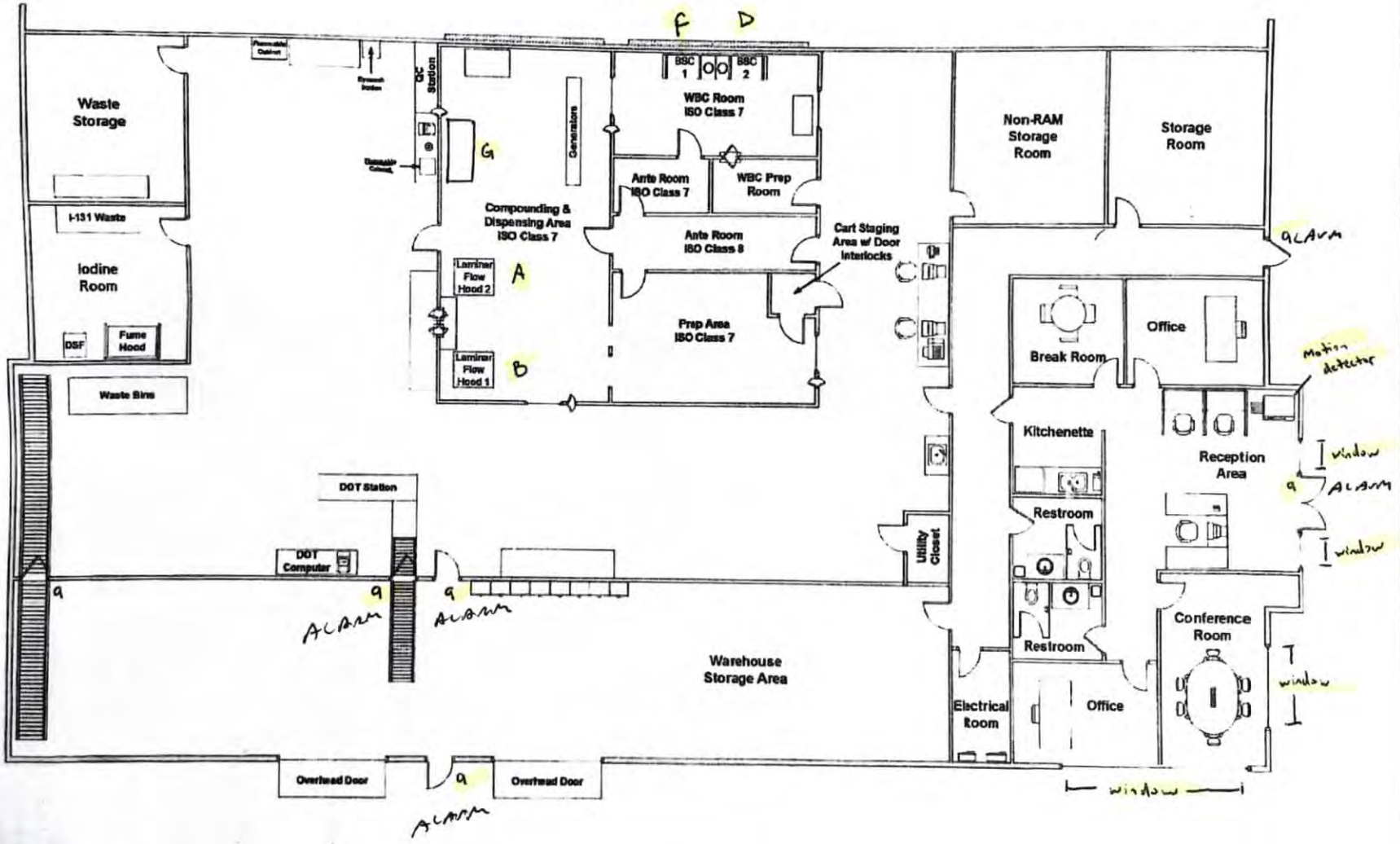
Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
Please use an additional sheet if necessary. APH=Advanced Practice Pharmacist, DEA=Drug Enforcement Administration.

1.	Dung Nguyen	RPH #	49030	Exp. Date:	8/31/2026
		APH#		Exp. Date:	
		DEA #		Exp. Date:	
2.	Norihiko Moriwaka	RPH #	41378	Exp. Date:	7/31/2025
		APH#		Exp. Date:	
		DEA #		Exp. Date:	
3.	Phuc Xuan Ngo Nguyen	RPH #	77417	Exp. Date:	8/31/2025
		APH#		Exp. Date:	
		DEA #		Exp. Date:	
4.		RPH #		Exp. Date:	
		APH#		Exp. Date:	
		DEA #		Exp. Date:	
5.		RPH #		Exp. Date:	
		APH#		Exp. Date:	
		DEA #		Exp. Date:	
6.		INT #		Exp. Date:	
7.		INT #		Exp. Date:	
8.		INT #		Exp. Date:	
9.	Franz Espino	TCH #	67180	Exp. Date:	10/31/2025
10.	Bronwen Genther	TCH #	44744	Exp. Date:	3/31/2026
11.	Kimberly Dames	TCH #	57081	Exp. Date:	4/30/2026

DN
PIC Initials

RLS (USA), Inc. – Fullerton Pharmacy
USP 797 Floor Plan
1516 E. Kimberly Avenue
Fullerton, CA 92831



1) Description of all hoods as to type and model number
    a. Laminar Flow Bench
        i. Hood A
            1. Type: Envirco
            2. P/N: 62738
            3. S/N: 9612085
        ii. Hood B
            1. Type: Envirco
            2. P/N: 62738
            3. S/N: 9612086
        iii. Hood G
            1. Type: GermFree
            2. MOD# BBF-2SS-CH
            3. S/N: 2S-15-CH-100057
        iv. Hood Generator
            1. Type: Envirco
            2. Mac 10
            3. SN: 181200744-OE-AS1CH
    b. Biological Safety Cabinet
        i. Hood D
            1. GermFree
            2. BBF-2SS-CH
            3. SN: 2S-15-CH-10058
        ii. Hood F
            1. GermFree
            2. BBF-2SS-CH
            3. SN: 2S-15-CH-10056
    c. Fume Hood (non-sterile hood)
        i. Iodine Hood

E

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 6/24/2024 Inspector: Marc Gasca

Firm: RLS USA INC Phone: (714) 278-4701

Address: 1516 KIMBERLY AVE City: FULLERTON Zip: 92831

Ownership: CORPORATION

Permit #: LSC101603 PHY57869 Permit Exp: 9/1/2024 DEA#: _____ DEA Exp: _____

Date of Self Assessment Form: 6/21/2023 Other Permit #: N/A Date of DEA Inventory:

Hours M-F: 12:30AM-4PM Hours Saturday: 4AM-12:30PM Hours Sunday: 4AM-12:30P

PIC DUNG T NGUYEN RPH49030 Administrator _____

RPH Consultant _____ _____

Staff RPH Name:	License #:	Staff Name:	License #:
PHUC X NGUYEN	RPH77417	BRONWEN D GENTHER	TCH44744
NORIHIKO MORIKAWA	RPH41378	FRANZ E ESPINO	TCH67180
		KIMBERLY A DAMES	TCH57081

Inspector Remarks:

Hybrid sterile compounding license renewal inspection

- ***Request for several documents for renewal of LSC 101603 was sent to PIC Dung Nguyen on 6/11/2024***
- ***Documents were received on 6/19/2024 and 6/22/2024, reviewed remotely***
- ***Inspection conducted in person at the facility on 6/24/2024, assisted remotely by PIC Dung Nguyen (contact email: dung.nguyen@rls.bio; contact phone number: 714-278-4701) and onsite by RPH Norihiko Morikawa***

General Information

RLS USA Inc. is a closed-door nuclear pharmacy, located in a business park complex. The pharmacy dispenses diagnostic and therapeutic radiopharmaceuticals for its patients, approximately 350 preparations/day. The preparations are delivered directly to hospitals and outpatient clinics for administration (pharmacy employs its own delivery drivers). The pharmacy is open for business Monday through Friday 12:30am-4pm, Saturdays and Sundays 4am-12:30pm. Pharmacist is available for consultation 24 hours per day, 7 days per week.

- Compounding Self-Assessment: completed on 6/21/2023
- Community Pharmacy/Hospital Outpatient Self-Assessment: completed on 6/21/2023
- Pharmacy Law Waivers: None used at this time, per PIC Nguyen
- FDA, DEA, and/or accreditation inspections w/ applicable reports issued within past 12 months: None to report, per PIC Nguyen
- Adverse drug reactions in the past 12 months: None to report, per PIC Nguyen
- Previous CA Board of Pharmacy Inspection Report
  - Reviewed previous inspection report issued on 7/14/2023 for corrections or written notice of noncompliance, previous noncompliance issues: Addressed with RPH Morikawa

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Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Sterile Compounding Area

No changes to the physical layout of the sterile compounding area, nor any changes to compounding equipment in the past 12 months, per PIC Nguyen

ISO 8 Gowning Room (+ Pressure) -> Leading to the following positive pressure ISO-7 classified areas (WBC ante, WBC, Prep, Dispensing)

- *ISO-7 Dispensing Room: ISO-5 vertical LAFW x 2, ISO-5 BSC x 1, ISO-5 Hood Generator x 1*
- *ISO-7 WBC Room: ISO-5 BSC x 2*

- Certification performed by CERTS on 1/19/2024
  - Dynamic testing, non-viable air sampling, HEPA filter leak testing, air changes, smoke study, viable air/surface sampling: Reviewed
  - Monthly in-house viable surface sampling performed, reviewed May 2024 results (education provided regarding sampling of any equipment permanently contained in PEC)

Standard Operating Procedures (SOPs)

- Annual review of SOPs by PIC, documented on 4/21/2024
- Reviewed the following SOPs:
  - Personnel Hygiene, Qualifications, and Training
  - Clean Room Entry
  - Certification of ISO Classified Environments
  - Environmental Monitoring: In-House Sampling

Recordkeeping

- Master formula/compounding record: Reviewed
- Refrigerator/freezer/incubator/room temperature logs: Reviewed
- Pressure differential logs: Reviewed
- Cleaning logs: Reviewed
  - Cleaning agents used: Cavicide, Decon-Quat, Decon-Spore, sIPA
  - Pharmacy staff responsible for daily and monthly cleaning of all ISO-classified areas

Labeling

- Radioactivity at date and time of calibration: Reviewed
- Standard Radiation Symbol: Reviewed
- *"Caution-Radioactive Material"* statement on label: Reviewed

Sterile Compounding Attire

- Low shedding coverall/gown, head cover, face mask, shoe covers: Available
- Sterile gloves and alcohol-based hand cleanser: Available

Training/Competency

- Pharmaceutical calculations, gloved fingertip sampling, media fill testing, observational skills assessments (hand hygiene/garbing, cleaning/disinfection, aseptic technique): Reviewed

Quality Assurance

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

- End-product testing performed in-house
  - Dose calibration performed for each radiopharmaceutical prior to dispensing
  - Sterility testing performed annually, reviewed February 2024 results (within specification)

Education

- Education provided regarding USP Chapter <825> as it pertains to:
  - Monthly surface sampling location requirements, including any equipment permanently contained in the PEC

Discussion

- The following links and resources stated below were provided to PIC Nguyen via email during the inspection:

November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated USP compounding standards.

The Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of federal law and USP General Chapters.

During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the Board's website.

Licensees are reminded to also ensure continuing compliance with other laws, regulations, and requirements that may apply to their activities, including, without limitation: the Federal Food, Drug, and Cosmetic Act (21 USC §§ 321–399i), including Section 503A thereof (21 USC § 353a); provisions of California's Sherman Food, Drug, and Cosmetic Law (Health and Safety Code §§ 109875–111929.4); and laws, regulations, and requirements related to radiopharmaceuticals and/or the handling of hazardous drugs, including requirements established by Cal/OSHA.

Educational Links and References:

1. Revisions to USP Compounding General Chapters <795> and <797> https://go.usp.org/2022_Revisions_795_797
   - BUD Scientific Rationale for the 2021 Proposed Revisions to <795>
   - BUD Reference for the 2021 Proposed Revisions to <795>
   - BUD Scientific Rationale for the 2021 Proposed Revisions to <797>
   - BUD Reference for the 2021 Proposed Revisions to <797>
2. 9/29/23, Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
   https://www.fda.gov/media/94155/download
3. FDA Drug Establishments Current Registration Site:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
4. FDA to Compounders: Know Your Bulks and Excipients Suppliers:
https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers

DISCLAIMER:

Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection may result in further communication after this report.

To complete this inspection, please provide the following to Inspector Marc Gasca via email (marc.gasca@dca.ca.gov) **no later than 7/9/2024:**

1. Revised surface sampling diagram, to include specific locations sampled within PEC (equipment permanently contained in the PEC)

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Norihiko Morikawa

Inspector (sign) _____

Inspector (print) Marc Gasca

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

F

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 60568

NAME: RLS (USA) INC

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

1516 KIMBERLY AVE
FULLERTON CA 92831
ORANGE COUNTY

ISSUANCE DATE

JANUARY 27, 2025

EXPIRATION DATE

JULY 25, 2025

CURRENT DATE / TIME

APRIL 24, 2025
7:0:52 AM

LICENSE RELATIONSHIPS

NAME: RLS (USA) INC

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 101992 **PRIMARY STATUS:** CLEAR

ADDRESS :
1516 KIMBERLY AVE
USP 797 CLEAN RM
FULLERTON CA 92831
ORANGE COUNTY

NAME: NGUYEN, DUNG TRAN

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 49030 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

License No. PHY 57869
Receipt No. 00193934

Valid Until: 9/1/2025

RLS USA INC
1516 KIMBERLY AVE
FULLERTON, CA 92831-5213

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm named hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator of pharmacist-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Sterile Compounding License

License No. LSC 101603
Receipt No. 00193937

Valid Until: 9/1/2025

RLS USA INC
1516 KIMBERLY AVE
FULLERTON, CA 92831-5213

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

The official status of this license can be verified at www.pharmacy.ca.gov

This permit is valid only at the address shown.

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW ----

WPHLSC 09/30/19

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 101992

NAME: RLS (USA) INC

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

1516 KIMBERLY AVE
USP 797 CLEAN RM
FULLERTON CA 92831
ORANGE COUNTY

ISSUANCE DATE

JANUARY 27, 2025

EXPIRATION DATE

JULY 25, 2025

CURRENT DATE / TIME

APRIL 24, 2025
7:1:41 AM

LICENSE RELATIONSHIPS

NAME: RLS (USA) INC

LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

LICENSE NUMBER: 60568 **PRIMARY STATUS:** CLEAR

ADDRESS :
1516 KIMBERLY AVE
FULLERTON CA 92831
ORANGE COUNTY

4GGG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☐ Non Publicly Traded Corporation – Pages 1-3 & 5
☑ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: TURBARE MANUFACTURING LLC

Physical Address: 945 Jeanette Drive

City: Conway State: AR Zip Code: 72032

Telephone: ~~501~~ 501 497 8499 Fax: N/A

Toll Free Number: 1-866-929-4867 (Required per NAC 639.708)

E-mail: Pic@Turbare.org Website: Turbare.org

Supervising Pharmacist: Garrett R. Sheumaker Nevada License #: 24549

SERVICES PROVIDED

Yes/No

☑ ☐ Parenteral
☑ ☐ Sterile Compounding
☑ ☐ Non Sterile Compounding
☐ ☑ Mail Service Sterile Compounding
☐ ☑ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: 5/15/25 Amount: $500-ck 2028143336

OWNERSHIP IS A PARTNERSHIP

General ✓ Limited ____

Partnership Name: Turbare Manufacturing LLC

Mailing Address: 975 Jeanette Dr

City: Conway State: AR Zip Code: 72032

Telephone Number: 501 497 8499 Fax Number: N/A

Contact Person: Laura Martin

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
Laura Martin	G	50
Joseph Gira	G	50

List names of 4 largest partners and percentage of ownership:

Name: Laura Martin %: 50

Name: Joseph Gira %: 50

Name: ____ %: ____

Name: ____ %: ____

List any physician shareholders and percentage of ownership.

Name: Joseph Gira %: 50

Name: ____ %: ____

Name: ____ %: ____

FEI Number (From FDA application): 9713689 41

Please provide the name of the facility as registered with the FDA and the registration number:
TurDare Manufacturing

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Garrett R. Sheumaker Nevada License Number: 14549

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☑

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

GARRETT SHEUMAKER

Print Name of Authorized Person

09 MAY 2025

Date

STATE OF MISSOURI

Denny Hoskins
Secretary of State

CORPORATION DIVISION
CERTIFICATE OF GOOD STANDING

I, DENNY HOSKINS, Secretary of State of the STATE OF MISSOURI, do hereby certify that the records in my office and in my care and custody reveal that

Turbare Manufacturing, LLC
LC014425330

was created under the laws of this State on the 13th day of December, 2022, and is active, having fully complied with all requirements of this office.

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, this 24th day of February, 2025.

Denny Hoskins
Secretary of State

Certification Number: CERT-02242025-0207

Arkansas Secretary of State
Cole Jester
State Capitol Building • Little Rock, Arkansas 72201-1094 • 501-682-3409

Certificate of Good Standing

I, Cole Jester, Secretary of State of the State of Arkansas, and as such, keeper of the records of domestic and foreign corporations, do hereby certify that the records of this office show

TURBARE MANUFACTURING, LLC

authorized to transact business in the State of Arkansas as a Limited Liability Company, filed Articles of Organization in this office November 21, 2022.

Our records reflect that said entity, having complied with all statutory requirements in the State of Arkansas, is qualified to transact business in this State.

In Testimony Whereof, I have hereunto set my hand and affixed my official Seal. Done at my office in the City of Little Rock, this 6th day of March 2025.

Cole Jester
Secretary of State

Online Certificate Authorization Code: 16299b5cfa2044c
To verify the Authorization Code, visit sos.arkansas.gov

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director

2025 - 2026 WHOLESALE DISTRIBUTOR LICENSE

Turbare Manufacturing

Located at:

945 Jeanette Drive, Conway, AR 72032

License #: WD06008 Original License Date: 06/26/2024

This is to certify that the Pharmacy named above is licensed under the provisions of the Arkansas Pharmacy Practice Act, other Arkansas statutes, and Arkansas Pharmacy Regulations.

License Expires: 12/31/2026

Pharmacist in Charge: Garrett Robert Sheumaker, PD15332

License #: WD06008 · Facility ID: 109722

Mailing Address: Turbare Manufacturing

945 Jeanette Drive
Conway, AR 72032

Reson Mailed:

The address above is the mailing address where all correspondence from the board will be sent, including renewal information. All changes to contact information can be made online at www.pharmacyboard.arkansas.gov under "License Maintenance and Online Renewals." Use the license number and facility ID above to log

Click on licensee name for license details.

Search Again?

Name:	Turbare Manufacturing
License Type:	Wholesale Distributor License
License Number:	WD06008
Issue Date:	06/26/2024
Expiration Date:	12/31/2026
Current Status:	Active
Current Standing:	Good Standing
Disciplinary Action:	No
Address:	945 Jeanette Drive Conway, AR 72032
Phone:	(501)497-8499
Fax:	(501)504-6635

Print Licensee Report

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201
Phone: 501-682-0190 | Fax: 501-682-0195
Contact Us | Google Map

Accessibility | Privacy | Security | Acceptable Use

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Registered Outsourcing Facilities

Facilities Registered as Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 4/15/2025

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Search: turbare

Show 10 entries

Export Excel

Facility	Contact	Initial Registration Date [1]	Most Recent Registration Date [1]	Last Inspection [2]	Form 483 Issued? [3]	Recall Conducted? [9]	Action Based on Last Inspection [4,5]	Intends to Compound Drugs From Bulk Subst
Turbare Manufacturing, Conway, AR	Deketric Smith 501-504-6635	6/23/2023	1/25/2025	1/24/25	Yes (/media/185399/download?attachment)	N/A	Open	Yes

Showing 1 to 1 of 1 entries (filtered from 91 total entries)

Previous 1 Next

Notes

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and the establishment fee was paid in full).

   Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. A facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

   Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Once an outsourcing facility is registered, the facility will be added to the list of facilities FDA intends to inspect according to a risk-based schedule. FDA plans to inspect outsourcing facilities within a reasonable period of time following initial registration, once it is confirmed that the facility has initiated drug production and distribution. However, the exact timing of the inspections can be affected by a number of variables, including the number of outsourcing facility registrants, other inspection priorities, and the operational status of the newly registered outsourcing facility.

   Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page Compounding: Inspections, Recalls, and other Actions (/node/363232) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

   Inspections may take place over several days, weeks or longer. The date of the inspection is the date a Form FDA 483 listing the investigators' observations was issued. If no FDA Form 483 was issued, the date is the last day of the inspection.

3. A Form FDA 483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.

4. This table does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a state enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites.
5. "Closed" means the inspection has been closed without further action. "Open" means FDA has not determined whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include warning letter, seizure or injunction.
6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A" indicates the registered outsourcing facility has not provided this information.
7. This outsourcing facility was the subject of at least one previous inspection relating to compounding that resulted in a Form FDA 483, warning letter or other action. For information about such inspections and resulting actions, visit Compounding: Inspections, Recalls, and other Actions (/node/363232).
8. A remote regulatory assessment (RRA) is an examination of an FDA-regulated establishment and/or its records, conducted remotely, to evaluate compliance with applicable FDA requirements. These assessments assist in protecting human and animal health, inform regulatory decisions and verify certain information submitted to the agency.
9. Based on inspectional findings, the inspection revealed significant issues. As a result, the outsourcing facility may have either initiated a recall on their own following conversation(s) with the FDA investigator or FDA recommended a recall at the conclusion of the inspection or both. Additionally, the outsourcing facility may have conducted multiple recalls or recalled multiple drugs.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RT0687294	11-30-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5,L1	MANUFACTURER	11-13-2024

TURBARE MANUFACTURING LLC
925 JEANETTE DR
CONWAY, AR 720326651

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RT0687294	11-30-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5,L1	MANUFACTURER	11-13-2024

TURBARE MANUFACTURING LLC
925 JEANETTE DR
CONWAY, AR 720326651

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director

July 2, 2024

Garrett Robert Sheumaker (PD15332)
C/O Turbaire Manufacturing (WD06008)
945 Jeanette Drive
Conway, AR 72032

RE: Facility Inspection Conducted June 24, 2024 through June 25, 2024

Dr. Sheumaker:

The following observations are as a result of a scheduled inspection occurring on the dates stated above. It should be noted that this dynamic operations inspection occurred during product development. Regulations within 21 CFR Part 210 and 211 were utilized during the review of the firm's cGMP operations. I appreciate the assistance and cooperation provided by you and your staff during this review:

CFR 211.28(a) Personnel responsibilities
Specifically, an operator was observed to inadequately don beard covering prior to entering CSP production room #5 (i.e., gowning room).

CFR 211.67(a) and CFR 211.67(b) Equipment cleaning and maintenance
Specifically, a visible residue left behind by cleaning agents was observed on windows and walls in the product production areas.

Specifically, change control HVAC-IOQ-002 associated with EMPQ-005 documentation indicated a "triple clean" had occurred on 3/12/24. This cleaning process was not defined within the facility SOP provided for review (SOP-041 Version 01). Staff stated this process was the "same as the monthly" cleaning/disinfection process, but the documentation from 3/12/24, did not match that specified as a monthly cleaning/disinfection.

CFR 211.46, 211.22(c) and 211.22(d) Ventilation, air filtration, air heating and cooling/Responsibilities of quality control unit
Specifically, the third-party certification reports dated 1/17/24 to 1/19/24 and 3/12/24 did not indicate these data had been reviewed by the quality control unit.

Specifically, the 1/17/24 to 1/19/24 and 3/12/24 third party certification report did not certify that CSP production south door of room #4 had been adequately sealed by way of a smoke study and the firm is not actively monitoring pressure gradients for this door.

CFR 211.22(c) Responsibilities of quality control unit
Specifically, the firm's pest control SOP (i.e., SOP-008) states all chemicals utilized are to be reviewed and approved by the quality control unit. An approved list of the quality department's reviewed and approved agents was not observed.

Specifically, FRM-034 (i.e., Pod surface sample contact plate sampling form) stated an action limit of greater than 1 CFU for ISO5 areas, although this did not match the findings within the firm's EMPQ or as defined as an "alert" and/or "action" limit in section 6.4 of SOP-048.

CFR 211.100(a) and CFR 211.100(b) Written procedures; deviations
Specifically, operators were observed to don shoe covers between CSP production area room #4 and room #5 (i.e., gowning) with an inconsistent approach (i.e., one operator stepped over a LOD each time a shoe cover was donned but another operator did not follow this process), and I did not observe within provided SOPs the expected procedure.

Specifically, it was observed that staff were unable to fully comply with SOP-038 as it relates to hand hygiene as it would have led to the required laundered scrubs sleeves becoming wet.

Specifically, it was observed that stability lot 042324@3 batch record stated visual inspections were to occur pursuant to "SOP-xxx" which staff staffed was to be SOP-061. A notation of a deviation was not observed on the batch documentation.

CFR 211.103 Calculation of Yield
Specifically, batch record review of stability lot 042324@3 stated a theoretical yield of 914 units but it was observed that only 677 units were in the final count. I did not observe documentation of a related investigation on the lack of congruence.

Your response to each finding should be forwarded to this office within thirty (30) days. These responses to the above findings must include an itemized list of each finding with the corrective/proposed corrective action, responsible individual, and completion/projected completion date. Once completed, you must forward supporting documentation (i.e., pictures, invoices, SOP, documentation, etc) to my attention at ASBP@arkansas.gov.

If we may be of assistance at any time, do not hesitate to contact our office.

Respectfully,

Kevin Robertson, Pharm.D.
Inspector/Investigator

Pharmacy Name: Fortune Manufacturing, LLC

Pharmacy Address: 925 Jasmine Drive, Conway, AR 72032

Arkansas Facility ID: 17012004

ARBOP Inspection Date: June 26th 2024

Facility Response to Arkansas Board of Pharmacy 503B Outsource Facility Inspection

Type of Response	ARBOP Inspection Report Page No.	ARBOP Inspection Report Token No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	1	CFR211.28(a)	Operator, AM, has been retrained on PPE requirements for CSP, non-classified room 65. There have been no Personnel Monitoring hits for AM since gowning qualification completed.	7/5/2024	Y	Training Packet for AM, Reference SOP-042 Aseptic Technique, SOP-038 Handwashing and Gowning, SOP-027 Gowning Qualifications. See Attachment #1.
Updates/New SOPs or P&Ps	1	7(a) and CFR	Updated SOP-041 Cleaning Program to include cleaning of Peridox or TBI-1000 residue from windows after dwell time with sterile Isopropyl Alcohol, see Section 7, 7.2.3, Terminal Clean (triple clean) procedure outlined in SOP-041, section 7.7. The documentation for 3/13/23 (should be 3/12/24 as referenced) does match the process for a Terminal Clean. Documentation of year of record error noted and corrected.	7/3/2024	Y	SOP-041 Cleaning Program, Section 7, 7.2.3, Section 7.7, Terminal Clean Form dated 3/12/2023 corrected for year to 3/12/2024. See attachment #2 and #2a.
Clarification or Further Explanation	1	11.46, 211.22	Quality review completed of 1/17/24 to 1/18/2024 and 3/12/2024 for AirSafe reports; quality is responsible for this vendor, if issue noted, quality will initiate investigation; if report is null then no action required. Door in ISO 8 room 84, is not utilized for ingress or egress of materials or personnel. Data from room shows positive pressure differential to outside of room. Inclusion of doorway into smoke study scheduled for July with third party vendor Air Safe will include door/wall.	7/1/2024	Y	Certification Reports for 1/17-1/18 of 2024 and 3/11/2024 signed to verify review (typically do not sign these; only review and if issue then follow up with quality intervention). Pressure Differential for room 84. See attachment #3a, 3b, 3c.
Updates/New SOPs or P&Ps	2	211.72(b)	Pest Control chemicals reviewed and approved by facility unit. FBM-034 with hits for >1 CFU, should have reflected action for 1 CFU for ISO 5 areas. Evaluation of EM shows not hits for this room, therefore no further action was taken.	6/14/2024 and 7/3/2024	Y	Approved pest control chemicals for SOP-038 Pest Control. Copy of SOP-041 Section 6.4.7 table for ISO 5 Alert and Action Limits. See attachment #4, 4a.
Updates/New SOPs or P&Ps	2	211.100(a)	Retraining of Aseptic operators with the LOA; SOP-038 states to "swing leg across demarcation line to clean side of gowning floor", SOP-038 Gowning and Handwashing Procedures for the CNC and ISO Cleanbot Aseptic, updated to reflect that technique: "Rinse hands holding them upright and perpendicular to sink, allowing water to drip off hands and towards wrists, but not wetting across." Batch record updated to reflect for SOP-081 reference for VI inspections.	7/5/24	Y	SOP-038 section bullet point "Don cleanroom boots"; section 7.8, bulleted list under "Must be completed before donning ISO classified zones". Batch record for Repackaged Avastin, 16 section and associated deviation. See attachment #5, 5a, 5b, 5c.
Updates/New SOPs or P&Ps	2	211.103	Batch 042324@2 held a theoretical yield of 216 units with consideration of needle and hub spacing, documentation on syringes stated "0" headspace so no calculation of the 0.5CmL space in syringe taken into account. The actual yield for this syringe device should be 018. This was noted on batch record and no investigation was conducted as root cause was identified and corrected. Batch record was not updated due to change in syringes for stability studies in different brand that do not have any headspace.	7/3/24	Y	Batch Record for Repackaged Avastin not updated for yield due to change in syringes utilized for final container. See attachment #6.

Pharmacy Name: Tuckaseg Manufacturing, LLC

Pharmacy Address: 925 Sonoma Drive, Conway, AR 72032

Arkansas Facility ID: WOS008

*ARBOP Inspection Date: June 24th-28th

Facility Response to Arkansas Board of Pharmacy 503B Outsource Facility Inspection

Type of Response	ARBOP Inspection Report Page No.	ARBOP Inspection Report Item No.)	Facility Response (Corrective Action/Comments)	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated on top of document attachment)

Pharmacy Name: Turbare Manufacturing, LLC

Pharmacy Address: 925 Jeanette Drive, Conway, AR 72032

Arkansas Facility ID: WD06008

ARBOP Inspection Date: June 24th-26th

Facility Response to Arkansas Board of Pharmacy 503B Outsource Facility Inspection

Type of Response	ARBOP Inspection Report Page No.	ARBOP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	1	CFR211.28(a)	Operator, AN, has been retrained on PPE requirements for CSP, non-classified room #5. There have been no Personnel Monitoring hits for AN since gowning qualification completed.	7/9/2024	Y	Training Record for AN, Reference SOP-042 Aseptic Technique, SOP-038 Handwashing and Gowning, SOP-037 Gowning Qualifications. See Attachment #1.
Updates/New SOPs or P&Ps	1	7(a) and CFR 2	Updated SOP-041 Cleaning Program to include cleaning of Peridox or TB1-3300 residue from windows after dwell time with sterile Isopropyl Alcohol, see Section 7, 7.2.3, Terminal Clean (Triple clean) procedure outlined in SOP-041, section 7.7. The documentation for 3/12/23 (should be 3/12/24 as referenced) does match the process for a Terminal Clean. Documentation of year of record error noted and corrected.	7/3/2024	Y	SOP-041 Cleaning Program, Section 7; 7.2.3, Section 7.7. Terminal Clean Form dated 3/12/2023 corrected for year to 3/12/2024. See attachment #2 and #2a.
Clarification or Further Explanation	1	211.46, 211.22	Quality review completed of 1/17/24 to 1/19/2024 and 3/12/2024 for AirSafe reports; quality is responsible for this vendor, if issue noted quality will initiate investigation; if report is null then no action required. Door in ISO 8 room #4, is not utilized for ingress or egress of materials or personnel. Data from room shows positive pressure differential to outside of room. Inclusion of doorway into smoke study scheduled for July with third party vendor Air Safe will include door/seal.	7/3/2024	Y	Certification Reports for 1/17-1/19 of 2024 and 3/12/2024 signed to verify review (typically do not sign these; only review and if issue then follow up with quality intervention). Pressure Differentials for room #4. See attachment #3a, 3b, 3c.
Updates/New SOPs or P&Ps	2	211.22(c)	Pest Control chemicals reviewed and approved by quality unit. FRM-034 with typo for >1 CFU, should have reflected action for 1 CFU for ISO 5 areas. Evaluation of EM shows not hits for this room, therefore no further action was taken.	6/24/2024 and 7/3/2024	Y	Approved pest control chemicals for SOP-008 Pest Control. Copy of SOP-048 Section 6.4 Table for ISO 5 Alert and Action Limits. See attachment #4, #4a.
Updates/New SOPs or P&Ps	2	211.100(a)(b)	Retraining of sterile operators with the LOD; SOP-038 states to "swing leg across demarcation line to clean side of gowning floor". SOP-038 Gowning and Handwashing Procedures for the CNC and ISO Classified Areas, updated to reflect that technique: "Rinse hands holding them upright and perpendicular to arm, allowing water to drip off hands and towards wrists, but not wetting scrubs." Batch record updated to reflect SOP-061 reference for VI inspections.	7/9/24	Y	SOP-038 section bullet point "Don cleanroom boots"; section 7.3, bulleted list under "Must be completed before entering ISO classified areas". Batch record for Repackaged Avastin, VI section and associated deviation. See attachment #5, 5a, 5b, 5c
Updates/New SOPs or P&Ps	2	211.103	Batch 042324@3 held a theoretical yield of 914 units with consideration of needle and hub spacing, documentation on syringes stated "0" headspace so no calculation of the 0.02mL space in syringe taken into account. The actual yield for this syringe device should be 688. This was noted on batch record and no investigation was conducted as root cause was identified and corrected. Batch record was not updated due to change in syringes for stability studies to different brand that do not have any headspace.	7/3/24	Y	Batch Record for Repackaged Avastin not updated for yield due to change in syringes utilized for final container. See attachment #6.

Pharmacy Name: Turbare Manufacturing, LLC

Pharmacy Address: 925 Jeanette Drive, Conway, AR 72032

Arkansas Facility ID: WD06008

ARBOP Inspection Date: June 24th-26th

Facility Response to Arkansas Board of Pharmacy 503B Outsource Facility Inspection

Type of Response	ARBOP Inspection Report Page No.	ARBOP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)

Retraining on CleanRoom Garbing - CB09JUL2024

Turbare Manufacturing, LLC	Attachment 1	FRM-003
Document Category: GEN		Version 01
Effective Date: 12JUN2024		Page 1 of 2

Training Record

Quality or designee shall initiate *Training Record* when appropriate. The form shall be completed as the process is followed, without skipping any sections. Check each applicable box as the process continues and initial and date for the section upon completion. The individual stated at the beginning of each section shall complete that section in its entirety.

1.0 Quality-
Employee Name: Andrew Nichols

BG 09JUL2024

Job Title: DOP

Employee Status: Regular ☑ Temporary ☐

Training Purpose:
New Document ☐ Document Change ☐ Obsoleted Document ☐
Other: _____
New Hire ☐
Re-Train ☑

Document Number: SOP-042 / SOP-038 / SOP-037
Document Name: Aseptic Technique/HandGowning/GownDoff
Version: 01 Effective Date: N/A
Add Attachment Page *(when training on more than one document)* ☐

Training Type:
Read Only ☐
On the Job ☑ Name of Trainer: BG
Instructor Led ☐ Name of Instructor: _____
Class Description: _____
Annual Competency Review/Assessment ☐

Assigned Deadline: Week of 1st July-12th July N/A

2.0 Employee-

Employee Name	Employee Signature	Date
Andrew Nichols		09JUL2024

3.0 Comments: N/A ☐

Focus on beard covering for appropriate clean room garbing

BG 09JUL2024

COPY

CONTROLLED NON-CLASSIFIED AREAS			
Site/Frequency	Daily	Weekly	Monthly
Surfaces and Counters	x	x	x
Floors	x	x	x

Sterile Primary Engineering Control (PEC)
At the beginning of each shift.
No longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring.
Before compounding/repackaging each batch.
After spills
When surface contamination is known or suspected.

ISO CLASSIFIED AREAS/CLEANROOMS			
Site/Frequency	Daily	Weekly	Monthly
Work Surfaces and Counters (including the PECs)	x	x	x
Floors	x	x	x
Walls and Doors			x
Ceiling			x
Storage Spaces (Cabinets, Shelving, Refrigerators, Freezers, etc.)			x
Equipment			x

7.2 GENERAL PRINCIPALS

7.2.1 All cleaning tools, such as wipers and mops, are non-shedding and dedicated to use in their buffer or clean area.

7.2.2 The mop trolley shall be cleaned daily with sterile PeridoxRTU, TB1-330, and 70% alcohol per daily, weekly, or monthly cleaning schedule.

7.2.3 If cleaning agents leave visible residue, follow use by wiping with sterile Isopropyl Alcohol (IPA) to remove.

7.2.4 Wipes are discarded after one use.

7.2.5 If cleaning tools are reused, their cleanliness is maintained by sanitization after use and by storing in a clean environment between uses.

7.2.6 Trash is collected in suitable plastic bags and removed with minimal agitation.

7.2.7 No shipping or other external cartons may be taken into the buffer or clean area.

7.2.8 All cleaning is documented when performed.

Copy of Terminal Clean Log for 9/12/24 - Corrected dating error sec W DD 09JUL2024

Attachment #2a

TURBARE MANUFACTURING

Document No.:	PRO/OPS FRM-004	
Version No.:	01	Page 1 of 1
Effective Date:	TBD	
Document Title:	Terminal Clean 3-12-23① Tues	

Please initial and record below for each triple clean task completed. Record Date of Cleaning and Maintenance: 3/12/23①

	Product	Date/Time	Date/Time	NOTES
Ceilings 1st Layer	Peridox	3-12-23①		BP,
2nd Layer	TB1-3300	3-12-23①		JAV
3rd Layer	TB1-3300	3-12-23①		☆
Walls 1st Layer	Peridox	3-12-23①		
2nd Layer	TB1-3300	3-12-23①	N/A CP	
3rd Layer	TB1-3300	3-12-23①		
Floors 1st Layer	Peridox	3-12-23①		
2nd Layer	TB1-3300	3-12-23①		
3rd Layer	TB1-3300	3-12-23①		
Surfaces 1st Layer	Peridox	3-12-23①		
2nd Layer	TB1-3300	3-12-23①	N/A CP	
3rd Layer	TB1-3300	3-12-23①		

Product Name	Lot/Expiration	NOTES
Peridox	GH3209111623IA 01/2026	COPY
TB1-3300	1027614-0-0-1 11/2025	
70% IPA		

① Incorrect Date 3-12-24. COP date format 12MAR2024. CBS 08JUL2024

Reviewed By: CDavis Date: 03/13/24

Air Safe Certification Report Review - CO 09JUL2024

Attachment #3a

AIR SAFE
The Certified Professionals

CONTROLLED ENVIRONMENT
PERFORMANCE TEST AND CERTIFICATION REPORT

Report ID#: 90642AB7

Client ID#: TML22
Turbare Manufacturing, LLC
925 Jeanette Drive
Conway, AR 72032

12 March 2024

PHARMACY CLEANROOM CERTIFICATION

(Partial Service)

The data presented in this report is an exact record of the controlled environment performance and was obtained in accordance with nationally recognized standard procedures. The results shown and information given in this report are certified to be accurate and complete, to the extent possible by equipment and procedures used on this date. Air Safe, LLC. warrants that the equipment or system contained in this report is operating at the levels specified herein, at and only at this time, and makes no other warranties, stated or implied, concerning the continued performance, operation, or safety in use of this equipment past this time.

Performed by:

Brett Monday RCP-SCF
Technician
Air Safe, LLC.

Reviewed by:
Brett Monday

Brett Monday RCP-SCF
CEO
Air Safe, LLC.

Reviewed by Client: Celeste Davis Date 09JUL2024

AS-12MAR24-TML22-PHARMACY-REPORT-90642-NN

Air Safe Certification Report Review - CO 09JUL2024

Attachment #36

AIR SAFE
The Certified Professionals

CONTROLLED ENVIRONMENT
PERFORMANCE TEST AND CERTIFICATION REPORT

Report ID#: 90642AA7

Client ID#: TML22
Turbare Manufacturing, LLC
925 Jeanette Drive
Conway, AR 72032

17-19 January 2024

PHARMACY CLEANROOM & DEVICE CERTIFICATIONS

As Built

The data presented in this report is an exact record of the controlled environment performance and was obtained in accordance with nationally recognized standard procedures. The results shown and information given in this report are certified to be accurate and complete, to the extent possible by equipment and procedures used on this date. Air Safe, LLC. warrants that the equipment or system contained in this report is operating at the levels specified herein, at and only at this time, and makes no other warranties, stated or implied, concerning the continued performance, operation, or safety in use of this equipment past this time.

Performed by:

Brett Monday RCP-SCF
Technician
Air Safe, LLC.

Reviewed by:
Brett Monday
Brett Monday RCP-SCF
CEO
Air Safe, LLC.

Reviewed by Client: Celeste Davis Date 09JUL2024

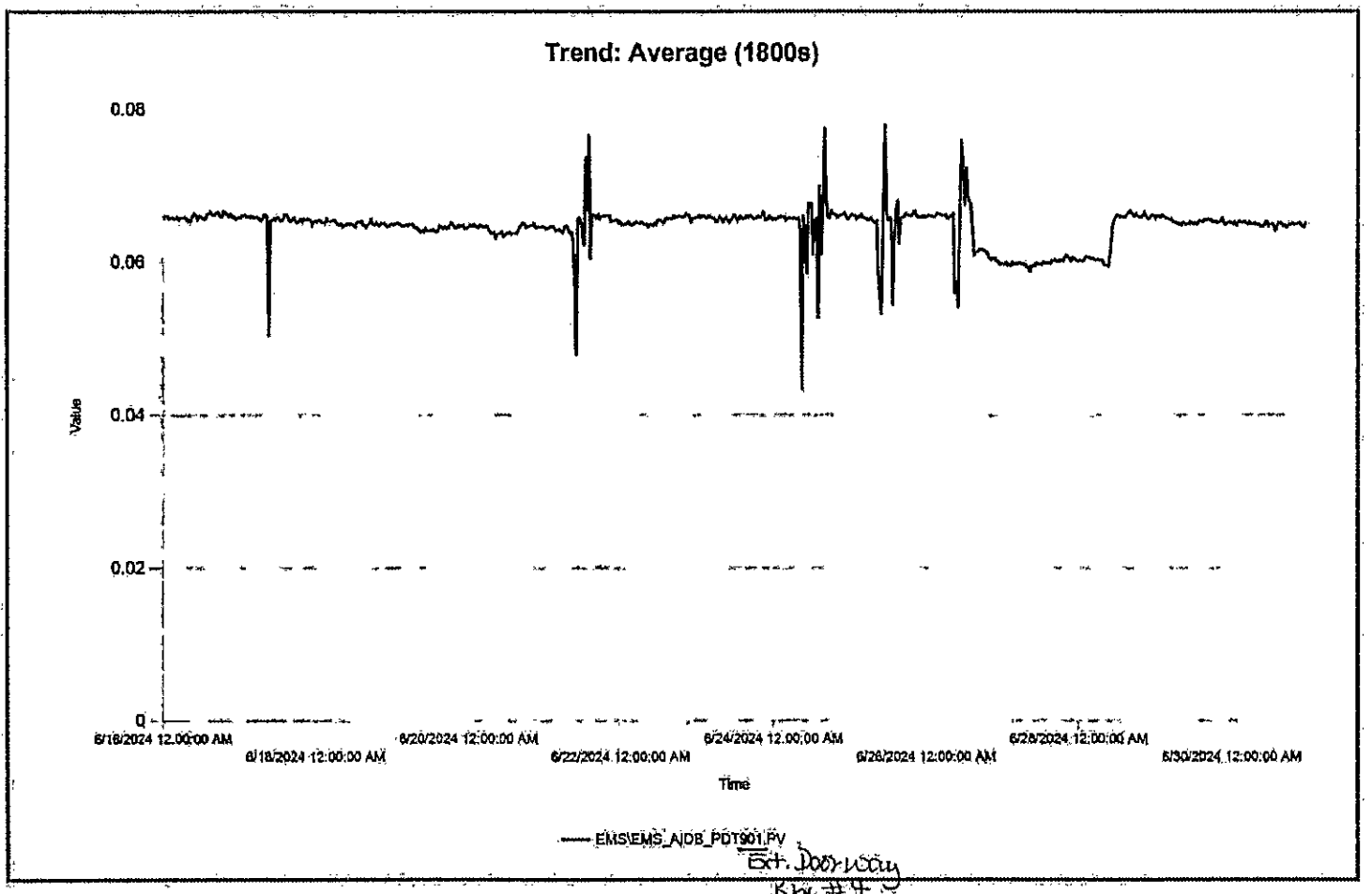
AIR SAFE ☆ A ☆ SINCE 1997 THE GUARANTEED PERFORMANCE COMPANY

129 S. Gallatin, Liberty, MO 64068 888.924.7723 816.792-8105 (fax) www.airsafeonline.com

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AS-17-19JAN24-TML22-PHARMACY-REPORT-9064-NN

Pressure differential for doorway - DDS. < 0.02
Data from 6/16/2024 - 6/30/2024



7/8/2024 2:01:19 PM

Turbare_R1

COPY

Attachment 3c

Pest Control Chemicals Review by QM – CQO 09JUL2024 Attachment #4

TURBARE
MANUFACTURING
"Only the BEST will do!"

To: Internal

From: Celeste Davis

CC: Quality

Date: 24JUN2024

RE: Approved chemicals for pesticide use

The following list of chemicals used by Central Arkansas Pest Services has been reviewed and approved by Quality for use as pesticides in and around buildings.

Permethrin, Deltamethrin

Boric Acid (InTice)

Wisdom Flowable

Any additional chemicals used will be reviewed and added per quality approval

Celeste Davis, CQO

Celeste Davis, PharmD, MSN, RN

Chief Quality Officer

925 Jeanette Drive Conway, AR 72032
501-497-8499
www.Turbare.org

COPY

Correction of SOP Table for Alert/Action Limits - CD 09JUL2024

NOTE: Sampling locations have been determined based upon results obtained during the Environmental Monitoring Performance Qualification Baseline study and U.S. FDA Aseptic Processing Guidance and will be re-evaluated periodically for appropriateness.

6.3 Incubation of Viable Samples

- Invert and incubate the plates at 20 - 25°C for 5-7 days. Examine plates for a preliminary read after 20 - 25°C incubation period to record CFU count only and determine if there is any excessive growth.
- Move the plates, still inverted, to 30 - 35°C incubation for an additional 2-3 days and record the final CFU count and colony morphology description for each plate. **NOTE:** End of incubation period for either temperature can be extended to the next business day, if necessary.

6.4 Evaluation of Result

- As stated in 4.1, results of NV testing will be evaluated immediately upon completion and compared to Alert and Action limits in the table below.

ISO Class	Viable Air (AV) (cfu / m^3)		Surface Viable (SV) (cfu / 55mm plate)		Total Particles (NV) (≥0.5µm / m^3)		Total Particles (NV) (≥5.0µm / m^3)	
	Alert	Action	Alert	Action	Alert	Action	Alert	Action
5	N/A	1	N/A	1	1,000	>3,520	N/A	≥1
7	2	5	5	10	5,000	>352,000	175	2,930
8	5	10	10	20	10,000	>3,520,000	750	29,300

NOTE: Alert and Action levels for each ISO class (see table above) have been determined based upon results obtained during the Environmental Monitoring Performance Qualification Baseline study and U.S. FDA Aseptic Processing Guidance and will be re-evaluated periodically for appropriateness.

COPY

SOP-038 Update for handwashing process – CR 09JUL2021 Attachment #5

- Upon entry to the CNC locker room.
  - Don shoe covers over street shoes.
- Personnel may don the designated non-sterile blue dedicated scrubs or don a white non-sterile lab coat over street clothes, if not entering cleanrooms.
- Personnel must change into dedicated shoes while in CNC or cleanroom areas.
  - Don safety glasses if cleaning areas with splashable liquids.
  - Don hair net and beard cover (if applicable)
  - Don sterile nitrile gloves.

- Prior to Material Transfer

  - If personnel are transferring materials from outside into the CNC over the line of demarcation, they may don the designated non-sterile blue dedicated scrubs or don a white non-sterile lab coat over street clothes. If wearing street shoes, shoe covers must be donned.
  - If personnel are transferring materials from the CNC area to the ISO 8 material transfer room, they must don the non-sterile blue dedicated scrubs.
  - Don non-sterile face mask.
  - Don sterile gloves.
  - Don hairnet and beard cover (if applicable).

7.3 HANDWASHING

- MUST BE COMPLETED BEFORE ENTERING ISO CLASSIFIED AREAS
  - Pull sleeves of scrubs as high as possible, exposing wrists or forearm area if possible.
  - Do not touch the faucet or sink during the hand hygiene process.
  - Begin hand washing by wetting hands. Remove debris from underneath fingernails using a nail pick under each nail. Apply antiseptic soap (e.g., chlorhexidine gluconate solution).
  - Wash all four surfaces of each finger and all surfaces of the hands and wrists with antiseptic soap and water for at least 30 seconds.
  - Rinse hands holding them upright perpendicular to arm and allowing water to drip off hands and towards wrists, but NOT wetting scrubs.
  - Dry hands and forearms completely using low lint wipes.

Correction of batch record for referenced VI SOP-061 -DD 09JUL202

Attachment #5a TURBARE MANUFACTURING	LOT# BUD:	Document Number	TEM-013
		Version Number	01
		Effective Date	18JUN2024
Drug Name and Strength:			7 of 14

6. Step Description

Description	Performed By: Initial/Date	Verified By: Initial/Date
1. Record Start Time: **START TIME:**		
2. Record Stop Time: **STOP TIME:**		
3. Record Final Count: **Final Count:** _____		

7. Visual Inspection

Description	Performed By: Initial/Date	Verified By: Initial/Date
7.1 Verify that visual inspection area is clear and free of any other product or labels.		
7.2 Determine the number of units received for visual inspection. Count: _____ *Must match number in 6.3*		
Perform visual inspection per SOP-061 *Visual Inspection* on each unit for Critical, Major, and Minor defects as categorized in table below:		

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Retraining for LOD – CO 09JUL2024

Attachment # 56

Turbare Manufacturing, LLC	FRM-003
Document Category: GEN	Version 01
Effective Date: 12JUN2024	Page 1 of 2

Training Record

Quality or designee shall initiate *Training Record* when appropriate. The form shall be completed as the process is followed, without skipping any sections. Check each applicable box as the process continues and initial and date for the section upon completion. The individual stated at the beginning of each section shall complete that section in its entirety.

1.0 Quality-

Employee Name: All Aseptic Operators Group — CO 09JUL2024

Job Title: Aseptic Operators / Supervising Pharmacist

Employee Status: Regular ☑ Temporary ☐

Training Purpose:

New Document ☐ Document Change ☐ Obsoleted Document ☐

Other: _____

New Hire ☐

Re-Train ☑

Document Number: Demarcation Lines on Gowning Room

Document Name: N/A

Version: N/A Effective Date: N/A

Add Attachment Page *(when training on more than one document)* ☐

Training Type:

Read Only ☐

On the Job ☑ Name of Trainer: GS/CO

Instructor Led ☐ Name of Instructor: _____

Class Description: _____

Annual Competency Review/Assessment ☐

Assigned Deadline: Week of 1st July - 12th July N/A

2.0 Employee-

BG/DD/MM/AW/ Glen Brook Gunson — 09JUL2024

Employee Name — Employee Signature — Date

3.0 Comments: N/A ☐

Focus on appropriate gowning & observance of demarcation line signalling clean vs dirty side of room. — CO 09JUL2024

COPY

Deviation for correction of BR reference to SOP-061 CD 07JUL2024

Turbare Manufacturing, LLC	Attachment 5c	FRM-018
Document Category: QRA		Version 01
Effective Date: 12JUN2024		Page 1 of 3

Process Deviation

This form is intended to document Process Deviations (PD) from documented processes and controls. This record should address the risks associated with deviations and provide justifications and data in support of those justifications. Sign-off on each section as the process is completed.

Procedure	Initial/Date
1.0 *Requestor* - **Document Information** List the document numbers that are being deviated from: Batch Record, TEM-013, for Repackaged Sterile Product, Section 7, reference to SOP did not list correct SOP instead denoted reference as SOP-XXX	CD 07JUL2024
2.0 *Requestor* - **Scope** List the part/lot numbers, or define the time period for the process deviation to be in effect: All batch records effected until SOP-061 was approved on 18JUN2024. Batch record updated for SOP-061 reference as of 07JUL2024.	CD 07JUL2024
3.0 *Requestor* - **Description** – List applicable details: who/what/where, impacts, risk, risk control mechanisms, and justification. Batch records for media and Avastin product development affected. Low risk due to training of personnel completed for VI process and no marketable product affected.	CD 07JUL2024
4.0 *Quality* - **Approval of Deviation Plan** Approval Signature: Name: Celeste Davis Title: CQO Signature: Celeste Davis Date: 07JUL2024	CD 07JUL2024
5.0 PD Closure Actions Completed By: Celeste Davis Date: 07JUL2024 QA Closure of PD Celeste Davis Date: 07JUL2024	CD 07JUL2024 07JUL2024

COPY

Batch Record 042324@3 – correction of yield CD 09JUL2024

Attachment # 1e

TURBARE MANUFACTURING	Lot #:042324@3	Document Number	
		Version Number	01
	BUD:NA	Effective Date	01JAN24
Document Title	Batch Record Repack of Sterile Aqueous Solutions		Page 5 of 13
Drug Name and Strength	Avastin 1.25mg/0.05mL repackaged in 1 mL syringe		

3.2.1.

Name	Initials	Signature	Date
Brook Powell	BP	Brook Powell	23APR2024

Agent used	Lot/Expiration	Start time	Stop time	Tote/Bag numbers
Pyndoxal RTU	GH3209111 2023/14	0845	0955	2

4. Confirmation of Product

Confirm Product and Batch Number information for this batch below:	Performed by/Date	Verified by/Date
Product Identity and Strength: Avastin 1.25mg/0.05mL	BP 23APR2024	AN 23APR2024
Product Type: Clear, aqueous solution	BP 23APR2024	AN 23APR2024
Theoretical number of units of size to produce: 914 units 0.07mL fill (1)	BP 23APR2024	AN 23APR2024
Target Fill Volume: 0.07-0.08mL	BP 23APR2024	AN 23APR2024
Total Target Fill Volume: 64 mL	BP 23APR2024	AN 23APR2024

5. Compounding Instructions

Step Description	Performed by/Date	Verified by/Date
Clean Room Prep: Verify clean room, BSC, equipment, and all work surfaces are clean and suitable for compounding.	BP 23APR2024	AN 23APR2024
Ensure BSC hood is on and has been running continuously for at least 30 minutes with sash at working height.	BP 23APR2024	AN 23APR2024
Verify that all environmental and personnel monitoring equipment and components are in place as applicable for the room.	BP 23APR2024	AN 23APR2024

COPY

(1) Theoretical yield calculated with 0mL dead space in Syringe 64mL/0.07mL = 914 syringes.
Actual dead space equals 0.033mL. 0.07mL + 0.033mL = ~~0.0433mL~~ 0.093mL. 64mL/~~0.0433mL~~ 0.093mL = 688.17 ≈ 688 syringes.
Theoretical should be 688 syringes. GRS 09JUL2024
for work performed 23APR2024 GRS 09JUL2024
Incorrect number GRS 09JUL2024
Incorrect number GRS 09JUL2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	1/14/2025-1/24/2025* FEI NUMBER 3027507354

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Laura E. Martin, CEO

FIRM NAME	STREET ADDRESS
Turbare Manufacturing	925 Jeanette Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Conway, AR 72032-6651	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

A)During media fill lot 11252024@1MM your firm recovered mold growth from personnel monitoring results of 1 CFU on the right chest sample. This technician was performing compounding activities in the ISO-5 hood for the media fill. Your firm identified the species of mold, *Curvularia intermedia,* but did not perform any investigation to determine where the mold originated or evaluate patient safety due to the presence of this mold on your personnel performing repackaging activities. Your firm's routine environmental monitoring procedure states that "Action responses are always triggered for viable samples regardless of CFU count when CFU identified are of any highly pathogenic organisms such as gram-negative rods, coagulase positive *Staphlyococcus species*, molds, or yeasts.

B)Your firm initiated an investigation into a personnel monitoring result of 1 CFU for fingertip monitoring for lot 11132024@1. The result was initially discovered on 11/19/2024. Your firm performed an investigation into this out of specification on 1/14/2025 with no documented justification for the lapse in time for not investigating this critical environmental result. Lot disposition decisions were made prior to the investigation opening. This lot was rejected and destroyed without a documented disposition decision from quality or a record of the destroyed lot.

Logan T Williams
Investigator
Signed by: [illegible]
Date Signed: 01-24-2025
10:09 CST

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Logan T Williams, Investigator	X	1/24/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	1/14/2025-1/24/2025* FEI NUMBER 3027507354

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Laura E. Martin, CEO	
FIRM NAME Turbare Manufacturing	STREET ADDRESS 925 Jeanette Dr
CITY, STATE, ZIP CODE, COUNTRY Conway, AR 72032-6651	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

C)Your firm failed to identify and open investigations for apparent AQL failures for Avastin repackaged lot 12122024@2 and 12192024@2. These lots were both released and distributed by your firm.

OBSERVATION 2

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet appropriate statistical quality control criteria as a condition for their approval and release.

Specifically,

Specifically,

Your firm's AQL sampling of 2% of the batch (15 syringes) is not statistically significant. In addition, acceptance criteria is not appropriately applied from AQL results.

Avastin repackaged lot 12192024@2, expiry 4/18/2025, had two major defects identified, both for particulate matter, during AQL sampling out of fifteen syringes evaluated. Your firm's AQL limit for major defects is 1.0%. Your firm calculated the AQL limit against the entire batch size of 729 syringes resulting in 0.3% major defects. Two syringes out of fifteen represents approximately 13% major defects in the AQL sample. Your firm passed this AQL result with no investigation or additional product inspection. This batch was released for distribution.

Avastin repackaged lot 12122024@2, expiry 3/14/2025, failed initial 100% visual inspection and was reinspected. After the 200% inspection was complete an AQL was performed. This AQL was performed with a sample size of fifteen syringes. One major defect for underfill was found during this AQL. Your firm's AQL limit for major defects is 1.0%. Your firm reported a result against the entire batch size of 739 syringes and resulting in 0.1% major defects. One out of fifteen represents approximately 7% major

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Logan T Williams, Investigator X	DATE ISSUED 1/24/2025

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1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax: (214)253-5314	1/14/2025-1/24/2025* FEI NUMBER 3027507354

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Laura E. Martin, CEO	
FIRM NAME Turbare Manufacturing	STREET ADDRESS 925 Jeanette Dr
CITY, STATE, ZIP CODE, COUNTRY Conway, AR 72032-6651	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

defects in the AQL sample. Your firm passed this AQL with no investigation or additional product inspection. This batch was released for distribution.

OBSERVATION 3

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

The defects contained in the visual inspection qualification kit are not well defined and contain approximately 80% defects. Your firm's classification of defects is not scientifically justified. Your firm's critical, major, and minor defect classifications are not defined in any procedure and defects have not been assessed for risk to patient. According to your firm's CEO, the defects for each category are:

Critical: container closure breach, discoloration or cloudiness, and cracked/broken container

Major: over fill, under fill, dark particulate, and light particulate

Minor: cosmetic defect or other defect

OBSERVATION 4

Employees engaged in the manufacture and processing of a drug product lack the training and experience required to perform their assigned functions.

Specifically,

1) Qualification of your visual inspectors is deficient, for example:

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	FEI NUMBER 3027507354

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Laura E. Martin, CEO	
FIRM NAME Turbare Manufacturing	STREET ADDRESS 925 Jeanette Dr
CITY, STATE, ZIP CODE, COUNTRY Conway, AR 72032-6651	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

- Your firm does not qualify inspection speed. During production 100 syringes can be inspected in less than 20 minutes, however, no documented inspection time was recorded during qualification activities.
- The characteristics of the defects within the qualification kit are not well defined. For example, particulate defects are listed as "light" or "dark" particulate matter of unknown size and composition. Your firm cannot evaluate the capabilities of visual inspectors without developing a well defined qualification kit.
- Your firm does not simulate fatigue during qualification.
- Defects in the qualification kit were prepared in house and the kit does not contain defects based on rejects from actual production. Particulate defects made in house do not necessarily represent defects that would be found from production.

2) Your firm does not have a reject library from which training and familiarization of defects can be studied by new hires or for refresher training.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

Aseptic processing simulations were performed without protocols developed for defining acceptance criteria and worst-case conditions to be simulated. Your firm is currently performing media fills on the 0.25mL syringe size at 25% of routine batch size without a documented rationale. According to your firm's CEO, this reduced batch size is used after process validation has been completed and operator qualification is being performed.

In addition, your firm qualified operators utilizing various syringe sizes; 0.25mL, 10mL, and 50mL without a documented rationale for this bracketing. Your firm's current commercial product uses a

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Logan T Williams, Investigator		DATE ISSUED 1/24/2025

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0.25mL syringe size with a batch size of 756 syringes. The 50mL syringe media fill is approximately 180 syringes with a shorter fill time and different processing steps than commercial production.

OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically,

Your firm's media fill procedure, SOP-039, was not implemented prior to performing media fills. Your firm's media fill procedure was implemented on 6/12/2024. This procedure does not define acceptance criteria, routine and non-routine interventions to be performed, fill volume, or minimum fill time to be achieved for each process to be simulated.

Your firm performed 12 media fills prior to implementing any media fill procedure. In addition, no media fill protocols were developed until 11/21/2024. Interventions performed were not documented until protocols were developed. One technician used in routine production has not performed a media fill on the 0.25mL syringe process since procedures were developed.

OBSERVATION 7

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

Your firm does not have a procedure to govern environmental monitoring investigations into alert and action limits being reached during routine sampling. Your firm's investigation procedure, Investigation

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Logan T Williams, Investigator	DATE ISSUED 1/24/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	1/14/2025-1/24/2025*
	FEI NUMBER 3027507354

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Laura E. Martin, CEO

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Conway, AR 72032-6651	Outsourcing Facility

Program, SOP-081, effective 1/7/2025, states that the routine environmental monitoring procedure governs excursions and investigations in environmental monitoring. The routine environmental monitoring procedure does not require an investigation into action levels being reached for sample results. Action responses are not defined within the environmental monitoring procedure.

OBSERVATION 8

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

Specifically,

Your firm does not require a second reviewer for environmental monitoring results unless 1 colony forming unit (CFU) is found. A single technician reads environmental plate counts and the worksheet with results is later reviewed, however, the physical plates are not verified unless growth is present.

***DATES OF INSPECTION**

1/14/2025(Tue), 1/15/2025(Wed), 1/16/2025(Thu), 1/17/2025(Fri), 1/21/2025(Tue), 1/22/2025(Wed), 1/24/2025(Fri)

Logan T Williams
Investigator
Digitally signed by [illegible]
Date: [illegible]

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Logan T Williams, Investigator	X	1/24/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

14 February 2025

Confidential: Contains Trade Secrets and Confidential Commercial Information

VIA ELECTRONIC MAIL: CompoundingInspections@fda.hhs.gov

Monica Maxwell
Program Division Director
Dallas District Office
US Food and Drug Administration
1201 Main Street, Suite 7200
Dallas, TX 75202
Monica.Maxwell@fda.hhs.gov

RE: FEI 3027507354, Response to Form 483 issued 24-Jan-2025

Dear Ms. Maxwell,

On January 24, 2025, Food and Drug Administration ("FDA" or the "Agency") concluded an inspection of the Turbare Manufacturing, ("Turbare" or the "Company") facility located at 925 Jeanette Dr., Conway, AR 72032-6651 and issued inspectional observations on a Form FDA 483 ("FDA-483"). Turbare would like to thank the Agency for the opportunity to provide Turbare's initial response to the FDA-483. Following this initial response, Turbare will submit a full progress update each calendar quarter until all identified action items have been completed resolved. The first quarterly update will be for action items completed in 2025-Q1 with submission to the Agency by April 30, 2025.

503B Facility Background

Turbare is an FDA-registered 503B outsourcing facility committed to patient care and safety. Turbare recognizes FDA's important role in the oversight of outsourcing facilities to enhance patient safety and, as such, sincerely appreciates the collaborative and collegial discussions with Logan T. Williams, Investigator, during this inspection. Turbare believes the corrective actions described herein demonstrate an understanding of the Agency's concerns and a willingness to continuously improve its operations.

The corrective action(s) for each inspectional observation are outlined below, preceded by FDA's observation in *italics*. For ease of reference, a summary is appended that outlines the proposed action and timeline of completion for each.

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Description:

A) During media fill lot 11252024@1MM your firm recovered mold growth from personnel monitoring results of 1 CFU on the right chest sample. This technician was performing compounding activities in the ISO-5 hood for the media fill. Your firm identified the species of mold, Curvularia intermedia, but did not perform any investigation to determine where the mold originated or evaluate patient safety due to the presence of this mold on your personnel performing repackaging activities. Your firm's routine environmental monitoring procedure states "Action responses are always triggered for viable samples regardless of CFU count when CFU identified are of any highly pathogenic organisms such as gram-negative rods, coagulase positive Staphylococcus species, molds, or yeasts.

B) Your firm initiated an investigation into a personnel monitoring result of 1 CFU for fingertip monitoring for lot 11132024@1. The result was initially discovered on 11/19/2024. Your firm performed an investigation into this out of specification on 1/14/2025 with no documented justification for the lapse in time for not investigating this critical environmental result. Lot disposition decisions were made prior to the investigation opening. This lot was rejected and destroyed without a documented disposition decision from quality or a record of the destroyed lot.

C) Your firm failed to identify and open investigations for apparent AQL failures for Avastin repackaged lot 12122024@2 and 12192024@2. These lots were both released and distributed by your firm.

Response to Observation 1:

Turbare acknowledges the deficiencies in the investigation procedures and has taken immediate corrective actions to ensure all discrepancies, environmental monitoring results, and AQL failures are properly investigated and documented:

A) In response to the mold growth recovery from personnel monitoring during media fill lot 11252024@1MM, Turbare has initiated a retrospective investigation to determine the potential source of contamination under NCR-25-002 (Attachment 1). As part of the retrospective investigation, the technician involved will be evaluated for similar incidents in the past and garbing and aseptic technique records have been reviewed for compliance. As discussed during the inspection, this event was deemed to be an isolated event as available environmental monitoring trend analyses did not reflect a broad contamination issue. However, Turbare is acutely aware of the necessity to document and investigate deviations associated with growth recovered during media fill execution. In addition to the retrospective investigation to assess the root cause, Turbare has also initiated DCR-071, *Environmental Monitoring Program Enhancements* (Attachment 2) to update SOP-048, *Routine Environmental Monitoring*, to include language specific to the requirement of media fill investigations when mold or other highly pathogenic organisms are identified, regardless of CFU count. In addition, this procedure will be renamed *Environmental Monitoring*, to encompass both production and routine monitoring requirements to ensure a robust EM program has been established at the facility. Turbare expects approval and implementation of this revision to be completed in Mar-2025. A copy of the approved and effective procedure along with applicable personnel training will be provided in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025.

B) At the time the personnel monitoring result of 1 CFU for fingertip monitoring for lot 11132024@1 was identified, Turbare was in the process of revamping the investigation workflow to ensure a robust process was in place. Although Turbare leadership took the conservative approach and rejected the batch as a result of the deviation, Turbare agrees with the observation regarding the lag time in opening an investigation to assess root cause, corrective actions, impact assessment, and tracking of lot disposition activities. As part of the corrective action to address the deficiency noted by the Agency, new investigation timelines shall be enforced to require all OOS or environmental monitoring deviations to be initiated within five (5) business days of discovery regardless of presumed lot disposition. Specifically, SOP-048, *Routine Environmental Monitoring*, will be updated to include language specific to investigation initiation requirements under the new *Environmental Monitoring* title outlined above. Included with this procedural enhancement, a template, TEM-034, *EM Investigation Template* (Attachment 3), has been established to ensure consistency across EM investigations as a result of the change.

In an effort to streamline EM investigation requirements as a result of the proposed changes, Turbare intends to create a separate Environmental Monitoring Excursion Response procedure to adequately govern investigation requirements as it relates to environmental monitoring excursions. As such, DCR-071 (Attachment 2), *Environmental Monitoring Program Enhancements* was initiated on 10-FEB-25 to include updates to SOP-048, *Routine Environmental Monitoring*, to reference the new excursion response procedure as well as to create SOP-087, *Environmental Monitoring Excursion Response*. The new procedure will appropriately define action levels, alert limits, and corresponding investigation requirements to include clear criteria for investigation requirements, defined steps for conducting root cause analyses, impact assessments, corrective actions required, and documentation and approval requirements for closure. As part of the DCR, any relevant forms and logs associated with excursion reporting shall also be established for tracking purposes. All relevant personnel will be retrained on the updated procedures and associated training records shall be provided along with other supporting documentation in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025.

Additionally, due to the observation regarding a lack of documentation for lot rejection, Turbare reviewed SOP-071, *Drug Product Disposal* (Version 01, effective 21-OCT-2024) where it was identified that more robust measures could be employed to ensure adequate documentation of waste destruction activities are properly executed. As a result, DCR-067, Waste Disposal Program (Attachment 4) was opened on 23-JAN-2025 to update the existing procedure to outline the requirements of appropriately ensuring lot rejection occurs with a documented and approved rationale and record. As part of DCR-067, FRM-078, *Drug Product Disposal Record* (Attachment 5), and LOG-044, *Drug Product Disposal Log* (Attachment 6), were also created to ensure appropriate documentation efforts occur with QA oversight and approval. DCR-067 was closed on 13-FEB-2025, and the following corresponding documents became effective on 13-FEB-2025, SOP-071, *Drug Product Disposal* (Version 02), LOG-044, *Drug Product Disposal Log*, FRM-078, *Drug Product Disposal Record*.

C) Turbare would like to clarify that the AQL deficiencies observed during the inspection were not true AQL failures; rather, there were instances in which the appropriate quantities were not selected for AQL inspection. Specifically, Avastin repackaged lots 12122024@2 and 12192024@2 documented 15 syringes inspected for AQL inspection with one (1) additional defect identified for lot 12122024@2 and two (2) additional defects identified for lot 12192024@2 (Attachments 7 and 8). During the inspection, Turbare staff obtained retained syringes from both lots to do an additional AQL inspection on 56 units of retained product, wherein zero (0) additional defects were identified (Attachment 9). As previously indicated with the investigation program overhaul, Turbare was also undergoing procedural enhancements to the visual inspection program to ensure a robust program is in place. Nonetheless, as a result of the observation noted during the inspection, Turbare initiated INC-25-002 as a retrospective investigation to determine root cause(s) of the events, necessary corrective actions, and to assess implementation plans moving forward (Attachment 10). DCR-063, *Visual Inspection Program Enhancements*, was opened on 20-JAN-2025 to track all the necessary changes to the visual inspection program (Attachment 11) and is discussed in detail below in the responses to observations 2 and 3.

Although Turbare vehemently believes there is no negative impact as a result of the AQL sampling criteria, out of an abundance of caution, Turbare has elected to voluntarily recall the two lots mentioned above to further show unwavering commitment to quality standards. Turbare will initiate the request for a voluntary recall on 12-FEB-2025 and all documented efforts regarding the recall activities will be provided in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025.

OBSERVATION 2:
Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet appropriate statistical quality control criteria as a condition for their approval and release.

Specifically,

Your firm's AQL sampling of 2% of the batch (15 syringes) is not statistically significant. In addition, acceptance criteria is not appropriately applied from AQL results.

Avastin repackaged lot 12192024@2, expiry 4/18/2025, had two major defects identified, both for particulate matter, during AQL sampling out of fifteen syringes evaluated. Your firm's AQL limit for major defects is 1.0%. Your firm calculated the AQL limit against the entire batch size of 729 syringes resulting in 0.3% major defects. Two syringes out of fifteen represents approximately 13% major defects in the AQL sample. Your firm passed this AQL result with no investigation or additional product inspection. This batch was released for distribution.

Avastin repackaged lot 12122024@2, expiry 3/14/2025, failed initial 100% visual inspection and was reinspected. After the 200% inspection was complete an AQL was performed. This AQL was performed with a sample size of fifteen syringes. One major defect for underfill was found during this AQL. Your firm's AQL limit for major defects is 1.0%. Your firm reported a result against the entire batch size of 739 syringes and resulting in 0.1 % major defects. One out of fifteen represents approximately 7% major defects in the AQL sample. Your firm passed this AQL with no investigation or additional product inspection. This batch was released for distribution.

Response to Observation 2:

Turbare acknowledges the deficiencies in the previous AQL sampling methodology, statistical justification, and failure to properly investigate atypical AQL results. As previously indicated, significant improvements and updates to the existing program were already being evaluated and updated at the time of the inspection. However, Turbare also acknowledges the lack of documentation available to support the ongoing efforts that had been made in this respect. As such, the following corrective and preventive actions have been taken to address the deficiencies not only with the AQL portion of the visual inspection program, but the program as a whole to ensure compliance with cGMP regulations.

SOP-075, *Acceptable Quality Limit (AQL) Inspection* (Version 01), was immediately updated to reflect statistically significant AQL figures based on ANSI/ASQ Z1.4 standard tables (Attachment 12) while ongoing efforts were being established to ensure a robust visual inspection program. Based on the updated AQL requirements, all calculations will be performed based on General Inspection Level II sampling requirements as outlined in ANSI/ASQ Z1.4. SOP-075 (Version 01) was immediately approved and implemented on 14-JAN-2025 to support the requirement to inspect additional units to ensure compliance. In tandem, DCR-063, *Visual Inspection Program Enhancements* (Attachment 11), was initiated on 20-JAN-2025 to enhance the overall visual inspection program to also outline requirements for failed AQL inspections, establish meaningful alert limits based on defect criticality, and to establish requirements in which investigations shall be initiated into atypical events. SOP-075 (Version 02) was made effective on 10-FEB-2025 (Attachment 13).

Specifically, the following documents were created as part of DCR-063 (Attachment 11) to enhance the qualification of personnel and processes related to visual inspection:

- SOP-075 (Version 02), *Acceptable Quality Limit (AQL) Inspection* (Attachment 13)
- SOP-061 (Version 02), *100% Visual Inspection* (Attachment 14)
- SOP-050 (Version 02), *Use and Maintenance of Extech Digital Light Meter* (Attachment 15)
- SOP-046 (Version 02), *Use and Maintenance of MIH-PORT Portable Inspection Station* (Attachment 16)
- MBR-002 (Version 01), *Primary Visual Inspection of Repackaged Syringe Master Batch Record* (Attachment 17)
- MBR-003 (Version 01), *Secondary Visual Inspection of Repackaged Syringe Master Batch Record* (Attachment 18)
- MBR-004 (Version 01), *Tertiary Visual Inspection of Repackaged Syringe Master Batch Record* (Attachment 19)

In addition to the above actions taken by Turbare, investigation INC-25-002, was initiated on 21-JAN-2025 to assess root cause and track all additional measures taken as a result (Attachment 10). As part of the investigation, a retrospective evaluation of all released batches using the previous AQL methodology was conducted to ensure these two incidents were isolated events. As no other events were identified in which defects were observed in the AQL inspection, the investigation focused on the two lots in question, 12192024@2 and 12122024@2. As indicated previously, an additional AQL inspection was conducted on 56 units of retained product for both lots, wherein zero (0) additional defects were identified (Attachment 9). A review of customer complaints and Adverse Drug Events (ADEs) was also conducted as part of the preliminary investigation where it was identified there have been zero (0) customer complaints or ADEs regarding either batch. As part of the investigation, additional AQL inspections were conducted with all unreleased lots at the facility under the new

procedure with the updated sampling requirements. The investigation was closed 12-FEB-2025 and has been provided in Attachment 10.

Although Turbare vehemently believes there is no negative impact as a result of the AQL sampling criteria, out of an abundance of caution, Turbare has elected to voluntarily recall the two lots mentioned above to further show unwavering commitment to quality standards. Turbare will initiate the request for a voluntary recall on 12-FEB-2025 and all documented efforts regarding the recall activities will be provided in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025.

OBSERVATION 3:
Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and drug product.

Specifically,

The defects contained in the visual inspection qualification kit are not well defined and contain approximately 80% defects. Your firm's classification of defects is not scientifically justified. Your firm's critical, major, and minor defect classifications are not defined in any procedure and defects have not been assessed for risk to patient. According to your firm's CEO, the defects for each category are:

Critical: container closure breach, discoloration or cloudiness, and cracked/broken container
Major: over fill, under fill, dark particulate, and light particulate
Minor: cosmetic defect or other defect

Response to Observation 3:
Turbare understands the need for robust written procedures outlining the qualification criteria for visual inspection. As outlined in the response to Observation 2 above, Turbare has committed to ensuring a robust visual inspection program including in-process controls, establishing meaningful trends, and ensuring a rigorous qualification program is in place. An assessment of SOP-061, *Visual Inspection* (Version 02)(Attachment 14), was conducted wherein it was identified that the current qualification program at Turbare requires additional development to ensure a comprehensive training program is established. As a result, DCR-064, *Visual Inspection Qualification Enhancements* (Attachment 20) was initiated on 20-JAN-2025 to include the creation of qualification procedures with corresponding forms, logs, and visual aids to ensure a robust and scientifically justified approach is addressed in qualification activities.

Specifically, the following documents were created as part of DCR-064 (Attachment 20) to enhance the qualification of personnel and processes related to visual inspection:

- SOP-084 (Version 01 Draft), *Visual Inspection Personnel Qualification* (Attachment 21)
- FRM-077 (Version 01 Draft), *Visual Inspection Personnel Qualification Record* (Attachment 22)
- LOG-043 (Version 01 Draft), *Visual Inspection Personnel Qualification Log* (Attachment 23)
- SOP-086 (Version 01 Draft), *Visual Inspection Exhibit Qualification* (Attachment 24)
- FRM-076 (Version 01 Draft), *Visual Inspection Exhibit Qualification Record* (Attachment 25), and
- LOG-042 (Version 01 Draft), *Visual Inspection Exhibit Qualification Log* (Attachment 26)

The qualification component of DCR-064 (Attachment 20) will focus not only on personnel qualifications, but also on exhibit development and qualification to establish a robust training program, consistency across operators, and qualification simulations in alignment with standard manufacturing processes. As part of the improvements, qualification test kits will be redesigned to contain a representative mix of acceptable product and known defect types, reducing defect concentration to ~10%, ensuring realistic training conditions. The defects obtained for qualification purposes will be indicative of the manufacturing process with adequate documentation outlining review and approval of each unit for qualification purposes. As the qualification component to the visual inspection program requires adequate time and oversight, the proposed

timeframe for the completion of all activities associated within DCR-064 (Attachment 20) is eight (8) weeks, with all relevant updates to be provided in the 2025-Q1 response update scheduled for submission to the Agency by 30-Apr-2025.

As part of the procedural updates captured under DCR-063 (Attachment 11) and DCR-064 (Attachment 20) an evaluation of empirical data and trends over the next six (6) months shall be a cornerstone of the visual inspection enhancements and will drive to establish meaningful thresholds during both qualification activities and visual inspection operations. CAPA-007, *Visual Inspection Program Overhaul* (Attachment 27) encompasses both DCR-063 (Attachment 11) and DCR-064 (Attachment 20) to effectively track completion of all required activities as a part of the visual inspection program overhaul. As qualification activities will take longer to implement, Turbare intends to close the CAPA in a phased approach, ensuring all critical components are adequately assessed and monitored as a result. Turbare expects approval and implementation of this CAPA to be completed in Apr-2025. A copy of the approved CAPA and all supporting documentation along with applicable personnel training will be provided in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025.

To address the deficiencies noted by the Agency in regards to defect classifications, Turbare has made prompt revisions to the existing visual inspection procedure to ensure all staff are trained on appropriate defect classifications based on potential safety risk. As part of DCR-063 (Attachment 11), a central component focused on updating SOP-061, *Visual Inspection* (Version 02, Attachment 14), to establish a robust defect classification system for critical, major, and minor defect categories with corresponding alert limits for each classification, requiring additional action. The defect classifications and corresponding definitions now more closely reflect the requirements as outlined in USP <790> and USP <1790>. As defect classifications and the appropriate assessment of patient risk are of utmost importance to Turbare, DCR-063 (Attachment 11) became effective on 10-Feb-2025. A copy of the initiation form, all impacted documents made effective, and applicable training on each document has been included in Attachment 11.

OBSERVATION 4:
Employees engaged in the manufacture and processing of a drug product lack the training and experience required to perform their assigned functions.

Specifically,

1) *Qualification of your visual inspectors is deficient, for example:*
   - *Your firm does not qualify inspection speed. During production 100 syringes can be inspected in less than 20 minutes, however, no documented inspection time was recorded during qualification activities.*
   - *The characteristics of the defects within the qualification kit are not well defined. For example, particulate defects are listed as "light" or "dark" particulate matter of unknown size and composition. Your firm cannot evaluate the capabilities of visual inspectors without developing a well defined qualification kit.*
   - *Your firm does not simulate fatigue during qualification.*
   - *Defects in the qualification kit were prepared in house and the kit does not contain defects based on rejects from actual production. Particulate defects made in house do not necessarily represent defects that would be found from production.*
2) *Your firm does not have a reject library from which training and familiarization of defects can be studied by new hires or for refresher training.*

Response to Observation 4:
As previously indicated in responses to Observations 2 and 3, Turbare acknowledges the importance of having written procedures that describe, justify, and document the in-process controls, tests, and examinations of each batch. DCR-063 (Attachment 11) was initiated on 20-JAN-2025 to address substantive improvement efforts to the visual inspection program and DCR-064 (Attachment 20) was initiated on 20-JAN-2025 to address the qualification component as it relates to the visual inspection program. Both DCRs encompass multiple SOPs, FRMs, LOGs, and associated MBRs to explicitly document workflows and requirements for visual inspection operations. As it relates to visual inspection qualification in

particular, SOP-084, *Visual Inspection Personnel Qualification* (Version 01 Draft, Attachment 21), has been included under DCR-064 (Attachment 20) to establish meaningful qualification activities to ensure personnel engaged in visual inspection operations are adequately trained to perform assigned job functions. SOP-084 (Attachment 21) includes the establishment of test kits in sufficient quantities to qualify inspection speed to ensure qualification events mimic normal production operations. Additionally, this procedure also outlines fatigue simulation requirements to ensure qualification activities allow for worst-case simulations. FRM-077, *Visual Inspection Personnel Qualification Record* (Version 01 Draft, Attachment 22), has also been included under DCR-064 (Attachment 20) to document inspection times during qualification activities. Additionally, LOG-043, *Visual Inspection Personnel Qualification Log* (Version 01 Draft, Attachment 23), has been established to adequately track and monitor qualification events and requalification timeframes.

As it relates to the characteristics of the defects within the qualification kit, DCR-064 (Attachment 20) also includes the creation of SOP-086, *Visual Inspection Exhibit Qualification* (Version 01 Draft, Attachment 24), which establishes requirements for qualification exhibits used for visual inspection personnel training and qualification. This procedure clearly outlines defect characteristics, creation and maintenance of qualification units, identification of units, and qualification and requalification requirements to ensure a well-defined qualification kit is selected from a larger sample of potential units. Each qualification unit will be appropriately evaluated by multiple Turbare staff via FRM-076, *Visual Inspection Exhibit Qualification Record*, and properly managed via LOG-042, *Visual Inspection Exhibit Log* (Attachments 25 and 26). These exhibit qualification units will contain defects from actual production primarily to ensure training and qualification activities are in alignment with standard manufacturing processes. In addition, the exhibit qualification sets will ensure a reject library exists for new hire training and/or employee refresher training as required.

As previously indicated, DCR-064 (Attachment 20) is targeted for completion on 07-APR-2025 with all relevant updates to be provided in the 2025-Q1 response update scheduled for submission to the Agency by 30-Apr-2025. As part of the closure requirements, all new hires will undergo qualification under the new program and all existing visual inspection personnel will undergo requalification on the updated process by 12-APR-2025. The annual requalification requirement will also ensure trends are adequately documented and assessed as required.

OBSERVATION 5:
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

Aseptic processing simulations were performed without protocols developed for defining acceptance criteria and worst-case conditions to be simulated. Your firm is currently performing media fills on the 0.25mL syringe size at 25% of routine batch size without a documented rationale. According to your firm's CEO, this reduced batch size is used after process validation has been completed and operator qualification is being performed.

In addition, your firm qualified operators utilizing various syringe sizes; 0.25mL, 1.0mL, and 50mL without a documented rationale for this bracketing. Your firm's current commercial product uses a 0.25mL syringe size with a batch size of 756 syringes. The 50mL syringe media fill is approximately 180 syringes with a shorter fill time and different processing steps than commercial production.

Response to Observation 5:
Turbare understands the need to strengthen aseptic process validation procedures, define clear rationale for media fill batch sizes and bracketing, and ensure all process simulations reflect worst-case conditions. As a point of clarification, Turbare would like to note that the statement *"Your firm is currently performing media fills on the 0.25mL syringe size at 25% of routine batch size[...]"* is inaccurate. Turbare performs aseptic process validation media fills of all aseptic processes at the full intended commercial scale batch size. The media fill identified in observation 5 which was listed at 25% of the routine batch size applied only to the qualification of specific personnel ("Aseptic Personnel Qualification") and NOT qualification of the established aseptic process. This is evidenced by Turbare's execution of *Summary Report Process Qualification for*

Repackaged 0.07mL of Sterile Product in StaClear Syringes with the media fill performed at full production scale in triplicate. (Attachment 28)

A formal media fill protocol was established on 03DEC2024 under TEM-028, *Syringe Repackaging Media Fill Protocol* (Attachment 29) that governs aseptic process qualification requirements including a maximum batch size of NLT 850 syringes. Although initial aseptic processing simulations were performed prior to the protocol approval defining acceptance criteria and worst-case conditions to be simulated, there is no negative impact as a result. For purposes of initial qualification, media fills were performed in triplicate at full scale on 13MAY2024 through 15MAY2024 to verify a high level of reproducibility prior to commercialization of product with passing results obtained (Attachment 30). However, to ensure appropriate documentation around the event, and to ensure this does not occur in the future, an investigation has been initiated under DEV-25-004 to assess root cause, corrective measures taken as a result, and to document ongoing continuous improvement initiatives as it relates to aseptic process qualification requirements (Attachment 31).

Aseptic Personnel Qualifications are conducted separately from aseptic *process* simulations and are conducted in each family specific media fill at a minimum of 25% of the family of drug product specific maximum batch size and are explicitly outlined in SOP-072, *Personnel Aseptic Qualification* (Version 01, Attachment 32). Personnel aseptic qualifications are an additional measure employed by Turbare as it relates to aseptic process simulations. As outlined in FDA Guidance for Industry – Sterile Drug Products Produced by Aseptic Processing (2004), routine media fills to demonstrate aseptic processing control are governed by SOP-074, *Aseptic Process Qualification* (Version 01, Attachment 33) in which the standard practice at Turbare includes aseptic process simulations that mimic routine batch sizes. Nonetheless, Turbare is committed to addressing the deficiencies noted during the inspection.

During requalification activities on 30JAN2025, MFP-25-001, *Syringe Repackaging Media Fill Protocol,* (Attachment 34) was utilized to ensure acceptance criteria, worst-case conditions, and processing parameters to be simulated were clearly outlined and approved prior to requalification events. As Turbare is currently awaiting incubation results, a summary report will be generated, reviewed, and approved for full closure of the requalification event. As part of the requalification requirements, personnel involved were adequately trained on the protocol and all training documentation shall be included with the summary report, along with any other supporting documentation, and provided in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025.

OBSERVATION 6:
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically,

Your firm's media fill procedure, SOP-039, was not implemented prior to performing media fills. Your firm's media fill procedure was implemented on 6/12/2024. This procedure does not define acceptance criteria, routine and non-routine interventions to be performed, fill volume, or minimum fill time to be achieved for each process to be simulated.

Your firm performed 12 media fills prior to implementing any media fill procedure. In addition, no media fill protocols were developed until 11/21/2024. Interventions performed were not documented until protocols were developed. One technician used in routine production has not performed a media fill on the 0.25mL syringe process since procedures were developed.

Response to Observation 6:
Turbare acknowledges the deficiencies noted in the existing media fill program and have taken steps to ensure full compliance with FDA guidelines for aseptic processing. As part of continuous improvement, a need to strengthen the aseptic process validation procedures and defining clear rationale for media fill batch sizes was recognized in October 2024. Thus, DCR-037, *Implementation of Personnel Aseptic Qualification*, and DCR-039, *Implementation of Aseptic Process Qualification*, (Attachment 35 and 36) were initiated on 11NOV2024. SOP-072, *Personnel Aseptic Qualification* (Version 01, Attachment 32), and SOP-074, *Aseptic Process Qualification* (Version 01, Attachment 33), were made effective on

13NOV2024. The newly established procedures define acceptance criteria, routine and non-routine interventions to be performed, and minimum fill time to be achieved for each process simulated in alignment with FDA guidance on aseptic processing. As of 21-NOV-2024, all process qualifying or requalifying media fills shall be conducted per approved protocols with the documentation of interventions as a mandatory component. In response to this observation, DCR-065, *Media Fill Program Enhancements* was initiated on 23JAN2025 to perform a comprehensive analysis of the media fill program to include enhancements to existing procedures and processes (Attachment 37). As part of the DCR, SOP-039, *Media Fills*, was obsoleted and SOP-074, *Aseptic Process Qualification* (Version 02 Draft, Attachment 38), defined procedures specific to respective process qualification events. Aseptic process simulation requalification was scheduled for 30JAN2025, and applicable documentation shall be included in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025. Additionally, the technician who has not performed a media fill on the 0.25mL syringe process will complete a qualification within the protocol initiated 30JAN2025.

Turbare is committed to maintaining compliance with FDA aseptic processing requirements and ensuring that all procedures governing media fills meet regulatory expectations. In regard to the 12 process qualifying media fills performed prior to the implementation of any media fill procedure; a retrospective review of previous media fills was conducted via DEV-25-004 (Attachment 31) to assess potential impact. The retrospective review concluded there have been zero (0) sterility failures or otherwise negative implications as a result. Employees have been adequately trained on the new processes and a periodic media fill schedule with appropriate Quality oversight has been established to ensure all processes and personnel remain qualified via LOG-033, *Media Fill Qualification Log* (Version 02, Attachment 39). Further, TEM-028, *Syringe Repackaging Media Fill Protocol*, was established on 03-DEC-2024 to ensure a media fill protocol/template exists which clearly outlines the requirements to be achieved for each process to be simulated (Attachment 29). For any new product development initiatives, Turbare is committed to establishing robust media fill protocols specific to each individualized process.

OBSERVATION 7:
Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

Your firm does not have a procedure to govern environmental monitoring investigations into alert and action limits being reached during routine sampling. Your firm's investigation procedure, Investigation Program, SOP-081, effective 1/7/2025, states that the routine environmental monitoring procedure governs excursions and investigations in environmental monitoring. The routine environmental monitoring procedure does not require an investigation into action levels being reached for sample results. Action responses are not defined within the environmental monitoring procedure.

Response to Observation 7:
Upon review of the observation, Turbare recognizes the need to establish a robust environmental monitoring program and define clear action responses for excursions. As SOP-081, *Investigation Program* (Version 01, Attachment 40), was recently revamped as part of ongoing continuous improvement initiatives, Turbare intends to create a separate Environmental Monitoring Excursion Response procedure to adequately govern investigation requirements as it relates to environmental monitoring excursions. As such, DCR-071 was initiated on 10-FEB-25 (Attachment 2) to include updates to SOP-048, *Routine Environmental Monitoring*, to reference the new excursion response procedure as well as to create SOP-087, *Environmental Monitoring Excursion Response*. The new procedure will appropriately define action levels, alert limits, and corresponding investigation requirements to include clear criteria for investigation requirements, defined steps for conducting root cause analyses, impact assessments, corrective actions required, and documentation and approval requirements for closure. As part of the DCR, any relevant forms and logs associated with excursion reporting shall also be established for tracking purposes. All relevant personnel will be retrained on the updated procedures and associated training records shall be provided along with other supporting documentation in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025.

OBSERVATION 8:
Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

Specifically,

Your firm does not require a second reviewer for environmental monitoring results unless 1 colony forming unit (CFU) is found. A single technician reads environmental plate counts and the worksheet with results is later reviewed, however, the physical plates are not verified unless growth is present.

Response to Observation 8:
Turbare recognizes the need to enhance existing procedures for verifying environmental monitoring results to ensure compliance with regulatory expectations. To address the deficiency noted, DCR-071 (Attachment 2) was initiated on 10-FEB-2025 to create SOP-088, *Reading of Microbiological Culture Media* to mandate a second person review of all environmental monitoring results, irrespective of colony-forming unit (CFU) count. As part of the change, all environmental monitoring plates will be subject to independent verification by a second qualified microbiologist or designated quality personnel. Additionally, associated training for all relevant staff will be included as part of the procedural updates to ensure adequate knowledge of the process and understanding of verification requirements. As a long-term measure, Turbare is also committed to performing periodic quality audits of laboratory records to confirm adherence to the new procedure. DCR-071 (Attachment 2) is targeted for completion in March-2025 and will be provided in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025.

Conclusion
Turbare respectfully submits these responses with a commitment to full compliance with FDA regulations. Turbare appreciates the opportunity to demonstrate its willingness and ability to comply with all requirements and expectations for 503B outsourcing facilities by completing the corrective actions described herein. Turbare is hopeful that continued collaborative and open dialogue can occur and welcomes the Agency's feedback on these planned corrective actions to ensure practices meet regulatory expectations. The following page summarizes the actions and timelines for completion, with follow-up with the Agency to occur in the 2025-Q1 response update scheduled for submission to the Agency on 30-Apr-2025 through completion of all items.

As further evidence of Turbare's commitment to compliance with the Agency's concerns, for all verbal discussion points, Turbare has also provided a separate formal response below to outline the corrective measures Turbare has taken, or intends to take, to ensure a robust quality system is in place at the facility. Should you require any additional information or verification of any of the proposed corrective actions contained within, please do not hesitate to reach out in the interim.

Summary of Actions with Timelines for Completion

Observation	Corrective Action Reference	Target Completion
1A	NCR-25-002 for Mold Growth Recovery DCR-071, *Environmental Monitoring Program Enhancements* SOP-048, *Routine Environmental Monitoring*	Mar-2025
1B	SOP-048, *Routine Environmental Monitoring* TEM-034, *EM Excursion Template* DCR-071, *Environmental Monitoring Program Enhancements* SOP-087, *Environmental Monitoring Excursion Response* DCR-067, *Waste Disposal Program* FRM-078, *Waste Destruction Record* LOG-044, *Waste Destruction Log*	Mar-2025
1C	MBR for Lot 12122024@2 MBR for Lot 12192024@2 AQL Forms for Retention Samples Evaluated INC-25-002 Investigation into AQL Discrepancy DCR-063, *Visual Inspection Program Enhancements* Recall of Lots 12122024@2 and 12192024@2	Feb/Mar-2025
2	SOP-075, *Acceptable Quality Limit (AQL) Inspection* (Version 01) SOP-075, *Acceptable Quality Limit (AQL) Inspection* (Version 02) SOP-061, *100% Visual Inspection* SOP-050, *Use and Maintenance of Extech Digital Light Meter* SOP-046, *Use and Maintenance of MIH-Port Portable Inspection Station* MBR-002, *Primary Visual Inspection of Repackaged Syringe Master Batch Record* MBR-003, *Secondary Visual Inspection of Repackaged Syringe Master Batch Record* MBR-004, *Tertiary Visual Inspection of Repackaged Syringe Master Batch Record* AQL Forms for Retention Samples Evaluated INC-25-002 Investigation into AQL Discrepancy DCR-063, *Visual Inspection Program Enhancements* Recall of Lots 12122024@2 and 12192024@2	Feb/Mar-2025
3	DCR-064, *Visual Inspection Qualification Enhancements* SOP-084, *Visual Inspection Personnel Qualification* FRM-077, *Visual Inspection Personnel Qualification Record* LOG-043, *Visual Inspection Personnel Qualification Log* SOP-086, *Visual Inspection Exhibit Qualification* FRM-076, *Visual Inspection Exhibit Qualification Record*	Apr-2025

	LOG-042, *Visual Inspection Exhibit Qualification Log* CAPA-007, *Visual Inspection Program Overhaul*	
4	DCR-063, *Visual Inspection Program Enhancements* DCR-064, *Visual Inspection Qualification Enhancements* SOP-084, *Visual Inspection Personnel Qualification* FRM-077, *Visual Inspection Personnel Qualification Record* LOG-043, *Visual Inspection Personnel Qualification Log* SOP-086, *Visual Inspection Exhibit Qualification* FRM-076, *Visual Inspection Exhibit Qualification Record* LOG-042, *Visual Inspection Exhibit Qualification Log*	Apr-2025
5	SOP-072, *Personnel Aseptic Qualification* SOP-074, *Aseptic Process Qualification* (Version 01) *Summary Report Process Qualification for Repackaged 0.07mL Sterile Product in StaClear Syringes* TEM-028, *Syringe Repackaging Media Fill Protocol Template* Initial Qualification Media Fill Results DEV-25-004 for Lack of Established Protocol Prior to Media Fill MFP-25-001, *Syringe Repackaging Media Fill Protocol*	Feb-2025
6	DCR-037, *Implementation of Personnel Aseptic Qualification* DCR-039, *Implementation of Aseptic Process Qualification* DCR-065, *Media Fill Program Enhancements* SOP-074, *Aseptic Process Qualification* (Version 02 Draft) DEV-25-004 for Lack of Established Protocol Prior to Media Fill LOG-033, *Media Fill Qualification Log* TEM-028, *Syringe Repackaging Media Fill Protocol Template*	Feb-2025
7	DCR-071, *Environmental Monitoring Program Enhancements* SOP-081, *Investigation Program* SOP-087, *Environmental Monitoring Excursion Response*	Mar-2025
8	DCR-071, *Environmental Monitoring Program Enhancements* SOP-088, *Reading of Microbiological Culture Media*	Mar-2025

List of Attachments

Attachments	Description
1	NCR-25-002 for Mold Growth Recovery from PM of Media Fill Lot 11252024@1MM
2	DCR-071, *Environmental Monitoring Program Enhancements*
3	TEM-034, *EM Investigation Template*
4	DCR-067, *Drug Product Disposal Requirements*
5	FRM-078, *Drug Product Disposal Record*
6	LOG-044, *Drug Product Disposal Log*
7	MBR for Lot 12122024@2
8	MBR for Lot 12192024@2
9	AQL Forms for Retention Samples Evaluated
10	INC-25-002 Investigation into AQL Discrepancy
11	DCR-063, *Visual Inspection Program Enhancements*
12	SOP-075, *Acceptable Quality Limit (AQL) Inspection* (Version 01)
13	SOP-075, *Acceptable Quality Limit (AQL) Inspection* (Version 02)
14	SOP-061, *100% Visual Inspection* (Version 02)
15	SOP-050, *Use and Maintenance of Extech Digital Light Meter* (Version 02)
16	SOP-046, *Use and Maintenance of MIH-PORT Portable Inspection* Station (Version 02)
17	MBR-002, *Primary Visual Inspection of Repackaged Syringe Master Batch Record* (Version 01)
18	MBR-003, *Secondary Visual Inspection of Repackaged Syringe Master Batch Record* (Version 01)
19	MBR-004, *Tertiary Visual Inspection of Repackaged Syringe Master Batch Record* (Version 01)
20	DCR-064, *Visual Inspection Qualification*
21	SOP-084, *Visual Inspection Personnel Qualification* (Version 01 Draft)
22	FRM-077, *Visual Inspection Personnel Qualification Record* (Version 01 Draft)
23	LOG-043, *Visual Inspection Personnel Qualification Log* (Version 01 Draft)
24	SOP-086, *Visual Inspection Exhibit Qualification* (Version 01 Draft)
25	FRM-076, *Visual Inspection Exhibit Qualification Record* (Version 01 Draft)
26	LOG-042, *Visual Inspection Exhibit Qualification Log* (Version 01 Draft)
27	CAPA-007, *Visual Inspection Program Overhaul*
28	*Summary Report Process Qualification for Repackaged 0.07mL of Sterile Product in StaClear Syringes*

Attachments	Description
29	TEM-028, *Syringe Repackaging Media Fill Protocol Template*
30	Initial Qualification Media Fill Results
31	DEV-25-004 for Lack of Established Protocol Prior to Media Fill Execution
32	SOP-072, *Personnel Aseptic Qualification* (Version 01)
33	SOP-074, *Aseptic Process Qualification* (Version 01)
34	MFP-25-001, Syringe Repackaging Media Fill Protocol
35	DCR-037, *Implementation of Personnel Aseptic Qualification*
36	DCR-039, *Implementation of Aseptic Process Qualification*
37	DCR-065, *Media Fill Program Enhancements*
38	SOP-074, *Aseptic Process Qualification* (Version 02 Draft)
39	LOG-033, *Media Fill Qualification Log* (Version 02)
40	SOP-081, *Investigation Program* (Version 01)
41	Verbal Observation Response
42	DCR-059, *Complaint Process Overhaul*
43	SOP-031, *Adverse Drug Event Reporting* (Version 02)
44	DCR-073, *Biannual Reporting*
45	SOP-029, *Biannual Product Reporting* (Version 01 Draft)
46	December 2024 Report

4HHH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FW8979520
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04565		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: WP Pharma Labs

Physical Address: 4001 McEwen Rd, STE 110

City: Dallas State: Texas Zip: 75244

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 469-722-4500 Toll Free # (NAC 639.708, NRS 639.23286): 800-441-0048

Fax: 800-715-6589 Contact Email: regulatoryaffairs@wppharmalabs.com

Website: www.wppharmalabs.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jerry Lance May

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22115

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jerry Lance May	NV Pharmacist Registration #: 22115
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): _____

Corporation/Organization Name: WP Pharma Labs Inc

Mailing Address: 4001 McEwen Rd, STE 110

City: Dallas State: Texas Zip: 75244

Telephone: 469-722-4500 Email: regulatoryaffairs@wppharmalabs.com

Contact Person Name: Kim Hiddessen

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacy Manager (title) for WP Pharma Labs Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Kim Hiddessen

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

3/25/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kim Hiddessen

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

3/25/2025

Date

Board Use Only	Date Received: 4/4/25	Amount: $500-ck 2247

BALOGH LAW LTD.
6680 Alhambra Ave., Ste 101
Martinez, CA 94553
925-575-8056

Jason Balogh
jason@baloghlaw.com
510-473-2697 (direct)

The complaint alleges that WP Pharma has marketed, sold, and distributed misbranded drugs and violated the FD&C Act Sections 502(a) and 201(n). The crux of the complaint are allegations that WP Pharma compounded BPC-157, CJC-1295, DHH-B, GHK-Cu, Ipamorelin, Melanotan II, Thymosin Alpha-1, and Thymosin Beta-4. A specific time period is not specified for which the alleged violations occurred.

As background, a competitor of WP Pharma, Empower Pharmacy CEO Shaun Noorian formed a limited liability company named Coalition for Responsible Compounding. Mr. Noorian through the LLC has sent inaccurate complaints to each state board of pharmacy in an attempt to harm his competitors. Mr. Noorian has sent the same complaint to every state board accusing many of his competitors of committing the exact same violations. These complaints have led to multiple lawsuits against the LLC. In the event these complaints ever lead to any action taken by a state board, WP Pharma will timely provide notice of that discipline as required by any applicable regulation or statute.

The allegation, taken as a whole, is untrue. WP Pharma has never sold or distributed DHH-B, GHK-Cu, or Melanotan II in Oregon. Furthermore, WP Pharma has not compounded with any unapproved bulk drug substances, including those listed in the letter since the FDA issued its relevant Interim Policy on Compounding Using Bulk Drug Substances in December 2023. In fact, WP Pharma voluntarily ceased compounding with any of the specified substances as early as September 2023. The last prescription filled in Oregon containing any currently unapproved bulk drug substance was filled on October 10, 2023.

WP Pharma maintains strict adherence to the FDA's standards governing the use of bulk drug substances in compounding, as well as the applicable United States Pharmacopoeia (USP) and National Formulary monographs where such exist. WP Pharma compounding processes are rigorously overseen by licensed pharmacists who follow all appropriate compounding protocols to ensure the safety and efficacy of the products dispensed. WP Pharma asserts that all compounded products dispensed into the state of Oregon were compounded with substances believed to be compliant with FDA standards, and WP Pharma had a reasonable belief that the products met all legal and regulatory requirements.

Yours truly,

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

WP PHARMA LABS, INC. D/B/A WP PHARMA LABS

LOUISIANA PHARMACY PERMIT NO. 8392 **Case No. 24-0059**

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on September 18, 2024 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of WP PHARMA LABS, INC. D/B/A WP PHARMA LABS (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 8392, 4001 McEwen Road, Suite 110, Dallas, Texas 75244, with pharmacy representative Melissa Stefko and attorney Jason Balogh appearing on behalf of Respondent.

WHEREAS, WP Pharma Labs dispensed approximately 606 prescriptions of compounding products into Louisiana that failed to conform to the minimal standards of acceptable pharmacy practice. Specifically, these products were compounded with unapproved bulk drug substances that are not eligible for human compounding.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37: 1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

LAC 46:LIII.2535: General Standards: A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the- counter medications, chemicals, compounds, or other components

2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, and in compliance with the Federal Food, Drug and Cosmetic Act of 1938 (FDCA) as subsequently amended, the current edition of Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the United States Pharmacopeia-National Formulary.

a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503-A of the FDCA and USP Chapter 797.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

WP PHARMA LABS, INC. D/B/A WP PHARMA LABS is ordered pay a fine of $9,090.00, and reimburse the Board $250.00 for administrative costs and $929.94 for investigative costs, with total payment due the Board of $10,269.94, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, recission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Nikki Good, authorized to act on behalf of and acting on behalf of WP PHARMA LABS, INC. D/B/A WP PHARMA LABS, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

SIGNED, AGREED TO AND ENTERED ON THIS 18 DAY OF October, 2024.

WP PHARMA LABS, INC. D/B/A WP PHARMA LABS – Louisiana Pharmacy Permit No. 8392

BY:
Authorized Representative

JASON BALOGH
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on November 20, 2024, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
President & Hearing Officer for the Board

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

JERRY LANCE MAY

PHARMACIST LICENSE NO. 22491 **Case No. 24-0242**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on September 18, 2024 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of **JERRY LANCE MAY** (hereinafter referred to as "Respondent"), holder of PHARMACIST LICENSE NO. 22491, with attorney Jason Balogh present on behalf of Respondent.

WHEREAS, WP Pharma Labs dispensed approximately 606 prescriptions of compounding products into Louisiana that failed to conform to the minimal standards of acceptable pharmacy practice. Specifically, these products were compounded with unapproved bulk drug substances that are not eligible for human compounding.

WHEREAS, Respondent serves as Pharmacist-in-Charge of WP Pharma Labs' non-resident Louisiana pharmacy permit, PHY.008392-NR.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37: 1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

LAC 46: LIII.2535: General Standards: A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the- counter medications, chemicals, compounds, or other components

2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, and in compliance with the Federal Food, Drug and Cosmetic Act of 1938 (FDCA) as subsequently amended, the current edition of Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the United States Pharmacopeia-National Formulary.

a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503-A of the FDCA and USP Chapter 797.

LAC, Title 46: LIII §2307(C): Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

JERRY LANCE MAY is ordered to pay a fine of $5,000.00 and reimburse the Board $250.00 for administrative costs, for a total of $5,250.00 due by *certified check or money order* at the signing of this agreement.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon his signing said Order.

I, **JERRY LANCE MAY**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of my case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

Respondent agrees that Respondent's execution of this Consent Agreement grants the Board the authority to collect any monies owed pursuant to this Consent Agreement and not paid to the Board notwithstanding the Board's acceptance of this Consent Agreement.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

SIGNED, AGREED TO AND ENTERED ON 17 DAY OF October, 2024.

Jerry Lance May

JERRY LANCE MAY
PHARMACIST LICENSE NO. 22491

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

Carlos Finalet

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on November 20, 2024, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay

Marty R. McKay
President & Hearing Officer for the Board

WPPHARMA LABS

4001 McEwen Rd, STE 110 | Dallas, Texas 75244 | 800-441-0048

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521
Tel: 775-850-1440

RE: WP Pharma Labs Inc. (NCPDP # 5930296)
Nevada Non-Resident Pharmacy License # PH04565

Effective immediately, Mr. Michael Flora will be replacing Ms. Nikki Good as an officer at our pharmacy. Please see below for the new officers assigned:

Michael Flora, VP of Operations
[redacted]

Kim Hiddessen, Pharmacy Manager
[redacted]

If additional information is needed, please contact us at regulatoryaffairs@wppharmalabs.com.

Alanah Myers, CPhT
Onboarding/Regulatory Specialist
P: (800) 441-0048 Ext. 106
E: regulatoryaffairs@wppharmalabs.com
4001 McEwen Rd, Suite 110
Dallas, Texas 75244
WWW.WPPHARMALABS.COM

WPPHARMA LABS

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for WP Pharma Labs, Inc. (file number 803300056), a Domestic For-Profit Corporation, was filed in this office on April 24, 2019.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on March 19, 2025.

Jane Nelson
Secretary of State

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

David Whitley
Secretary of State

Office of the Secretary of State

CERTIFICATE OF FILING
OF

WP Pharma Labs, Inc.
File Number: 803300056

The undersigned, as Secretary of State of Texas, hereby certifies that a Certificate of Formation for the above named Domestic For-Profit Corporation has been received in this office and has been found to conform to the applicable provisions of law.

ACCORDINGLY, the undersigned, as Secretary of State, and by virtue of the authority vested in the secretary by law, hereby issues this certificate evidencing filing effective on the date shown below.

The issuance of this certificate does not authorize the use of a name in this state in violation of the rights of another under the federal Trademark Act of 1946, the Texas trademark law, the Assumed Business or Professional Name Act, or the common law.

Dated: 04/24/2019

Effective: 04/24/2019

David Whitley
Secretary of State

Form 201		
Secretary of State P.O. Box 13697 Austin, TX 78711-3697 FAX: 512/463-5709 Filing Fee: $300	**Certificate of Formation** **For-Profit Corporation**	Filed in the Office of the Secretary of State of Texas Filing #: 803300056 04/24/2019 Document #: 804243640002 Image Generated Electronically for Web Filing

Article 1 - Entity Name and Type

The filing entity being formed is a for-profit corporation. The name of the entity is:

WP Pharma Labs, Inc.

The name must contain the word "corporation," "company," "incorporated," "limited," or an abbreviation of one of these terms. The name must not be the same as, deceptively similar to or similar to that of an existing corporate, limited liability company, or limited partnership name on file with the secretary of state. A preliminary check for "name availability" is recommended.

Article 2 – Registered Agent and Registered Office

☑ A. The initial registered agent is an organization (cannot be corporation named above) by the name of:

Business Filings Incorporated

OR

☐ B. The initial registered agent is an individual resident of the state whose name is set forth below:

C. The business address of the registered agent and the registered office address is:

Street Address:

701 Brazos Street, Ste. 720 Austin TX 78701

Consent of Registered Agent

☐ A. A copy of the consent of registered agent is attached.

OR

☑ B. The consent of the registered agent is maintained by the entity.

Article 3 - Directors

The number of directors constituting the initial board of directors and the names and addresses of the person or persons who are to serve as directors until the first annual meeting of shareholders or until their successors are elected and qualified are set forth below:

Director 1: Jason McLaren

Address: 4001 McQwen Rd., #110 Dallas TX, USA 75244

Article 4 - Authorized Shares

The total number of shares the corporation is authorized to issue and the par value of each of such shares, or a statement that such shares are without par value, is set forth below.

Number of Shares	Par Value (must choose and complete either A or B)	Class	Series
10000	☑ A. has a par value of $1 ☐ B. without par value.		

If the shares are to be divided into classes, you must set forth the designation of each class, the number of shares of each class, and the par value (or statement of no par value), of each class. If shares of a class are to be issued in series, you must provide the designation of each series. The preferences, limitations, and relative rights of each class or series must be stated in space provided for supplemental information.

Article 5 - Purpose

The purpose for which the corporation is organized is for the transaction of any and all lawful business for which corporations may be organized under the Texas Business Organizations Code.

Supplemental Provisions / Information

[The attached addendum, if any, is incorporated herein by reference.]

Effectiveness of Filing

☑ A. This document becomes effective when the document is filed by the secretary of state.

OR

☐ B. This document becomes effective at a later date, which is not more than ninety (90) days from the date of its signing. The delayed effective date is:

Organizer

The name and address of the organizer is set forth below.

Jason McLaren 4001 McQwen Rd., #110 Dallas, Texas 75244

Execution

The undersigned affirms that the person designated as registered agent has consented to the appointment. The undersigned signs this document subject to the penalties imposed by law for the submission of a materially false or fraudulent instrument and certifies under penalty of perjury that the undersigned is authorized under the provisions of law governing the entity to execute the filing instrument.

Jason McLaren

Signature of organizer

FILING OFFICE COPY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler WP Pharma Labs Inc

Pharmacy/Wholesaler License # (if applicable) 33003

Physical Address 4001 McEwen Dr, STE 110

City Dallas State Texas Zip 75244

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 469-722-4500 Website www.wppharmalabs.com

Licensing Company Email regulatoryaffairs@wppharmalabs.com

Section 2: Personal Information

First Kim Middle M. Last Hiddessen

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Long Island University, Arnold and Marie Schwartz College of Pharmacy		08/94 - 05/03	
Address	**City**	**State**	**Zip**
1 University Plaza	Brooklyn	NY	11201
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Plainview Old Bethpage John F. Kennedy High School		08/90 - 05/94	
Address	**City**	**State**	**Zip**
50 Kennedy Dr	Plainsview	NY	11803
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
06/18-03/25				
From - To (MM/YY – MM/YY)				
09/12-06/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
WP Pharma Labs Inc				
Business Address		**City**	**State**	**Zip**
4001 McEwen Rd, STE 110		Dallas	TX	75244
Phone	**Title**		**Number of Employed Hours**	
469-722-4500	Pharmacy Manager		11,248	
Description of Duties				
Responsible for regulatory and processing prescriptions and managed staff. Oversees and ensures appropriate utilization of medication technology, and computer systems. Oversees pharmacist, technician and intern workflow.				

Business Name			From - To (MM/YY – MM/YY)	
Maverick Pharmacy			09/2018 - 02/2019	
Business Address		**City**	**State**	**Zip**
2155 Chenault Dr		Carrollton	TX	75006
Phone	**Title**		**Number of Employed Hours**	
	Staff Pharmacist / Pharmacist-In-Charge		1,088	
Description of Duties				
Responsible for regulatory and processing prescriptions and managed staff.				

Business Name			From - To (MM/YY – MM/YY)	
Downing Labs/Rockwall Drug & General			03/2015 - 09/2018	
Business Address		**City**	**State**	**Zip**
4001 McEwen Rd, STE 110		Dallas	TX	75244
Phone	**Title**		**Number of Employed Hours**	
214-347-4008	Staff Pharmacist/Pharmacist-In-Charge		6,939	
Description of Duties				
Responsible for regulatory and processing prescriptions and managed staff.				

Business Name			From - To (MM/YY – MM/YY)	
United Health Care			03/2013 - 10/2014	
Business Address		**City**	**State**	**Zip**
1311 W President George Bush Hwy		Richardson	TX	75080
Phone	**Title**		**Number of Employed Hours**	
469-251-4401	Clinical Care Coordinator		3,256	
Description of Duties				
Responsible for drafting approval, denial, termination and the reduction of service letters for Medicaid and/or Medicare clients. Teamed with department Call Center staff of 10 to handle calls from doctors and patient daily per SOPs.				

Business Name			From - To (MM/YY – MM/YY)	
Plainview Family Pharmacy			06/2010 - 07-2012	
Business Address		**City**	**State**	**Zip**
142a, Manetto Hill Rd		Plainview	NY	11803
Phone	**Title**		**Number of Employed Hours**	
516-932-7077	Staff Pharmacist		4,232	
Description of Duties				
Executed daily Pharmacist duties which involved dispensing, counseling and the compounding of medications for both adult and pediatric patients.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
CVS Pharmacy			08/2003 - 07/2010	
Business Address		City	State	Zip
341 Commack Rd		Commack	NY	11725
Phone	Title		Number of Employed Hours	
631-462-9077	Pharmacist-In-Charge		13,563	
Description of Duties				
Responsible for regulatory and processing prescriptions and managed staff.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	✓	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1,2,3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/05		NY		Suffolk
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
DUI				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Kim Hiddessen				
Name of Business/Industry/Entity				

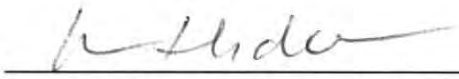
Provide explanation below:

On or about December 18th 2005, I was charged with a DUI. I had been sick with an upper respiratory infection and was due to go back to work at CVS that morning. I was taking controlled medications prescribed by my physician. A new cough medicine was added to my regular regimen, and I had an adverse reaction that left me feeling dizzy and uncoordinated.

I called out sick to work, but was told by my supervisor that I had to go because there was no one to cover me. Against my better judgment, I got in my car and drove to work. I know almost immediately upon entering the highway that I should not have been driving and I pulled over to the shoulder.

A few moments later, a police car pulled up behind me. I explained the situation, and he had me exit the vehicle and perform a field sobriety test, which I failed. He placed me under arrest and took me back to the station. They performed a breathalyzer which revealed no alcohol in my system. I was charged for a DUI for failing the field sobriety test and admittedly having a controlled medication (via prescription) in my system. I plead no contest and was reprimanded with Community Service and a fine.

This statement is to the best of my knowledge to be complete and accurate. The court records are sealed.



Original Signature (electronic, copies or stamps not accepted)

03/24/2025

Date

I, Kim Hiddessen, **certify that as the designated representative for**

WP Pharma Labs Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KH I am at least 21 years of age;
3. KH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kim Hiddessen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/24/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kim Hiddessen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/24/2025

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/24/2025

Date

Subscribed and Sworn to before me this 24TH day of MARCH, 2025.

Notary Public Signature

MARTHA J. ROZELL
My Notary ID # 6450477
Expires April 16, 2028

(Seal)

Explanation of Past Charges- Kim Hiddessen
Date of Occurence 12/2005
State: Suffolk County, NY
Charge: DUI
Explanation: On or about December 18, 2005 I was charged with DUI. I had been sick with an upper respiratory infection and was due to go back to work at CVS that morning. I was taking controlled medications prescribed by my physician. A new cough medication was added to my regular regimen. I had an adverse reaction that left me feeling dizzy and uncoordinated. I called out sick to work but was told by my supervisor I had to go because there was no one to cover me. Against my better judgement, I got in my car and drove to work. I knew almost immediately upon entering the highway that I should not have been driving. I pulled over to the shoulder. A few minutes later a police car pulled behind me. I explained the situation. He had me exit the vehicle and perform a field sobriety test. I failed. He placed me under arrest and took me back to the station. They performed a breathalyzer which revealed no alcohol in my system. I was charged for a DUI for failing the field sobriety test and admittingly having controlled medication (via prescription) in my system. I pled no contest and was reprimanded with Community Service and a fine.

This statement is to the best of my knowledge complete and accurate. The court records are sealed.



Kim Hiddessen, PharmD, RPh

CONFIDENTIAL

TEXAS STATE BOARD OF PHARMACY

May 14, 2019

FIRST CLASS MAIL
- and -
ELECTRONIC MAIL

Kim M Hiddessen, R.Ph.
2204 Bennington Dr
Melissa, TX 75454

RE: In the Matter of Kim M Hiddessen

Dear Ms. Hiddessen:

Enclosed is a copy of Agreed Board Order (ABO) #M-19-011 that was entered by the Texas State Board of Pharmacy concerning the above-referenced matter. The Board entered this Order on May 7, 2019.

As a result of the entering of this ABO, the probation period imposed by ABO #L-13-028 is terminated, effective May 17, 2019. In addition, the following conditions and restrictions are applicable.

(1) **Applications to Renew Your Pharmacist License**

Prior to the next expiration date of your pharmacist license, you will complete a license renewal application for the Texas State Board of Pharmacy. This application will require you to answer the question:

> "Have you been the subject of any professional disciplinary action or are any such actions pending against you by a regulatory authority within the last 36 months?..."

As a result of the entry of ABOs #M-19-011 and #L-13-028, you must answer "yes" to this question for 36 months from the date of the termination of all sanctions. Consequently, you must answer "yes" to this question on any renewal applications submitted beginning May 7, 2019 and ending 36 months after the termination of all sanctions.

(2) **Applications to Serve as a Preceptor**

Please note that you may not serve as a preceptor, as explained below. Board Rule 283.6(c) states, in part:

> "No pharmacist may serve as a pharmacist preceptor if his or her license to practice pharmacy has been the subject of an order of the board imposing any penalty set out in the Act, §565.051, during the period he or she is serving as a pharmacist preceptor or within the three-year period immediately preceding application for approval as a pharmacist preceptor."

As a result of the entry of ABOs #M-19-011 and #L-13-028, you may not serve as a preceptor until three years after the termination of all sanctions. Board Rule 283.6(c) also allows you to petition the Board, in writing, for approval to act as a preceptor. However, until such petition is granted, you may not serve as a preceptor.

(3) **Public Information**

Under current Texas law, the agency is required to disclose that you have been the subject of a confidential ABO upon request. Although the agency generally does not release a copy of a confidential Order to a requestor, there are statutory exceptions which allow or require this agency to release a copy of a confidential Order. For example, a confidential Order may be disclosed in agency disciplinary hearings or subsequent trials or appeals, to the pharmacist licensing or disciplinary authorities of other jurisdictions, pursuant to court order, or as otherwise provided by law.

If you have any questions about this Order, please contact Angela Castillo, Enforcement Specialist, at 512-305-8019.

Sincerely,

Robert Rivera
Enforcement Program Manager

Enclosure: Agreed Board Order #M-19-011

c: Angela Castillo
Enforcement Specialist

Eden Males, LCSW, PRN Director

AGREED BOARD ORDER #M-19-011

RE: IN THE MATTER OF
KIM M. HIDDESSEN
(PHARMACIST LICENSE #56009)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacist license number 56009 issued to Kim M. Hiddessen (Petitioner).

By communication received by the Board on January 14, 2019, Petitioner requested an informal conference before a Board panel to consider modification of Agreed Board Order #L-13-028. By letter dated February 1, 2019, the Texas State Board of Pharmacy notified Petitioner of the procedures for modification.

PREVIOUS HISTORY

On or about November 4, 2014, the Texas State Board of Pharmacy entered Agreed Board Order #L-13-028 in the matter of the application for pharmacist licensure by Kim M. Hiddessen (previously licensed as Kim M. Zitkus). The Order was based on a 2012 disciplinary action by the New York State Board of Pharmacy regarding two dispensing errors by Ms. Hiddessen. The Order was also based on allegations that Ms. Hiddessen received treatment for polysubstance abuse, was diagnosed with benzodiazepine abuse and major depressive disorder, and had developed an incapacity that prevented her from safely practicing pharmacy. The Order granted Ms. Hiddessen's license and, effective upon issuance, suspended her license until she was found able to safely practice pharmacy by a mental health professional, followed by a five-year probation with conditions.

An informal conference was held in the Board's office on April 11, 2019, with Petitioner; Emily Abel, L.C.S.W., Senior Case Manager, Professional Recovery Network; and Tara Russell, L.M.S.W., Case Manager, Professional Recovery Network, in attendance. The informal conference was heard by a Board panel comprised of: Dennis F. Wiesner, R.Ph., Board Member; Julie Spier, R.Ph., Board Member; and Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary; with Kerstin Arnold, General Counsel. Also in attendance were: Eamon Briggs, Staff Attorney, and Angela Castillo, Enforcement Specialist.

At the aforementioned conference, Petitioner waived the right to be represented by legal counsel. By signing this Order, Petitioner neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that effective ten (10) days after the entry of this Order, the requirements of Agreed Board Order #L-13-028 shall be terminated and of no further force and effect.

And it is so ORDERED.

Pursuant to Chapter 564 of the Texas Pharmacy Act, this Order is confidential and is not subject to disclosure under the Public Information Act or in a civil action. The Board may disclose that the license subject to this Order has been subject to disciplinary action or the manner in which the license is limited, but not the nature of the impairment or other information that resulted in the Board's action.

SIGNED AND ENTERED ON THIS 7th day of May, 2019.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Kim M. Hiddessen, R.Ph.

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

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AGREED BOARD ORDER #L-13-028

RE: IN THE MATTER OF
KIM M. ZITKUS
(APPLICANT FOR PHARMACIST
LICENSURE BY RECIPROCITY)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of the Application for Pharmacist Licensure by Reciprocity submitted by Kim M. Zitkus (Applicant).

By letter dated January 16, 2014, the Board gave preliminary notice to Applicant of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Applicant may have violated:

> Sections 565.001(a)(1), (2), (4), (12) and (16); and 565.001(b) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011); and
>
> Section 281.7(a)(13) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2012), as alleged in the Counts below.

The conduct described in the New York State Board of Pharmacy Consent Order is substantially similar to conduct described in:

> Section 565.001(a)(1), (2), (12) and (13) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011);
>
> Sections 281.7(a)(12), (13) and (29)(A); 291.31(1), (14) and (15); 291.32(c)(1)(E) and (F); 291.32(c)(2)(D); and 295.3(b) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2012); and
>
> Sections 431.003; 431.021(a) and (b); and 431.112(a)(1) of the Texas Food, Drug, and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. (2011).

COUNTS

(1) On or about July 16, 2012, the New York State Board of Pharmacy entered a Consent Order against the New York pharmacist license number 049347 held by Kim Zitkus. The Order was based on allegations that on two occasions while working as a pharmacist at a CVS/pharmacy in Bayport, New York, Ms. Zitkus erroneously dispensed a prescription for Dilaudid 8mg tablets to patient J.Z. On the first occasion, the prescription vial inaccurately indicated that the vial contained Dilaudid 4mg tablets, and on the second occasion she dispensed 150 tablets when the prescription called for 90 tablets. The Order imposed a two-year probation and a $5,000 fine.

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(2) During the investigation of Kim Zitkus' reciprocity application, Texas State Board of Pharmacy Staff learned that Ms. Zitkus received treatment for polysubstance abuse from June 3, 2013, through August 26, 2013. Specifically, on or about June 3, 2013, through June 7, 2013, Ms. Zitkus received inpatient treatment for polysubstance abuse, depression and active suicidal thoughts at Methodist Richardson Medical Center after being transferred from Medical Center of McKinney Emergency Room. Upon admission, Ms. Zitkus tested positive for benzodiazepines, and admitted to self-medicating with 30 clonazepam 2mg tablets and 30 carisoprodol 350 mg tablets for jaw pain, chronic back pain, and anxiety in the previous four days. Ms. Zitkus was diagnosed with benzodiazepine abuse and major depressive disorder. Ms. Zitkus was discharged from inpatient treatment with a recommendation that she complete a Chemical Dependence Intensive Outpatient Program (CDIOP), and she completed 26 sessions of CDIOP through Methodist Richardson Medical Center from June 10, 2013, through August 26, 2013. She was diagnosed upon discharge from the CDIOP with polysubstance dependence and given a recommendation to attend a formal sobriety support group.

This conduct constitutes probable cause that Ms. Zitkus has developed an incapacity of a nature that prevents a pharmacist or applicant from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public.

An informal conference was held in the office of the Texas State Board of Pharmacy on March 4, 2014, with Applicant and Emily Abel, L.M.S.W., Case Manager, Professional Recovery Network, in attendance. The informal conference was heard by a Board panel comprised of: Phyllis A. Stine, Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin Arnold, General Counsel. Stacy Martyak, Staff Attorney, was also in attendance.

At the aforementioned conference, Applicant waived the right to be represented by legal counsel. By signing this Order, Applicant neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Applicant shall be granted a Texas Pharmacist License after successfully completing the requirements of licensure as set forth in the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2013) and the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

(2) Effective upon issuance of the license, Applicant's license shall be suspended until such time as written documentation is provided by a Board-approved mental health professional (hereinafter referred to as "MHP") which states that Applicant does not have an incapacity that prevents Applicant from practicing pharmacy with reasonable skill, competence and safety to the public, and is able to practice pharmacy without posing a danger to Applicant or the public. This documentation shall include an evaluation of Applicant's current status and Applicant's capacity to engage in the practice of pharmacy and, if necessary, a recommended schedule of future treatment and/or after-care. During the period of suspension, Applicant shall:

(a) surrender said license and any renewal certificate and personal identification card pertaining to said license;

(b) not practice pharmacy in this state or be employed in any manner requiring a license with the Board or allowing access to prescription drugs in a pharmacy; and

(c) comply with the requirements of Paragraph (4)(a) through (q) listed below.

(3) If within one (1) year after the entry of this Order, Applicant fails to provide written documentation from a Board-approved MHP, as required by Paragraph (2), said license issued to Applicant shall be revoked and of no further force and effect, effective one (1) year after the entry of this Order. In the event that said license issued to Applicant is revoked, Applicant shall not practice pharmacy in this state or be employed in any manner requiring a license with the Board or allowing access to prescription drugs in a pharmacy.

(4) Upon the completion of the initial suspension outlined in Paragraph (2) above, Applicant's license shall be suspended for an additional period of five (5) years. Such suspension shall be probated under the conditions that Applicant abide by the requirements of this Order, all Federal laws and laws of the State of Texas and any other state with respect to pharmacy, controlled substances, and dangerous drugs, and all rules and regulations adopted pursuant to the above-mentioned statutes, in that Applicant shall:

(a) participate in the Professional Recovery Network of the Texas Pharmacy Association (hereinafter referred to as "PRN Program"). Participation in the PRN

Program shall include entering into a contract with the PRN Program and abiding by all terms of the PRN Program contract. Failure to comply with all provisions and recommendations of the PRN Program shall constitute a violation of this Order;

(b) comply with the treatment and/or aftercare recommended by his/her Board-approved MHP, and continue under the care of the MHP if the MHP determines further treatment and/or after-care is needed. Applicant shall authorize and request the MHP and/or representative of the after-care program to furnish written quarterly reports or as requested to Board Staff and the PRN Program concerning the status of Applicant's recovery and compliance with treatment. Within thirty (30) days after any written request of Board staff or the PRN Program, Applicant shall obtain a current written evaluation by a Board-approved MHP. Failure to comply with such a request, failure to cause the MHP to furnish written quarterly reports, or failure to comply with all current or future recommendations of the MHP or after-care program, shall constitute a violation of this Order;

(c) authorize the persons listed below, as applicable, to discuss and/or disclose the terms of this Order, the nature of the complaint(s) resulting in the entry of the Order, the status and conduct of Applicant, and any other relevant matter, with each other:

(i) staff of the Board;

(ii) intervenors and staff of the PRN Program;

(iii) MHP and/or any physician or other health-care practitioner who is evaluating or treating (or who has evaluated or treated) Applicant;

(iv) representative(s) of any after-care program evaluating or treating (or that has evaluated or treated) Applicant;

(v) supervising pharmacist and any employer or potential employer of Applicant; and

(vi) any other person who Applicant, by oral or written notification to Board staff, has authorized to receive this information;

(d) inform any and all physicians or other health-care practitioners who treat Applicant for any reason or condition that Applicant has a history of substance-abuse, and that Applicant is the subject of this Order. Unless a medical emergency exists, Applicant shall also provide a copy of this Order to any treating physician for review prior to the physician's authorization of prescription medication for Applicant;

(e) cause any treating physician or other health-care practitioner to provide Board staff, upon request, with information and patient records, including information about any and all prescriptions authorized for Applicant. By signing this Order, Applicant does hereby authorize any and all physicians or other health-care practitioners treating Applicant for any reason or condition to provide Board staff with information, including patient records, regarding prescriptions authorized for Applicant;

(f) abstain from the consumption, absorption, or use of alcohol, any products containing alcohol (including over-the-counter products and prescription drugs), dangerous drugs, and/or controlled substances in any form unless prescribed, within one (1) year if a dangerous drug, or within six (6) months if a controlled substance, by a practitioner for a legitimate and documented therapeutic purpose and unless used for the same therapeutic purpose as originally prescribed;

(g) register with a drug screening company as specified by Board staff to participate in a drug and alcohol analysis program. If Applicant fails to register with a drug screening company as specified by Board staff within ninety (90) days after the entry of this Order, said license issued to Applicant shall be surrendered, effective ninety (90) days after the entry of this Order, until such registration has been completed. In the event that said license issued to Applicant is surrendered, Applicant shall not practice pharmacy in this state or be employed in any manner requiring a license with the Board or allowing access to prescription drugs in a pharmacy;

(h) submit fingerprint information as specified by Board staff for the purpose of obtaining past, current, or future criminal history based on fingerprint results. If Applicant fails to submit fingerprint information as specified by Board staff within ninety (90) days after the entry of this Order, said license issued to Applicant shall be surrendered, effective ninety (90) days after the entry of this Order, until such information as been submitted. In the event that said license issued to Applicant is surrendered, Applicant shall not practice pharmacy in this state or be employed in any manner requiring a license with the Board or allowing access to prescription drugs in a pharmacy;

(i) submit, within twenty-four (24) hours, to the performance of unscheduled urinalysis or other types of drug or alcohol analysis as specified by Board staff or others authorized by Board staff, such as a MHP, PRN Program representative, or supervising pharmacist;

(j) maintain a copy of chain-of-custody document(s) from the collection site for any urinalysis or other type of drug or alcohol analysis, as required by subparagraph (i), for which Applicant has submitted a sample. Applicant shall provide a copy of said chain-of-custody document(s) to Board staff upon request;

(k) maintain and provide a copy of any and all current prescriptions taken by or in possession of Applicant to Board staff. Within ten (10) days of any and all new prescriptions prescribed by a treating physician or other health-care practitioner who has reviewed this Order, Applicant shall provide a copy of any and all new prescriptions to Board staff;

(l) provide a written statement from a treating physician or other health-care practitioner, who has reviewed this Order, for all current sample medication taken by or in possession of Applicant to Board staff. The statement shall include the patient's name, drug name, quantity provided, date provided, directions for use, and prescriber's name. Within ten (10) days of any and all new sample medication provided by a treating physician (or other health-care practitioner), who has reviewed this Order, Applicant shall provide a copy of such a statement to Board staff;

(m) be in violation of this Order, and shall surrender said license until such time as a panel of the Board reviews the alleged violation and if the panel determines that there is sufficient evidence of a violation, the matter is resolved by further disciplinary action, e.g., the entry of an agreed board order or board order, in the event that:

(i) the results of any alcohol or drug analysis indicate the presence of alcohol or drugs unless the dangerous drug was prescribed within one (1) year or the controlled substance was prescribed within six (6) months from the date of the analysis for a legitimate and documented therapeutic purpose by a practitioner who reviewed the terms of this Order before authorizing the prescription; and/or

(ii) any health-care practitioner submits written documentation that Applicant has developed an incapacity of a nature that may prevent Applicant from engaging in the practice of pharmacy with reasonable skill, competence and safety to the public;

(n) participate in the activities and programs of Alcoholics Anonymous, or any other substantially similar program that has been approved by Board staff, on a regular basis as directed by Board staff. Applicant shall maintain documentation as to the number and location of meetings attended and make such documentation available to Board staff upon request;

(o) submit to Board staff personal quarterly reports containing information as specified by Board staff, such as rehabilitation activities and, if applicable, employment status;

(p) not hold any of the individuals providing reports to Board staff or the PRN Program liable in any manner for the contents of such reports;

(q) provide written information to Board staff with the name and telephone number of an individual or individuals to contact in case of a medical emergency, and authorize the Board staff to disclose to such individual(s) any relevant information regarding this Order or the medical emergency; and

(r) comply with the following while practicing pharmacy in Texas or while employed in any manner that would allow access to prescription drugs in Texas, in that Applicant shall:

(i) practice pharmacy only under the supervision of a Texas licensed pharmacist, approved by Board staff, who meets the qualifications required of a preceptor defined by the Texas Pharmacy Board Rules, with the level of such supervision, conditions of supervision, maximum number of hours that can be worked per week, and other conditions of pharmacy practice to be determined by Board staff, taking into account any recommendations made by the MHP evaluating and/or treating Applicant. Failure to practice under the designated level of supervision and conditions of supervision and practice shall constitute a violation of this Order. Board staff may increase or decrease supervision levels by notifying Applicant in writing, after considering information such as MHP recommendations, physician recommendations, supervising pharmacist recommendations, or PRN Program recommendations;

(ii) notify Board staff of Applicant's initial place of employment in Texas and the name of Applicant's supervising pharmacist and of any subsequent change of employment or supervising pharmacist and the reasons for such change. Such notifications shall be submitted in writing to Board staff within thirty (30) days after Applicant's probationary period begins, and within ten (10) days of any subsequent employment or change of supervising pharmacist;

(iii) authorize and request the supervising pharmacist to provide written quarterly reports concerning the status and conduct of Applicant to Board staff;

(iv) provide a written agreement signed by the supervising pharmacist, which states that he/she has reviewed and understands the terms of this Order and that he/she agrees to be the supervising pharmacist for Applicant and that he/she agrees to provide written quarterly reports to Board staff and the PRN Program. Such agreement shall be submitted in writing to Board staff within thirty (30) days after Applicant's probationary period begins, and within ten (10) days of any subsequent employment or change of supervising pharmacist;

(v) inform any and all employers that Applicant is the subject of this Order; and

(vi) not work more than fifty (50) hours per week as a pharmacist or in employment that provides access to prescription drugs, and not serve as pharmacist-in-charge of any pharmacy. Upon written request, modification of these restrictions may be determined by Board staff based on recommendations from Applicant's MHP, physicians, supervising pharmacist(s), and/or the PRN Program.

(5) The time period of the five-year probation under this Order shall be extended for any period of time in which Applicant is not practicing pharmacy or employed in any manner in which Applicant has access to prescription drugs working at least twenty (20) hours per week in Texas. If Applicant ceases to be employed as such, Applicant shall notify Board staff in writing within ten (10) days of the last date that Applicant ceased to be employed. The requirements of the probation under Paragraph (4)(a) through (q) are applicable during any period that this Order is tolled.

(6) Applicant shall pay a probation fee of one thousand two hundred dollars ($1,200). This probation fee is due ninety (90) days after Applicant's probationary period begins.

(7) If Applicant fails to pay the probation fee within ninety (90) days after Applicant's probationary period begins, said license issued to Applicant shall be suspended, effective ninety (90) days after Applicant's probationary period begins, until such payment is received by Board staff. In the event that said license issued to Applicant is suspended, Applicant shall:

(a) not practice pharmacy in this state or have access to prescription drugs during the period said license is suspended; and

(b) surrender to the Board the license and any renewal certificate and personal identification card pertaining to said license as specified by Board staff.

(8) If within six (6) months after Applicant's probationary period begins, Applicant fails to pay the probation fee, said license issued to Applicant shall be revoked, effective six (6) months after Applicant's probationary period begins. In the event that said license number is revoked, Applicant shall not practice pharmacy in this state or have access to prescription drugs during the period said license is revoked.

(9) Applicant shall be responsible for all costs relating to compliance with the requirements of this Order.

(10) Applicant shall allow Board staff to directly contact Applicant on any matter regarding the enforcement of this Order.

(11) Applicant shall not be convicted of or receive deferred adjudication for an alcohol-related or drug-related offense.

(12) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2013), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

And it is so ORDERED.

Pursuant to Chapter 564 of the Texas Pharmacy Act, this Order is confidential and is not subject to disclosure under the Public Information Act or in a civil action. The Board may disclose that the license subject to this Order has been subject to disciplinary action or the manner in which the license is limited, but not the nature of the impairment or other information that resulted in the Board's action.

SIGNED AND ENTERED ON THIS 4th day of November, 2014.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Kim M. Zitkus

APPROVED AS TO FORM:

Kurstin Arnold, General Counsel
Texas State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: WP Pharma Labs Inc

NV Pharmacy or Outsourcing facility license # (if applicable): PH04565

Physical Address: 4001 McEwen Dr, STE 110

City: Dallas State: Texas Zip: 75244

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 469-722-4500 Toll Free # (NAC 639.708, NRS 639.23286): 800-441-0048

Fax: 800-715-6589 Contact Email: regulatoryaffairs@wppharmalabs.com

Website: www.wppharmalabs.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jerry Lance May

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22115

Name of Designated Person(s) as defined by revised USP-797 guidelines: Kim Hiddessen

Email of Designated Person(s): khiddessen@wppharmalabs.com

Telephone of Designated Person(s): 469-722-4500

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ■ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 03/20/2025

6. What is the frequency of the recertification for the ISO classified areas? 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Weekly

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Testosterone Cypionate, Testosterone Enanthate, Testosterone Propionate, Nandrolone, Anastrozole, DHEA, Methionine, Inositol, Chromium Picolinate, Methylcobalamin, Gonadorelin, Sermorelin, NAD+, Semaglutide and Tirzepatide.

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway, STE 546

City: Oklahoma City State: OK Zip: 73104

Telephone: 800-393-1595

13. What is your procedure for visual inspection of compounded sterile products?

Finished sterile products are inspected by a Quality Control technician and a Sterile Compounding Pharmacist in a light box with both white and black backgrounds to detect particles present in the solution and to inspect for any flaws in the vial or closure. Each batch undergoes 100% visual inspection by a Quality Control Technician and is then submitted for AQL inspection (0.65% AQL per USP <790>) by a Sterile Compounding Pharmacist before being released from quarantine.

14. How often do you perform glove fingertip and medial fill testing?

Glove fingertip testing is performed at the completion of every sterile compounded batch. Gowning validation and media fill testing is performed quarterly for sterile compounding staff.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Personnel must attend a professional sterile compounding training course before being allowed to begin on-the-job training. Personnel must then complete a computer-based in-house didactic sterile compounding training course. Gowning validation must be performed three times consecutively with no failures before personnel can enter the clean room during compounding. Personnel are trained in cleaning and decontamination of the clean room suite and the process of disinfection of materials to be brought into the clean room suite prior to being allowed to commence a media fill test. A media fill test conducted under the most challenging conditions must be completed prior to being involved in the compounding process - whether as compounder or as support. These are repeated quarterly. Any personnel responsible for mixing sterile compounds must pass a finished product assay test to establish their ability to mix products to the required specifications.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Interior surfaces of ISO 5 primary engineering controls and exterior surfaces in ISO 7 Buffer Area are cleaned with sporicidal disinfectant (Spor-Klenz) at the beginning of each day upon which sterile compounding occurs. The ISO 5 work surfaces are cleaned after each product compounded with a deactivation/decontamination agent (Peridox RTU). The counters and floors of the ISO 7 secondary engineering controls (Buffer Area) are cleaned at the conclusion of compounding with sporicidal disinfectant (Spor-Klenz). The floors of each ISO-classified area are disinfected at the end of each day upon which they have been entered. Additionally, the walls and ceilings of all ISO-classified areas are disinfected on a monthly basis. A breach clean is performed following 1) entry to lab by non-certified personnel such as outside contractors, maintenance personnel or semi-annual certification personnel, 2) the completion of any repair or maintenance work which has the capacity to disrupt pressure differentials or generate viable or non-viable particles, 3) After a power outage interrupting the operation of the HEPA filters.

17. Who performs the sterile compounding process at your facility?

Kim Hiddessen, PharmD, Lien Le, PharmD, Kristen Salinas, CPhT, Evie Jerdee, CPhT, and Maribel Munguia, CPhT.

18. Who is responsible and accountable for the sterile compounding process at your facility?

Kim Hiddessen, PharmD

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Packaged in insulated mailing pouches with frozen cold packs. Volume of cold packs is increased during warmer months. Shipping speed (same-day courier, Next-Day Air or Second Day Air) is determined as required by outdoor weather conditions, storage requirements of the medication being shipped and the travel distance for the medication to arrive at th

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? ISO-5 Integrated Vertical Laminar Flow Zone		
2. Are you complying with all USP 800 guidelines?	Yes	■ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	■ No
5. Do you have a negative pressure buffer room at your facility?	Yes	■ No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	■ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	■ No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Guidance is provided with each prescription dispensed covering the following topics:
1. Proper storage of medications
2. Preventing contamination of sterile medications
3. Proper disposal of expired and unused medications
4. Proper disposal of unused, expired or discontinued injectable medications
5. Descriptions of physical appearances of products which indicate a potential problem with the medication - e.g. broken capsules, cloudy solutions, broken emulsions.
6. Explanation of drop-off sites and National Take Back Day for drug disposal.
7. Contact information for staff pharmacist for patients and providers to obtain additional information.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Gowning validation must be performed three times consecutively with no failures before personnel can enter the clean room during compounding.
Personnel are trained in cleaning and decontamination of the clean room suite and the process of disinfection of materials to be brought into the clean room suite prior to being allowed to commence a media fill test.
A media fill test conducted under the most challenging conditions must be completed prior to being involved in the compounding process - whether as compounder or as support. These are repeated quarterly. Any personnel responsible for mixing sterile compounds must pass a finished product assay test to establish their ability to mix products to the required specifications.
Specific to hazardous drugs, personnel are trained in the proper safe handling and containment of chemicals and materials. Specific gowning items (gloves, sleeves and masks) are utilized. Personnel are made aware of the risks involved with compounding and handling hazardous drugs and the importance of proper PPE to minimize the potential for exposure.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Testosterone Cypionate, Testosterone Enanthate, Testosterone Propionate, Nandrolone, Anastrozole, DHEA, Methionine, Inositol, Chromium Picolinate, Methylcobalamin, Gonadorelin, Sermorelin, NAD+, Semaglutide and Tirzepatide.

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Glove fingertip testing is performed at the completion of every sterile compounded batch. Gowning validation and media fill testing is performed quarterly for sterile compounding staff.

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

Monthly

5. What is the frequency for completing surface sampling? Weekly		
6. What is the frequency for using sporicidal agents? Daily		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

X Kim Hiddessen

Name of Person who Completed the Form

PHARMACY MANAGER

Title

Signature (copies or stamps not accepted)

3/31/25

Date

Board Use Only	Date Received: 4/4/25	Date Approved: _____	Approved By: _____

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *WP PHARMA LABS*

License Number: *33003*

Address: *4001 MCEWEN RD STE 110, DALLAS, TX 75244*

Phone: *(800) 441-0048*

Email:

Class of License: *AS*

License Expiration: *11/30/2025*

DEA #: *FW8979520*

DEA Expiration: *05/31/2025*

Inspection Information

Type: *Compliance*

Purpose: *Routine*

Date: *11/13/2023*

Arrival Time: *9:00 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Kim Hiddessen *Pharmacist in Charge* *56009*

Witness

Isaac Gonzalez

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *WP PHARMA LABS*

License Number: *33003*

Class of License: *AS*

Inspection Information

Type: *Compliance*

Purpose: *Routine*

Date: *11/13/2023*

Arrival Time: *9:00 AM*

Departure Time: *1:45 PM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Not Applicable*
17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Satisfactory*

291.17(c).

Annual inventory.

(1) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy shall take an inventory on May 1 of each year, or on the pharmacy's regular general physical inventory date. Such inventory may be taken within four days of the specified inventory date and shall include all stocks of all controlled substances (including out-of-date drugs).

(2) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy applying for renewal of a pharmacy license shall include as a part of the pharmacy license renewal application a statement attesting that an annual inventory has been conducted, the date of the inventory, and the name of the person(s) taking the inventory.

(3) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the time the inventory

69. Annual controlled substance inventory *(continued)* — *Satisfactory*

was taken (as specified in subsection (a)(7) of this section) and shall sign and date the inventory with the date the inventory was taken. The signature of the pharmacist-in-charge and the date of the inventory shall be notarized within three days after the day the inventory is completed, excluding Saturdays, Sundays, and federal holidays.

Comment

Ensure the inventory shall is notarized within three days after the day the inventory is completed, excluding Saturdays, Sundays, and federal holidays.

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?) — *Satisfactory*

34. Notifications — *Satisfactory*

76. PIC (Does the pharmacy have a pharmacist-in-charge?) — *Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean — *Satisfactory*

04. Balance inspection — *Satisfactory*

05. Equipment Inspection — *Satisfactory*

07. Security — *Satisfactory*

08. Environment — *Satisfactory*

48. Drugs (procurement, temperature, security, out-of-date, samples) — *Satisfactory*

90. TSBP complaint notification — *Satisfactory*

Comment

Advised to notify patients of complaint information.

Controlled Substances

10. Prescriptions separated — *Satisfactary*

24. Theft/Loss — *Satisfactory*

Comment

No theft or lass has occurred.

26. Controlled substance prescription compliance — *Satisfactory*

30. Controlled substance invoices dated/initialed by pharmacist — *Satisfactory*

35. Controlled substance invoices separated — *Satisfactory*

46. Drug distribution — *Satisfactory*

53. Possession of controlled substances	*Satisfactory*
57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Satisfactory*
45. Proper dispensing/labeling	*Satisfactory*
54. Proper prepackaging procedures	*Not Applicable*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Satisfactory*
61. Supervision of supportive personnel	*Satisfactory*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Satisfactory*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Satisfactory*
56. Prescription transfers	*Satisfactory*
67. Written drug information provided	*Satisfactory*
80. Patient counseling	*Satisfactory*
82. Patient Medication Records	*Satisfactory*

291.34(c).

Patient medication records.

(1) A patient medication record system shall be maintained by the pharmacy for patients to whom prescription drug orders are dispensed.

(2) The patient medication record system shall provide for the immediate retrieval of information for the previous 12 months that is necessary for the dispensing pharmacist to conduct a prospective drug regimen review at the time a prescription drug order is presented for dispensing.

(3) The pharmacist-in-charge shall assure that a reasonable effort is made to obtain and record in the patient medication record at least the following information:

(A) full name of the patient for whom the drug is prescribed;

(B) address and telephone number of the patient;

(C) patient's age or date of birth;

(D) patient's gender;

82. Patient Medication Records *(continued)* — *Satisfactory*

(E) any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs currently being used by the patient which may relate to prospective drug regimen review;

(F) pharmacist's comments relevant to the individual's drug therapy, including any other information unique to the specific patient or drug; and

(G) a list of all prescription drug orders dispensed (new and refill) to the patient by the pharmacy during the last two years. Such lists shall contain the following information:

(i) date dispensed;

(ii) name, strength, and quantity of the drug dispensed;

(iii) prescribing practitioner's name;

(iv) unique identification number of the prescription; and

(v) name or initials of the dispensing pharmacists.

(4) A patient medication record shall be maintained in the pharmacy for two years. If patient medication records are maintained in a data processing system, all of the information specified in this subsection shall be maintained in a retrievable form for two years and information for the previous 12 months shall be maintained online. A patient medication record must contain documentation of any modification, change, or manipulation to a patient profile.

(5) Nothing in this subsection shall be construed as requiring a pharmacist to obtain, record, and maintain patient information other than prescription drug order information when a patient or patient's agent refuses to provide the necessary information for such patient medication records.

Comment

Advised to make a reasonable effort to complete PMR with all required information.

84. Drug regimen review — *Satisfactory*

86. Absence of pharmacist records — *Satisfactory*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs — *Satisfactory*

92. Automated dispensing policy & procedures/SOPs — *Not Applicable*

Non-Sterile Compounding

38. Area for non-sterile compounding — *Satisfactory*

43. Records for non-sterile compounding — *Satisfactory*

Compounded Dosage Forms

Allergen extracts — *No*

Parenteral solutions — *No*

Parenteral suspensions — *No*

Preservative-free parenterals — *No*

Ophthalmic preparations	*No*
Oral or nasal inhalation preparations (not topical spray)	*No*
Bath or soaks for live organs/tissues	*No*
Irrigations for wounds or body cavities	*No*
Any other sterile preparations (implants, pellets, etc) [list]	*No*
Investigational drugs	*No*
Blood products or other biological materials (wound care, autologous, eye drops, etc)	*No*
Any compounds using federally controlled substances Schedule I-V (list and percentage)	*Yes*

Comment

Testosterone, 5 to 7%

Does the pharmacy use lyophilizer?	*No*

Environment (Sterile)

S109. Is the cleanroom clean and free of objects that shed particles?	*Satisfactory*
S110. Is the cleanroom used only for sterile preparations?	*Satisfactory*
S119. Does the cleanroom contain only appropriate supplies?	*Satisfactory*
S101. Does the ante-area provide at least ISO Class 8 air quality under dynamic conditions?	*Satisfactory*
S115. Does the ante-area contain a hands-free sink with hot and cold running water?	*Satisfactory*
S102. Does the buffer area provide at least ISO Class 7 air quality under dynamic conditions?	*Satisfactory*
S106. Is the buffer area free from sources of water (e.g., sink, floor drains)?	*Satisfactory*
S108. Is there hands-free access to the buffer area?	*Satisfactory*
S113. Are floors, walls, ceilings & fixtures smooth, impervious and free from cracks & crevices?	*Satisfactory*
S112. Does the floor covering enable regular disinfection?	*Satisfactory*
S118. Are supplies stored above the floor to permit adequate floor cleaning?	*Satisfactory*
S127. Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area and ante-area and between the ante-area and the general environment? Is the pressure differential at least 0.02" wc?	*Satisfactory*
S116. Are temperature and humidity monitored, documented and within the required range?	*Satisfactory*
S167. Is there a thermometer available for the cleanroom and refrigerator(s)?	*Satisfactory*

Primary Engineering Control (PECs) Device

S126. Is the laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02" wc?	*Satisfactory*

S121. Is the PEC able to maintain at least ISO Class 5 conditions while compounding sterile preparations?	*Satisfactory*
S246. Are hazardous drugs prepared in a Class II/III vertical flow BSC or CACI located in an ISO Class 7 area physically separated from other areas?	*Satisfactory*
S247. Does the area where the BSC or CACI is located have not less than 0.01" wc negative pressure adjacent to the positive pressure ISO Class 7 area?	*Satisfactory*
S105. Does the CAI or CACI provide unidirectional airflow?	*Not Applicable*
S104. If the CAI or CACI is used for high-risk sterile compounding, is it placed in an ISO Class 8 area?	*Not Applicable*
S122. If the CAI is not required to be placed in an ISO Class 7 area, does the pharmacy maintain documentation from the manufacturer?	*Not Applicable*
S124. Is the PEC certified by an independent contractor every 6 months and when relocated?	*Satisfactory*
S125. Are prefilters inspected periodically and replaced as needed?	*Satisfactory*
S128. Are differential pressures monitored and documented at least every work shift (at a minimum daily) or by a continuous recording device?	*Satisfactory*

Equipment and Supplies

S174. Does the pharmacy have disposable needles, syringes, and other required or applicable supplies?	*Satisfactory*
S177. Does the pharmacy have lint-free towels or wipes?	*Satisfactory*
S180. Does the pharmacy have masks, caps, gowns with tight cuffs, shoes covers, and beard covers (if applicable)?	*Satisfactory*
S176. Does the pharmacy have handwashing agents with bactericidal action?	*Satisfactory*
S175. Does the pharmacy have disinfectant cleaning solutions and dedicated cleaning supplies?	*Satisfactory*
S179. Does the pharmacy have hazardous spill kits, if applicable?	*Satisfactory*
S171. Does the pharmacy have appropriate containers for needles and syringes?	*Satisfactory*
S170. Does the pharmacy have sterile isopropyl alcohol, sterile gloves, and waterless alcohol-based surgical hand scrub?	*Satisfactory*
S178. Does the pharmacy have appropriate filters and filtration equipment?	*Satisfactory*
S181. If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy, and document at least daily?	*Satisfactory*
S172. Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?	*Satisfactory*

High Risk CSPs

S103. If high-risk CSPs are compounded, does the buffer area provide physical separation from other compounding areas?	*Satisfactory*

S231. Is sterility testing performed if CSPs are prepared in groups > 25, or	*Satisfactory*
S232. If MDVs are prepared for multiple patients or when exposed > 12 hours at 2-8 degrees C before sterilized, or	*Satisfactory*
S233. If exposed > 6 hours at warmer than 8 degrees C before sterilized?	*Satisfactory*
S237. Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk sterile compounding?	*Satisfactory*
S238. Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2-micron filter to remove particulate matter? Is sterilization by filtration performed with a sterile 0.2 – 0.22 micrometer pore size filter within an ISO Class 5 environment or better?	*Satisfactory*
S165. Are filter integrity tests being performed and documented (e.g., bubble point test)?	*Satisfactory*
S239. Are pre-sterilization procedures (weighing and mixing) completed in an ISO Class 8 environment or better?	*Satisfactory*

Sterile Library

S154. Does the pharmacy have a reference on injectable drugs?	*Satisfactory*
S155. Does the pharmacy have a specialty reference?	*Satisfactory*
S156. Does the pharmacy have all of the required (USP chapters 71, 85, 795, 797, 1163) and applicable USP chapters?	*Satisfactory*

Hazardous CSPs

S242. Do personnel wear protective apparel at all times when hazardous drugs are handled?	*Not Applicable*
S243. Do personnel use appropriate safety and containment techniques when preparing hazardous CSPs?	*Not Applicable*
S244. Do personnel dispose of hazardous waste in compliance with local, state, and federal regulations?	*Not Applicable*
S245. Do personnel affix a proper label, including proper precautions inside and outside of the packaging?	*Not Applicable*
S248. Does the pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?	*Satisfactory*
S249. Does the pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment (e.g., closed-system vial transfer device within a BSC)?	*Satisfactory*
S250. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	*Satisfactory*
Does the pharmacy have a plan to comply with USP <800> by the implementation date?	*Yes*
Are hazardous drugs stored separately in compliance with USP <800> (negative pressure at least -0.01" wc to adjacent areas and with at least 12 ACPH)?	*Yes*

Is hazardous drug waste quarantined in a designated area?	*Yes*
Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?	*Yes*

Personnel Cleansing, Garbing, Hand Hygiene

S202. Does hand sanitizing and gowning occur in the ante-area (outside of the buffer area)?	*Satisfactory*
S180. Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclose at the neck? Is the order of garbing appropriate (dirtiest to cleanest)?	*Satisfactory*
S194. Before entering the buffer area, do compounding personnel remove cosmetics?	*Satisfactory*
S195. Before entering the buffer area, do compounding personnel remove all hand, wrist, and other body jewelry/piercings?	*Satisfactory*
S196. Are natural nails kept neat and trim and no wearing of artificial nails or extenders?	*Satisfactory*
S200. Do compounding personnel remove debris from underneath fingernails using a nail cleaner under running warm water?	*Satisfactory*
S192. Are personnel with an apparent illness or open lesions compounding sterile preparations?	*Satisfactory*
S241. When compounding personnel temporarily exit the ISO Class 7 environment, are re-donning procedures properly followed?	*Satisfactory*
S201. Do compounding personnel engage in proper hand hygiene?	*Satisfactory*
S203. Do compounding personnel completely dry hands and forearms using lint-free disposable towels or hand dryer?	*Satisfactory*
S204. Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside the buffer area and prior to donning sterile gloves?	*Satisfactory*
S206. Is sterile isopropyl alcohol applied to gloves throughout the day and when non-sterile surfaces are touched?	*Satisfactory*

Cleaning/Disinfection Procedures

S182. Does the pharmacy have written procedures on the cleaning and disinfecting of the direct and contiguous compounding areas (e.g., beginning of shift, every 30 minutes, before each batch, spills)?	*Satisfactory*
S230. Is cleaning performed by trained personnel using approved agents (described in written SOPs)?	*Satisfactory*
S228. Are supplies & equipment that are removed from shipping cartons wiped with a disinfecting agent (e.g., sterile IPA)?	*Satisfactory*
S226. Are work surfaces and floors in the ante-area and buffer area cleaned and disinfected daily with dedicated supplies?	*Satisfactory*
S227. Are walls, ceilings and shelving in the ante-area and buffer area cleaned and disinfected at least monthly?	*Satisfactory*

S229. Does the pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, name of individual who performed the cleaning)? *Satisfactory*

Comment

Advised to ensure proper documentation and frequency of cleaning is maintained and contains the required information.

Environmental Sampling

S270. Is surface sampling conducted in all ISO classified areas on a periodic basis? *Satisfactory*

S272. Is viable air sampling performed? *Satisfactory*

S273. Is viable air sampling documented by properly trained individuals for all risk levels every 6 months? *Satisfactory*

S271. Are environmental sampling results evaluated and addressed (i.e., action levels followed)? *Satisfactory*

Records of CSPs

S252. Does the pharmacy maintain records relating to CSPs for a minimum of 2 years? *Satisfactory*

S253. Do compounding records include the date and time of preparation of a CSP? *Satisfactory*

S254. Do compounding records include the complete formula of a CSP? *Satisfactory*

S257. Do compounding records include the quantities of materials used in a CSP? *Satisfactory*

S255. Do compounding records include the signature or initials of who prepared a CSP? *Satisfactory*

S256. Do compounding records include the signature or initials of who conducted the final check of a CSP? *Satisfactory*

S258. Do compounding records include the container used and the number of units prepared for a CSP? *Satisfactory*

S259. Do compounding records include the criteria used to determine the beyond-use date of a CSP? *Satisfactory*

S260. Do compounding records include the documentation of performance of quality control procedures? *Satisfactory*

S261. Are master worksheets and preparation worksheets for batch compounding complete? *Satisfactory*

S262. Are master worksheets developed and approved by a pharmacist? *Satisfactory*

General Operational Requirements

S166. Is a pharmacist available at all times (24/7)? *Satisfactory*

S187. Are written SOPs developed and implemented for all significant procedures in the compounding area to include at a minimum: the facility, equipment, personnel, preparation evaluation, quality assurance, preparation recall, packaging, and storage of CSPs? *Satisfactory*

S188. Does the pharmacy have all required written policies (e.g., pharmaceutical care services, sampling plan, recalls)?	*Satisfactory*
S158. If the pharmacy compounds commercially available products, does the pharmacy document the need by verifying and monitoring a drug shortage list (including if the preparation is quarantined/not available once removed from the shortage list)? Or,	*Satisfactory*
S158. Does the pharmacy document the need for compounding commercially available products by individual patient needs determined by the prescribing practitioner (i.e, hypersensitivity to inactive ingredients or alternate dosage form)?	*Satisfactory*
S275. If the pharmacy dispenses prescriptions to patients in other states, does the pharmacy have proper licensure in those states?	*Satisfactory*

Office Use Compounding & Distribution of CSPs

S163. Does the pharmacy have a written agreement with the prescriber that meets all requirements to distribute compounded sterile preparations to practitioners for office use?	*Not Applicable*
S162. If the pharmacy is distributing CSPs to another pharmacy, does the pharmacy meet the requirements for such distribution?	*Not Applicable*
Is the pharmacy registered with the FDA as an Outsourcing Facility (503B)?	*Not Applicable*

Quality Control & Verification of Compounding Accuracy

S207. Does a pharmacist review all compounding records for accuracy and perform the final check of a CSP?	*Satisfactory*
S185. Are periodic in-process checks for CSPs defined in written procedures and conducted as defined?	*Satisfactory*
S191. Are all drug components USP/NF grade substances manufactured in an FDA-registered facility? If USP/NF grade substances are not available, are the drug components of chemical grade in CP, AR, ACS, or Food Chemical Codex categories?	*Satisfactory*
S191. Is a Certificate of Analysis available for all components of the preparation if materials are not purchased through an FDA-registered facility?	*Satisfactory*
S191. Are any CSPs prepared by the pharmacy listed on the federal FDA list of drug products that are withdrawn or removed from the market for safety reasons?	*Satisfactory*

Veterinary Compounding

Are APIs or other components labeled for veterinary use segregated or marked to prevent use for human compounding?	*Not Applicable*
Does the pharmacy meet the same standards for animal compounding as human compounding?	*Not Applicable*
Is the pharmacist knowledgeable or does the pharmacy have up-to-date references regarding species limits that can result in toxicity when compounding with particular drugs/excipients?	*Not Applicable*
Does the pharmacy document if the animal is a pet or used for food?	*Not Applicable*

Is the pharmacist familiar with, or does the pharmacy have the most up-to date references regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals?	*Not Applicable*
Does the pharmacy have a list of drugs and components that have been designated by state or federal authorities as prohibited ingredients in CSPs for food-producing animals?	*Not Applicable*
Is the pharmacist familiar with, or does the pharmacy have the most up-to-date reference regarding regulations for drug use in performance animals?	*Not Applicable*

Label

S209. Is the CSP properly labeled to include the generic name(s), and	*Satisfactory*
S210. For outpatient prescriptions, does the label include a statement that the CSP has been compounded by the pharmacy?	*Not Applicable*
S211. Does the label include a beyond-use date?	*Satisfactory*
S213. If the CSP is compounded as a batch, does the label contain a unique lot number assigned to the batch, and	*Satisfactory*
S214. Quantity, and	*Satisfactory*
S215. Appropriate ancillary instructions, such as storage or cautionary statements, and	*Satisfactory*
S216. Any device-specific instructions, if appropriate?	*Satisfactory*
S220. Are CSPs assigned a beyond-use date based on the specified labeling for the drug, appropriate literature sources, or direct testing?	*Satisfactory*

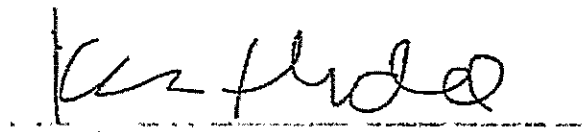
Training & Competency Testing

S129. Has each pharmacist completed the required education and training prior to engaging in sterile compounding?	*Satisfactory*
S130. Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?	*Satisfactory*
S142. Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation/testing (e.g., media-fill testing, gloved fingertip/thumb testing)? Does the pharmacy have an on-the-job training program?	*Satisfactory*
S144. Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel (e.g., observation of aseptic technique, media-fill testing, gloved fingertip/thumb testing, continuing education)?	*Satisfactory*

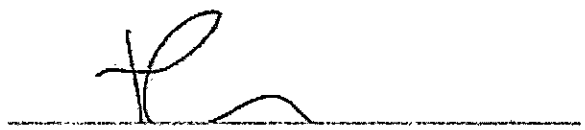
Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Kim Hiddessen



Isaac Gonzalez

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

KH — I am the Pharmacist-in-Charge (PIC) of *WP PHARMA LABS*, pharmacy license number *33003*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *11/13/2023*.

KH — I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

KH — I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

KH — If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

KH — I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: Kim Hiddessen Date: *11/13/2023*

Printed Name: *Kim Hiddessen* License No.(if applicable): *56009*

This certifies that the pharmacy named below is hereby licensed to operate as a Class **AS** pharmacy.

License No. **33003** Expiration Date: **11/30/2025**

Balances: **5**

WP PHARMA LABS
4001 MCEWEN RD STE 110
DALLAS TX 75244

TEXAS STATE BOARD OF PHARMACY

Daniel R. Carroll, Pharm.D.,
Executive Secretary/Director

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 33003

WP PHARMA LABS

License Information

License Status Active
License # 33003
Expiration Date 11/30/2025
Date License Issued 11/21/2019

Address

4001 MCEWEN RD STE 110
DALLAS, TX 75244
County DALLAS
Phone (800) 441-0048

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy
Community Sterile Compounding
Type of Ownership Corporation
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
HIDDESSEN, KIM M

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	No
Translating services (Listed Below If Available)	

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 1027047 33003 WPPHARMALABS 2019-11 11-2024.pdf
- 1027047 33003 WPPHARMALABS 2020-08 08-2025.pdf
- 1027047 33003 WPPHARMALABS 2021-11 11-2026.pdf
- 1027047 33003 WPPHARMALABS 2023-11 11-2028.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	No

Ship Prescription Out of State	Yes
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	Yes
Compounding Sterile-Risk Level Med	Yes
Compounding Sterile-Risk Level High	Yes
Compounding Non-Sterile	Yes
24 Hour Service	No
Closed Door	Yes
Compounding, Office Use	No
Home Delivery	No
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
BROCK, BIANCA VIVIAN	59733	10/21/2016	03/31/2027	Staff	Active
DUONG, TUNHI	73619	12/21/2023	06/30/2027	Staff	Active
GINN, JOSEPH MARK	33234	09/26/2001	05/31/2027	Staff	Active
HIDDESSEN, KIM M.	56009	11/24/2014	12/31/2026	PIC	Active
LE, GIAO QUYNH	47281	06/11/2009	07/31/2027	Staff	Active
LE, LIEN	59162	08/17/2016	02/28/2026	Staff	Active
MAY, JERRY LANCE	31737	04/27/1990	03/31/2027	Staff	Active
NGUYEN, KAREN	71131	08/25/2022	01/31/2027	Staff	Active
PAUL, KAYRA MICHELLE	71910	01/05/2023	05/31/2027	Staff	Active
RUST, BRUCE W.	31282	07/27/1989	09/30/2026	Staff	Active
THACKER, AUSTIN J.	70758	07/21/2022	06/30/2026	Staff	Active

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Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
ABJORNSON, AMY JANINE	381334	12/17/2024	12/31/2026	Staff	Active
AQUINO, ROMELYN	346551	10/24/2022	11/30/2026	Staff	Active
BARRERA FLORES, JESSICA	252747	02/25/2016	07/31/2025	Staff	Active
BOUDREAUX, CARMEN ANN	360314	09/12/2023	09/30/2025	Staff	Active
BOYD, SPENCER REESE	374321	07/30/2024	07/31/2026	Staff	Active
CROCIATA, GIANNA MARIE	317876	02/09/2021	01/31/2026	Staff	Active
ERPELDING, SARAH	374973	08/13/2024	08/31/2026	Staff	Active
FASCHING, BRITTANY KRISTIN	382330	01/21/2025	01/31/2027	Staff	Active

FLORES, JUANA	147270	05/04/2007	08/31/2025	Staff	Active
GARRIS, COURTNEY CROOM	377343	09/23/2024	09/30/2026	Staff	Active
HOAG, JAMES NELSON	352348	03/09/2023	04/30/2026	Staff	Active
JERDEE, EVIE L	172886	03/30/2011	07/31/2025	Staff	Active
JUAREZ, AMPARO	339173	05/09/2022	06/30/2026	Staff	Active
KHWAJA, RAISA IRENE	338288	04/08/2022	10/31/2026	Staff	Active
MARQUEZ, NICHOLAS ALEXANDER	362425	10/27/2023	10/31/2025	Staff	Active
MARQUEZ, SAMANTHA GARCIA	174589	05/29/2009	10/31/2025	Staff	Active
MCKINNEY, DANIELLE JOCQUALE	373645	07/16/2024	07/31/2026	Staff	Active
MUENTES, RUTH ESTHER	182078	03/09/2011	05/31/2027	Staff	Active
MUNGUIA, MARIBEL	221554	07/31/2013	07/31/2027	Staff	Active
MYERS, KELSEY ALANAH	233168	08/06/2014	06/30/2026	Staff	Active

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Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
WP PHARMA LABS INC	OWNER	701 BRAZOS ST STE 720,	AUSTIN	TX	78701
GOOD, NIKKI	OFFICER	,			

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The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

4III

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☑ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FA3701871
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☑ Non-sterile Compounding
			☐ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Adegen Pharmacy

Physical Address: 1620 Gateway Circle

City: Grove City State: OH Zip: 43123

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 6145220429 Toll Free # (NAC 639.708, NRS 639.23286): 8552060573

Fax: 6145220429 Contact Email: lisa@adegen.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Lisa Hartig-Mawhorr

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): NV: 24555, OH: 03319816

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Lisa Hartig-Mawhorr	NV Pharmacist Registration #: 24555
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: OH

Parent Company (if any): N/A

Corporation/Organization Name: Adegen Pharmacy LLC

Mailing Address: 1620 Gateway Circle

City: Grove City State: OH Zip: 43213

Telephone: 6145220429 Email: john@adegen.com

Contact Person Name: John Goss, CEO

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist-in-Charge (title) for Adegen Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Lisa Hartig-Mawhorr

Print Name of Authorized Person

Lisa Hartig-Mawhorr

Original signature of Authorized Person (copies or stamps not accepted)

5/19/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Lisa Hartig-Mawhorr hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge (title) for Adegen Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Lisa Hartig-Mawhorr

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19th day of May, 2025

Notary Public

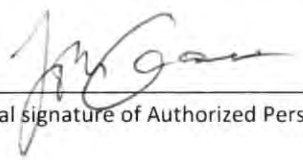
NOTARY PUBLIC STATE OF OHIO

ACADIA GAVER
Notary Public
State of Ohio
My Comm. Expires
September 19, 2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Goss

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

5.19.25

Date

Board Use Only	Date Received: 5/22/25	Amount: $500 - ck 9601709221

Adegen Pharmacy is 100% owned and operated by Adegen Pharmacy, LLC.

Adegen Pharmacy, LLC is 100% owned and operated by CEO John Goss.

John Goss



Frank LaRose
Ohio Secretary of State

Sun May 18 2025

Entity#: 4928653

Filing Type: DOMESTIC LIMITED LIABILITY COMPANY

Original Filing Date: 09/20/2022

Location: ---

Business Name: ADEGEN PHARMACY, LLC

Status: Active

Exp. Date: -

Agent/Registrant Information

NORTHWEST REGISTERED AGENT SERVICE, INC.
6545 MARKET AVE, NORTH STE 100
NORTH CANTON OH 44721
09/20/2022
Active

Filings

Filing Type	Date of Filing	Document ID
OHIO LLC - ARTICLES OF ORGANIZATION	09/20/2022	202226302310
FICTITIOUS NAME/ORIGINAL FILING	07/26/2024	202421100768

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF SECRETARY OF STATE

I, Frank LaRose, Secretary of State of the State of Ohio, do hereby certify that this is a list of all records approved on this business entity and in the custody of the Secretary of State.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 18th of May, A.D. 2025

Ohio Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Adegen Pharmacy

Pharmacy/Wholesaler License # (if applicable) Pending

Physical Address 1620 Gateway Circle

City Grove City State OH Zip 43123

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 6145220429 Website _____

Licensing Company Email acadia@adegen.com

Section 2: Personal Information

First Lisa Middle _____ Last Hartig-Mawhorr

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
CVS Pharmacy #1223			09/20 - present
Business Address	**City**	**State**	**Zip**
3575 Broadway	Grove City	OH	43123
Phone	**Title**		**Number of Employed Hours**
614-875-0261	Part-time Floater, prn		part-time relief, prn
Description of Duties			
Supervision of technicians, Patient Care/Patient Counseling, Prescription Verification, Drug Utilization Review, Vaccine Administration			

Business Name			From - To (MM/YY – MM/YY)
Revco/CVS Pharmacy			07/93 - 09/20
Business Address	**City**	**State**	**Zip**
3282 Tremont Rd	Upper Arlington	OH	43221
Phone	**Title**		**Number of Employed Hours**
614-326-1288	Staff Pharmacist/Pharmacist In Charge		FT (40+ Hrs/Wk)
Description of Duties			
Responsible for daily pharmacy operations in a community outpatient setting, supervision of staff, inventory management, patient care and counseling, Drug Utilization Review and Medication Therapy Management, Prescription Validation			

Business Name			From - To (MM/YY – MM/YY)
Adegen Pharmacy			10/23 - present
Business Address	**City**	**State**	**Zip**
1620 Gateway Circle	Grove City	OH	43123
Phone	**Title**		**Number of Employed Hours**
614-522-0429	Pharmacist In Charge		Full time
Description of Duties			
Mail Order Start Up Pharmacy. Responsible for daily pharmacy operations.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: The Ohio State University College of Pharmacy			From - To (MM/YY – MM/YY): 09/88 - 06/93
Address: Parks Hall, 500 W. 12th Ave.	City: Columbus	State: OH	Zip: 43210
Diploma/Degree obtained, if any: Bachelor of Science in Pharmacy			
School Name: Grove City High School			From - To (MM/YY – MM/YY): 09/84 - 06/88
Address: 4665 Hoover Rd	City: Grove City	State: OH	Zip: 43123
Diploma/Degree obtained, if any: High School Diploma			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 11/12 - present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Lisa Hartig-Mawhorr, **certify that as the designated representative for**

Adegen Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LKH I am at least 21 years of age;
3. LKH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LKH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LKH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LKH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LKH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lisa Hartig-Mawhorr

Print Name (First, Last)

Lisa Hartig-Mawhorr

Original Signature (electronic, copies or stamps not accepted)

5/19/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lisa Hartig-Mawhorr

Print Name (First, Last)

Lisa Hartig - Mawhorr — 5/19/25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Lisa Hartig-Mawhorr, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Lisa K. Hartig-Mawhorr — 5/19/25

Original Signature — **Date**

Subscribed and Sworn to before me this 19th day of May.

ACADIA GAVER
Notary Public
State of Ohio
My Comm. Expires
September 19, 2026

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Adegen Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Pending

Physical Address: 1620 Gateway Circle

City: Grove City State: OH Zip: 43123

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 614-522-0429 Website:

Licensing Company Email: acadia@adegen.com

Section 2: Personal Information

First: John Middle: Last: Goss

Alias(es, nicknames, name changes, etc.):

[redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Michigan State University			12/03 - 06/06	
Address		City	State	Zip
426 Auditorium Road		East Lansing	MI	48824
Diploma/Degree obtained, if any				
Bachelors degree / Human resources management				

School Name			From - To (MM/YY – MM/YY)	
Scottsdale Community College			08/01 - 12/03	
Address		City	State	Zip
9000 E Chaparral Rd		Scottsdale	AZ	85256
Diploma/Degree obtained, if any				
Associates Degree				

School Name			From - To (MM/YY – MM/YY)	
Grove City High School				
Address		City	State	Zip
4665 Hoover Rd		Grove City	OH	43123
Diploma/Degree obtained, if any				
high school diploma				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
03/24 - 06/25				
From - To (MM/YY – MM/YY)				
04/22 - 03/24				
From - To (MM/YY – MM/YY)				
06/21 - 04/22				
From - To (MM/YY – MM/YY)				
06/16 - 06/21				
From - To (MM/YY – MM/YY)				
01/11 - 06/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Goss Holdings Inc.			01/15 - 06/25	
Business Address		**City**	**State**	**Zip**
7501 WILES ROAD - SUITE 103		CORAL SPRINGS	FL	33067
Phone	**Title**			
310-310-5527	President			
Description of Duties				
Founder and running of business.				

Business Name			From - To (MM/YY – MM/YY)	
Adegen LLC			04/20 - 06/25	
Business Address		**City**	**State**	**Zip**
30 N Gould St Ste R		Sheridan	WY	82801
Phone	**Title**			
310-310-5527	Founder & CEO			
Description of Duties				
CEO of company and managing business duties.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Goss

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/13/25

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, John Goss, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/13/25

Date

Subscribed and Sworn to before me this 13 day of June '25.

Notary Public Signature

NOTARY PUBLIC STATE OF OHIO

ACADIA GAVER
Notary Public
State of Ohio
My Comm. Expires
September 19, 2026

(Seal)

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0232000435

Adegen Pharmacy Llc

1620 Gateway Cir
Grove City, OH 43123-8650
Franklin County

Terminal - Pharmacy - Category 3

USP 797 and 795 Inspection

March 5, 2025

License 0232000435 - Adegen Pharmacy Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Alex Seminara
Start 3/5/2025 10:00 AM
End 3/5/2025 11:39 AM

Organization

Name
Adegen Pharmacy Llc

License Type
Terminal - Pharmacy - Category 3

Category

License Number
0232000435

Business Type
II - Independent Community Retail (1 Outlet)

DEA Number

Responsible Person
Lisa Hartig-Mawhorr, R.Ph.

Hours of Operation

Contact

Address
1620 Gateway Cir
Grove City, OH 43123-8650
Franklin County

Primary Number
(614) 371-9270

Fax Number

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Lisa Hartig-Mawhorr, R.Ph.		Responsible Person	03319816		lisa@adegen.com
Ripal Patel, R.Ph.			03224806		ripal@adegen.com

1) *Initial Inspection Information

1) Personnel conducting inspection

Observation
Compliance Specialist Alex Seminara
614-306-0616

2) Were multiple inspection guides used during this inspection?

No

3) Facility Description

Observation
Pharmacy - Category 3
This inspection is performed to change license subtype from Independent -1 Outlet to Specialty Pharmacy (to include compounding)

4) *Does the TDDD have a valid registration issued by the Drug Enforcement Administration?

Yes

Observation
FA3701871

5) Is the Responsible Person present during the inspection?

Yes

6) Does the TDDD distribute dangerous drugs outside of Ohio?

Yes

Observation
Currently, no prescriptions are dispensed out of state. As business grows, the plan is to ship to all states where it is legal to do so.

7) Does the TDDD ensure all individuals are acting within their scope of practice?

Yes

2.1) Definitions – pharmacy compounding (OAC 4729:7-2-01)

1) Does the pharmacy compound?

Yes: Non-sterile Compounding

2.3) Drugs compounded in a pharmacy (OAC 4729:7-2-03)

1) Does the pharmacy compound non-sterile drug products?

Yes: The pharmacy compounds non-sterile drug products and must be in compliance with USP<795>

2) Does the pharmacy compound sterile drug products?

No

3) Does the pharmacy compound antineoplastic hazardous drug preparations listed in table 1 of the NIOSH list?

No.

4) Does the pharmacy compound non-antineoplastic hazardous drugs listed in NIOSH table 1, and/or compounds with hazardous drug preparations listed in NIOSH table 2 or 3?

Yes.

Observation
Dutasteride and Finasteride, Table 2

5) How does the pharmacy comply with OAC 4729:7-2-03 for non-antineoplastic compounded hazardous drug preparations listed in NIOSH table 1 and/or for compounded hazardous drug products listed in NIOSH table 2 or 3?

Pharmacy states it complies with USP 800

8) Do only appropriate personnel engage in compounding at a pharmacy?

Yes: Pharmacist

9) Is a pharmacist responsible for compounded drug preparations?

Yes: A pharmacist conducts the final check of a compounded drug preparation

Yes: A pharmacist is responsible for dispensing compounded drug preparations

Yes: A pharmacist maintains all compounding records

Yes: A pharmacist is responsible for the proper maintenance, cleanliness and use of all equipment used in compounding

10) Are drugs compounded pursuant to a patient specific prescription issued by a licensed health professional authorized to prescribe drugs?

Yes.

11) Does the pharmacy compound a limited quantity of drug in anticipation of a patient specific prescription based on routine, regularly observed prescribing patterns?

No.

Observation
Discussed: At this time, the pharmacy is not compounding in anticipated need.

13) Reminder: Compounded drugs are labeled for inpatients in accordance with OAC 4729:5-9-02.8

Observation

OAC 4729:7-2-03 | Drugs compounded in a pharmacy. Effective 03/07/2024
(K) In addition to the requirements of this rule, compounded drug preparations dispensed to an inpatient shall be labeled according to the inpatient labeling requirements in agency 4729 of the Administrative Code.
OAC 4729:7-2-03

Rule 4729:5-9-02.8 | Labeling of prescriptions for patients. Effective 2/1/22
(A) All dangerous drugs dispensed for use by inpatients in an institutional facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

(1) The label of a single unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

(a) The non-proprietary or proprietary name of the drug;

(b) Dosage form and route of administration;

(c) The strength and volume, where applicable, of the drug;

(d) The control number and expiration date;

(e) National drug code, universal product code, or formulary code, if applicable, which may be embedded in a barcode or quick response (QR) code on the label;

(f) Identification of the manufacturer, packer or distributor, or, if the repackager is the dispensing pharmacy, identification of the repackager shall be by name or by the final seven digits of their terminal distributor of dangerous drugs license number, and such identification shall be clearly distinguishable from the rest of the label; and

(g) Special storage conditions, if required.

(2) At least the name of the patient must be placed on all medication containers too small to bear a complete label and dispensed in a container bearing a complete label.

(B) All drugs dispensed to inpatients for self-administration or dispensed for outpatient use shall be labeled in accordance with rule 4729:5-5-06 of the Administrative Code.

(C) Prior to dispensing, admixtures of parenteral solutions shall bear a distinctive label indicating:

(1) The patient's full name;

(2) The name and amount of the parenteral solution;

(3) The name and amount of the drug(s) added;

(4) The expiration date or beyond-use date;

(5) The name and address of the institutional pharmacy;

(6) Cautionary statements, if required.

(D) Supplemental labels created by a pharmacy that contain a barcode or QR code for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:

(1) Association of the barcode to the drug product;

(2) Association of the label to the drug product.

14) Do compounded drugs labeled for outpatients include the additional labeling requirements of the rule?

Yes: Contains the statement "compounded drug" or similar statement

Yes: Contains the name and address of the pharmacy as it appears on the TDDD license

Yes: Contains the full name of the patient, or if an animal, the last name of the owner, the animal name and species.

Yes: Contains the directions for use of the drug

Yes: Contains the date of dispensing

Yes: Contains any cautions required by federal law

Yes: Contains the serial number of the prescription

Yes: Contain the proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug dispensed, and the strength, if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission and such request is documented

Yes: Contain the quantity of the drug dispensed

Observation
Discussed: Liberty dispensing software maintains these required elements on the label

15) Does the pharmacy receive schedule II controlled substance narcotic prescriptions by facsimile?

No

16) Does the pharmacy maintain a system for the safe disposal of drug waste?

Yes

Observation
Discussed McKesson and Stericycle will be providing system for safe disposal of drug waste

18) Does the pharmacy report to the board within 72-hours upon discovery any product quality issue attributed to a compounded drug preparation dispensed by the pharmacy?

Yes: The pharmacy reports incidents that cause the compounded drug or its labeling to be mistaken for or applied to another article

Yes: The pharmacy reports any contamination of compounded drugs including, but not limited to mold, fungal, bacterial, or particulate contamination.

Yes: The pharmacy reports any significant chemical, physical, or other change or deterioration of dispensed compounded drugs within the assigned beyond-use date.

Observation
FYI:
OAC 4729:7-2-03 | Drugs compounded in a pharmacy. Effective 03/07/2024

(P) A pharmacy shall report to the state board of pharmacy within seventy-two hours upon discovery, and in a manner determined by the board, any product quality issue attributed to a compounded drug preparation dispensed by the pharmacy.

(1) As used in this paragraph, a product quality issue means any of the following:

(a) Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;

(b) Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or

(c) Any significant chemical, physical, or other change or deterioration of the dispensed compounded drug preparation within the compounded drug preparation's assigned beyond-use date.

(2) A product quality issue does not include an isolated allergic reaction to a substance included in a compounded drug preparation.

19) Does the pharmacy report to the board within 72-hours of receipt any warning letters, injunctions, or decrees issued in relation to the pharmacy by the FDA?

Yes: Warning letters, injunctions, or decrees issued to the pharmacy by the FDA were reported to the board within 72-hours.

Observation
FYI:

OAC 4729:7-2-02 |Drugs Compounded in a Pharmacy |Effective 7/1/2021

(Q) A pharmacy shall report to the state board of pharmacy within seventy-two hours of issuance or receipt, and in a manner determined by the board, any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration.

2.4) Record keeping (OAC 4729:7-2-04)

1) Do records of drugs compounded in a pharmacy include all of the required elements?

Yes: Includes the patient name

Yes: Includes the drug name, strength or activity, and dosage form

Yes: Includes the assigned internal identification number (e.g., prescription, order, lot number)

Yes: Includes the date and time of preparation

Yes: Includes the name of each ingredient

Yes: Includes the vendor, lot number, and expiration date for each ingredient for compounded drug preparations prepared for more than one patient and for any sterile compounded product prepared from nonsterile ingredients

Yes: Includes the weight or volume of each ingredient

Yes: Includes the total quantity compounded

Yes: Includes the disposition of unused controlled substances drug(s), and amount

Yes: Includes the assigned beyond-use date

Yes: Inlcudes the positive identification of the pharmacy personnel responsible for preparing the compounded drug preparation

Yes: Includes the positive identification of the pharmacist conducting the final check of the compounded preparation

Yes: Includes the positive identification of the pharmacist who dispensed the compounded drug preparation

Yes: Includes records that are compliant to USP 795, 797 and 800 requirements

Observation
FYI:

OAC 4729:7-2-04 | Record Keeping | Effective 07/01/2021
(A) In addition to the pharmacy record keeping requirements of agency 4729 of the Administrative Code, a pharmacy shall maintain records of all drugs compounded that include, at a minimum, all the following:

(1) The name of the patient;
(2) Name of drug, strength or activity, and dosage form;
(3) Assigned internal identification number (e.g., prescription, order, lot number);
(4) Date and time of preparation;
(5) Name of each ingredient;
(6) Vendor, lot number, and expiration date for each ingredient for compounded drug preparations prepared for more than one patient and for any sterile compounded product prepared from nonsterile ingredient(s);
(7) Weight or volume of each ingredient;
(8) Total quantity compounded;
(9) The disposition of unused controlled substances drug(s) and amount;
(10) Assigned beyond-use date;
(11) The positive identification of the following:
(a) The pharmacy personnel responsible for preparing the compounded drug preparation;
(b) The pharmacist conducting the final check of the compounded drug preparation; and
(c) The pharmacist who dispenses the compounded drug preparation.
(12) All other drug compounding records as required by USP 795, USP 797, and USP 800.

2) Compounding records are readily retrievable and uniformly maintained for at least 3 years.

Yes, records are readily retrievable

Yes; records are uniformly maintained

Yes; records are maintained for at least 3 years

3) Are all records maintained for at least 3 years?

Yes: Records are kept on-site for 3 years

4) Does the pharmacy have documentation for off-site record storage approval?

Not Applicable: All records maintained on site

5) Are off-site record storage locations secure and accessible only to authorized personnel or contractors of the pharmacy?

Not Applicable: No off-site record storage

2.6.1) Introduction and Scope

1) Informational: USP Definition of Compounding and Scope

Observation
FYI:

USP 795 | Effective 11/1/2023
This chapter describes the minimum standards to be followed for the preparation of compounded nonsterile preparations (CNSPs) for humans and animals. For purposes of this chapter, nonsterile compounding is defined as combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
The requirements in this chapter must be followed to minimize harm, including death, to human and animal patients that could result from 1) excessive microbial contamination, 2) variability from the intended strength of correct ingredients (e.g., ±10% of the labeled strength), 3) physical and chemical incompatibilities, 4) chemical and physical contaminants, and/or 5) use of ingredients of inappropriate quality.
Handling of nonsterile hazardous drugs (HDs) must additionally comply with Hazardous Drugs—Handling in Healthcare Settings □800□.

2) USP 795 GLOSSARY

Observation
FYI:
USP 795 | Effective 11/01/2023
GLOSSARY
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as Bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration: The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of healthcare personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD): The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance: See the entry for Active pharmaceutical ingredient.
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning: The process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device: A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.
Component: Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP): A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area: An area that is specifically designated for nonsterile compounding.
Compounding personnel: Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR): Documents the compounding of each CNSP.
Container closure system: Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE): A full or partial enclosure that uses ventilation principles to capture, contain, and

remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA: US Food and Drug Administration.
Formulation: The specific qualitative and quantitative composition of the final CNSP.
Hazardous drug (HD): Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See □800□.
Label: The part of the labeling on the immediate container.
Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.
Master formulation record (MFR): A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph: A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight: The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation even if not physically present.
Preservative: A substance added to inhibit microbial growth.
Purified water: The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See □1231□, 3.1.1 Purified Water.)
Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution: The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent: An agent for reducing, on inanimate surfaces, the number of microorganisms (e.g., 70% isopropyl alcohol).
SDS: Safety data sheet.
SOP: Standard operating procedure.
Specification: The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify: To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (aw): A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that aw is not water content.▲ (Official 1-Nov-2023)

3) Does the facility compound CNSPs (compounded nonsterile products)?

Yes: Topical preparations (i.e., creams, gels, and ointments)

4) Does the facility perform any practies that are not considered compounding, and are therefore not subject to the requirements of USP 795?

No: The facility does not perform any practices not subject to the requirements of USP 795.

5) Are compounding leadership and all personnel involved in preparing, storing, transporting, packaging, and dispensing CNSPs responsible for compliance with USP 795?

Yes: Compounding personnel are responsible for ensuring that the applicable practices and quality standards in USP 795 are continually and consistently applied to their operations.

Yes: Compounding personnel proactively identify and remedy potential problems within their operations.

Yes: Personnel engaged in compounding and dispensing of CNSPs comply withy laws and regulations of the applicable regulatory jurisdiction.

6) Has the facility appointed a designated person?

Yes

Observation
Designated Person: Lisa Hartig-Mawhorr, RPh

7) What activities is the designated person responsible for?

Oversees a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs
Selecting components
Monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed
Ensuring that standard operating procedures (SOPs) are fully implemented.
Ensuring that follow-up is carried out if problems, deviations, or errors are identified
Establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs

2.6.2) Personnel Training and Evaluation

1) Do all personnel who compound or have direct oversight of compounding receive initial training before being allowed to perform their job functions independently?

Yes

2) Has the designated person created and implemented a training program that equips personnel with knowledge and training in the required skills necessary to perform their assigned tasks?

Yes: Frequency of training is described

Yes: Process for evaluating the competency of personnel is described

Yes: Equips personnel with the skills to perform their assigned tasks.

3) Do personnel who compound or have direct oversight with compounding personnel complete training initially and at least every 12 months?

Yes

4) Do SOPs describe training requirements for personnel who do not compound and only perform functions such as in-process checks, final verification, or dispensing?

Not Applicable: All personnel are fully trained

5) Does facility training demonstrate knowledge and competency initially and at least annually in the core competencies?

Yes: Hand hygiene

Yes: Garbing

Yes: Cleaning and sanitizing

Yes: Handling and transporting components and CNSPs

Yes: Mixing and measuring

Yes: Proper use of equipment and devices selected to compound CNSPs

Yes: Documentation of the compounding process

6) Do training procedures include a review of appropriate written materials?

Yes: USP 795

Yes: Staff understand and interpret safety data sheets (SDSs)

Yes: Staff understandi certificates of analysis (CofA)

Yes: Staff read and understand procedures related to their compounding duties

7) Does the training process document personnel have been trained and successfully completed competency assessments?

Yes: Personnel are observed and guided throughout the training process.

Yes: Personnel are expected to repeat procedures independently under direct supervision.

Yes: Personnel are permitted to perform the procedure without direct supervision only after independently demonstrating understanding and competency.

Yes: Upon completion of the training program the designated person or assigned trainer documents personnel have been successfully trained and completed competency assessments.

8) Does the designated person monitor and observe compounding activities?

Yes: Routinely monitors and observes compounding activities

Yes: Takes immediate corrective action if deficient practices are observed.

Observation
Discussed: Designated Person is the currently the only employee at this pharmacy

9) Does the facility have SOPs that describe the procedures for monitoring and observing compounding activities and personnel?

Other

Observation
Unable to observe policy during inspection
USP 795 | Effective 11/01/2023
Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel.

2.6.3) Personal Hygiene and Garbing

1) Does the facility require that individuals entering the compounding area maintain appropriate personal hygiene?

Yes: Individuals are trained to report conditions that present a personal risk of potential contamination to the compounding environment and CNSP to the designated person.

Yes: The designated person evaluates whether individuals should be excluded from working in the compounding area until personal conditions resolve.

2) Do personnel remove items that are not easily cleanable and that might interfere with garbing prior to entering the compounding area?

Yes: Personnel remove outer garments (e.g., bandanas, coats, hats and jackets) prior to engaging in compounding.

Yes: Personnel remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing or hand hygiene (e.g., watches, rings) prior to engaging in compounding.

Yes: Personnel remove earbuds/headphones prior to engaging in compounding.

3) Does the designated person permit accommodations for personal items provided that the quality of the environment and CNSP are not affected?

No accommodations for personal items are provided.

4) Do compounding staff perform appropriate hand hygiene procedures when entering the compounding area?

Yes: Personnel wash hands with soap and water for at least 30 seconds

Yes: Personnel dry hands completely with disposable towels or wipers

Yes: Personnel don gloves

5) Does the facility wipe or replace other items before beginning to compound a CNSP that has different components?

Yes

6) Do compounding personnel inspect gloves for holes, punctures or tears?

Yes

Yes: Gloves are replaced immediately if defects are detected.

7) Are gloves worn for all compounding activities?

Yes

8) Is other garb appropriate for the type of compounding performed?

Yes: Garb protects personnel from chemical exposures

Yes: Garb prevents CNSP contamination

Yes: Garbing requirements are determined by the facility and documented in the SOPs.

Yes: Frequency of changing garbing is determined by the facility and documented in the facility's SOPs.

9) Is garbing replaced immediately if it becomes visibly soiled or if its integrity is compromised?

Yes

10) Is garb stored in a manner that minimizes contamination?

Yes

11) Is garb removed and discarded when leaving the compounding area?

Yes

Yes: All garb, except gowns (as applicable), are removed and discarded when leaving the compounding area.

Yes: Unsoiled/undamaged gowns remain in the compounding area for reuse during the same shift.

12) Do facility SOPs describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment?

Not Applicable

13) Is appropriate PPE worn and disposed of in accordance with USP 800 for hazardous drug compounding?

Yes

2.6.4) Buildings and Facilities

1) COMPOUNDING AREA: Is there a designated area for nonsterile compounding?

Yes

2) Is the compounding area suitable?

Yes: The compounding area is well lit, clean, orderly, and sanitary condition

Yes: The compounding area is in a good state of repair.

Yes: The compounding area is not carpeted.

3) Does the compounding area provide for the orderly placement of equipment and materials?

Yes

4) STORAGE AREA: Are temperatures monitored and recorded in the compounding area?

Yes: Temperatures are monitored with a continuous recording device.

Yes: Temperatures are stored in the continuous temperature device and are retrievable.

5) Is temperature monitoring equipment calibrated or verified for accuracy?

Yes: As recommended by the manufacturer

6) Does the facility have a process to evaluate CNSPs exposed to temperature excursions?

Other

Observation
Unable to observe policy:
USP 795 | Effective 11/01/2023
The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s).
When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised, and, if so, the CNSP or component must be discarded.

7) Are all CNSPS, components, equipment and containers stored off the floor?

Yes

8) WATER SOURCES: Does the facility have an easily accessible sink with hot and cold water?

Yes

9) Is the sink empty of all items unrelated to compounding?

Yes

10) Is the sink cleaned when visibly soiled before being used to clean compounding equipment?

Yes

11) Are plumbing systems free of defects that may contribute to CNSP contamination?

Yes

12) Is purified water used for rinsing equipment and utensils?

Yes

Observation
Discussed: Equipment and utensils will be rinsed with distilled water (gallon jugs)

2.6.5) Cleaning and Sanitizing

1) Are work surfaces cleaned at appropriate intervals?

Yes: Beginning and end of each shift

Yes: After spill/splash contamination is known or suspected

Yes: Between compounding CNSPs with different components

2) Are floors cleaned at appropriate intervals?

Yes: On days compounding occurs

Yes: After spills

Yes: When surface contamination is known or suspected

3) Are walls cleaned at appropriate intervals?

Yes: When visibly soiled

Yes: After spills

Yes: When surface contamination is known or suspected

4) Are ceilings cleaned at appropriate intervals?

Yes: When visibly soiled

Yes: When surface contamination is known or suspected

5) Is storage shelving cleaned at appropriate intervals?

Yes: at least every 3 months

Yes: After spills

Yes: When surface contamination is known or suspected

6) Are surfaces resistant to damage caused by cleaning and sanitizing agents?

Yes

7) Are floors in the compounding area easily cleanable?

Yes: Floors are non-porous.

Yes: Floors are not particle generating.

8) Are appropriate cleaning and sanitizing agents used?

Yes

Observation

FYI:

USP 795 | Effective 11/01/2023

Cleaning and sanitizing agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues.

If cleaning and sanitizing are performed as separate steps, cleaning must be performed first

2.6.6.1) Equipment

1) Is the equipment used in the compounding process suitable?

Yes: Equipment surfaces are not reactive, additive or sorptive.

Yes: Equipment surfaces do not alter the quality of the CNSP.

Yes: Disposable or dedicated equipment is used to reduce the chance of bioburden and cross contamination.

Observation

The C-PECs used for manipulation of nonsterile HDs has redundant–HEPA filters in series

2) Is the equipment used in compounding stored in a manner that minimizes the risk of contamination?

Yes. Equipment is stored in a manner that minimizes contamination risk.

Yes: Equipment is located to facilitate use, maintenance and cleaning.

3) Is equipment used in compounding or testing of compounded preparations properly inspected and maintained?

Yes: Inspected prior to use

Yes: Equipment is verified for accuracy as recommended by the manufacturer or at least every 12-months.

Yes: Equipment is cleaned after compounding

4) Are activities that generate airborne chemical particles performed in a closed-system processing device?

Yes: There is a process in place to identify components that could generate airborne chemical particles.

Yes: Particle generating components are manipulated in a closed system processing device

Yes: Facility SOPs document the assessment of particle generating components.

5) Are CVSs and/or BSCs certified at least every 12-months?

Yes: The CVE or BSC is certified according to manufacturer specifications.

Observation

Discussed CVE is maintained on a manufactures recommended schedule
USP 795 | Effective 11/1/2023
If a CVE or BSC is used, it must be certified at least every 12 months according to manufacturer specifications or other laws and regulations of the applicable regulatory jurisdiction.
If a BSC, CVE, or other nondisposable device is used, it must be cleaned as described in Table 2.

6) CVE: Is the CVE cleaned and sanitized according to minimum USP frequencies?

Yes: Beginning and end of each shift on days when compounding occurs

Yes: After spills/surface contamination is known or suspected

Yes: The horizontal work surface of the CVE is cleaned between compounding CNSPs with different components.

8) Are other devices and equipment used in compounding cleaned according to USP minimum frequencies?

Yes: Before their first use

Yes: According to manufacturer recommendations

Yes: Cleaned between compounding CNSPs with different components, if no manufacturer recommendation is available

2.6.6.2) Components

1) Does the facility have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP?

Yes

2) Are SDSs readily accessible to all personnel working with components?

Yes

3) Is the designated person responsible for component selection?

Yes

4) API COMPONENT SELECTION: Do APIs used in compounding comply with USP 795?

Yes: Components comply with USP monographs, if one exists.

Yes: Components have a COA that includes specifications and test results showing the API meets expected quality.

Yes: Components are manufactured at an FDA-registered facility.

5) COMPONENTS OTHER THAN APIs: Do other components used in compounding comply with USP 795?

Yes: Components are accompanied by a COA that verifies the component meets the criteria in the USP/NF, if one exists.

Yes: Components are manufactured in an FDA-registered facility.

Yes: If a component cannot be obtained form an FDA-registered facility, the designated person selects a component for suitable for the intended use.

6) WATER: Is purified water or better quality used for compounding nonsterile drug preparations?

Yes

8) COMPONENT RECEIPT: Does the facility has a process to identify and label components that lack a vendor expiration date?

Yes: Marks components with the date of receipt.

Yes: Assigns a BUD of not more than 3 years from the date of receipt.

Yes: APIs and added substances that are used in sterile compounding are assigned a BUD of not more than 1-year from the date of receipt.

Yes: APIs and added substances known to be susceptible to degradation are assigned a 1-year expiration date.

9) COMPONENT RECEIPT: Are components found to of unacceptable quality are promptly rejected?

Yes: labeled as rejected and segregated from active stock

Yes: Other lots of rejected components from the same vendor are examined

10) COMPONENT EVALUATION: Are components visually inspected prior to use?

Yes

11) COMPONENT EVALUATION: Is a process in place to ensure components are of the correct identity and were properly stored prior to each use?

Yes

12) COMPONENT HANDLING: Are components handled in accordance with manufacturer instructions and/or pre applicable laws and regulations?

Yes

13) COMPONENT HANDLING: Are components removed from the original container discarded if not used?

Yes

14) COMPONENT SPILL AND DISPOSAL: Does the facility maintain current chemical hazard and disposal information?

Yes

15) COMPONENT SPILL AND DISPOSAL: Is the facility prepared to handle a nonhazardous component spill?

Yes: The management and documentation of nonhazardous component spills and disposal is described in the facility SOPs.

Yes: Spill kit is readily accessible in the compounding area.

Yes: Personnel required to remediate spills receive training in spill management of chemicals used and stored in the compounding facility.

Yes: Spill training is conducted and documented at least every 12 months for all personnel required to clean up spills.

16) COMPONENT SPILL AND DISPOSAL: Is component waste disposed of in accordance with laws and regulations?

Yes

Observation
Observed corresponding policy

2.6.7) Master Formulation and Compounding Records

1) MASTER FORMULAS: Does the facility have a master formula for each unique formulation of a CNSP?

Yes

Yes: Changes and alterations are approved and documented

Yes: SOPs describe how master formulas are created, altered and approved

2) MASTER FORMULAS: Do master formulas contain all required elements?

Yes: Contain the name, strength or activity, and dosage form

Yes: Contain the identities and amounts of all components

Yes: Contain the relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility, etc.), if appliable

Yes: Contain the container closure system

Yes: Contain complete instructions for preparing the CNSP

Yes: Contain the equipment and supplies needed

Yes: Contain a description of the compounding process

Yes: Contain a physical description of the final CNSP

Yes: Contain beyond-use date and storage requirements

Yes: Contain a reference source for assigned BUD

Yes: Contain calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s), where appliable

Yes: Contain labeling requirements (e.g. shake well)

Yes: Contain quality control (QC) procedures (e.g., pH testing, visual inspection, etc.) and expected results

Yes: Contain other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature, etc.)

3) COMPOUNDING RECORDS: Does the facility create a compounding record for each CNSP?

Yes

4) COMPOUNDING RECORDS: Do compounding records contain all the required elements?

Yes: Contain the name, strength or activity, and dosage form

Yes: Contain the date (or date and time) of preparation

Yes: Contain an assigned internal identification number (Rx number or lot number)

Yes: Contain a method to identify individuals involved in the compounding process

Yes: Contain a method to identify the individual(s) verifying the final CNSP

Yes: Include the name, vendor or manufacturer, lot number, and expiration date of each component

Yes: Include the weight or measurement of each component

Yes: Include the total quantity of CNSP compounded

Yes: Contain the assigned beyond-use date

Yes: Contain the storage requirements of the CNSP

Yes: Contain calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s), where applicable

Yes: Contain a physical description of the final CNSP

Yes: Contain the results of quality control procedures (e.g., pH testing, visual inspection, etc.)

Yes: Contain a reference to the master formula record for the CNSP

2.6.8) Release Inspections and Testing

1) Are all release inspections included in the facility's documentation?

Yes

2) Do visual inspections confirm the CNSP is ready for releasing and dispensing?

Yes

3) Are CNSPs not dispensed or released on day of preparation visually inspected before being dispensed?

Yes

2.6.9) Labeling

2) Do prepared CNSP contain a label with the minimum required information in USP 795?

Yes: Contain the assigned internal identification number

Yes: Contain the active ingredients and their amounts, activities, or concentrations

Yes: Contain the storage conditions, if other than controlled room temperature

Yes: Contain the beyond use date

Yes: Contain the dosage form

Yes: Contain the total amount or volume, if it is not obvious from the container

Observation
(Lot number, Rx number, etc.)

3) Do labels on dispensed CNSPs contain all information required by USP 795?

Yes: Contain the route of administration

Yes: Indicate the preparation was compounded

Yes: Include any applicable special handling instructions

Yes: Iclude any applicable warning statements

Yes: Contain the compounding facility name and contact information if the CNSP is sent outside the facility or healthcare system in which it was compounded

4) Do facility SOPs describe labeling procedures?

Yes: Labeling procedures are defined in facility SOPs.

Yes: Procedures include processes to prevent labeling errors.

Yes: CNSP label verification includes confirmation of the prescription or medication order.

Yes: CNSP label verification includes confirmation of the master formula record and compounding record.

Observation
FYI:
USP 795 | Effective 11/01/2023
Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups.
The label of the CNSP must be verified to ensure that it conforms with the following:
Prescription or medication order;
MFR (see 7.1 Creating Master Formulation Records); and
CR (see 7.2 Creating Compounding Records).

2.6.10.1) Terminology and Parameters

1) Does the CNSP label state the beyond use date?

Yes

2) Does the facility consider parameters which may affect CNSP quality when assigning a BUD?

Yes: Includes a review of chemical and physical stability properties of the API and added substances

Yes: Includes a review of the compatibility of the container closure system with the finished preparation

Yes: Includes a review of the degradation of the container closure system

Yes: Includes a review of the potential for microbial proliferation in the CNSP

Yes: Includes a review for significant deviations from essential compounding steps

2.6.10.2) Establishing a BUD

1) INFORMATION: General BUD description.

Observation
USP 795 | Effective 11/01/2023
The BUDs in Table 4 are based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply.

The aqueous and nonaqueous dosage forms in Table 4 are defined based on the water activity (aw) of the most similar drug preparations described in Table 3 or Application of Water Activity Determination to Nonsterile Pharmaceutical Products □1112□. In general, the use of aw aids in assessing the susceptibility of CNSPs to microbial contamination and the potential for API degradation due to hydrolysis. The aw is different from the water content and may be considered as the available water to support microbial growth and hydrolytic reactions. Nonaqueous dosage forms will not support spore germination or microbial growth due to their low aw. Reduced aw greatly assists in the prevention of microbial proliferation in conventionally manufactured products and is expected to convey the same benefit to CNSPs.

Compounders are not required to measure aw for CNSPs. While the manufactured products in □1112□, Table 2 and compounded preparations in Table 3 below are not exhaustive, they provide examples of dosage forms that have an aw < 0.6 and those that have an aw ≥ 0.6 and can assist personnel in determining the BUD by dosage form using Table 4.

When preparing CNSPs, raw materials and equipment contribute a bioburden to the final preparation. CNSPs with an aw ≥ 0.6, and a BUD within the limits of Table 4, should contain suitable antimicrobial agents to protect against the proliferation of bacteria, yeast, and mold contamination that may be inadvertently introduced anytime during the compounding process or throughout the BUD under appropriate handling and storage conditions. All CNSPs with an extended BUD must follow 10.5 Extending BUDs for CNSPs. Careful consideration should be taken when selecting a preservative to ensure microbiological effectiveness and stability. When antimicrobial preservatives are contraindicated in a CNSP, storage of the preparation in a refrigerator is required if such storage does not change the physical or chemical properties of the CNSP (i.e., precipitation).

4) Does the facility assign BUDs in accordance with USP 795?

Yes: Non-preserved aqueous dosage forms: 14 days refrigerated.

Yes: Preserved aqueous dosage forms: 35 days refrigerated or room temperature

Yes: Non-aqueous oral liquids: 90 days refrigerated or room temperature

Yes: Other non-aqueous dosage forms: 180 days refrigerated or room temperature

Yes: CNSPs are protected from moisture, freezing, and excessive heat, and where necessary, from light.

2.6.10.3) CNSPs Requiring a Shorter BUD

1) Does the facility have a process to determine if data shows a CNSP requires a shorter BUD?

No

2.6.10.4) Extending BUDs for CNSPs

1) Are all CNSPs with a USP-NF monograph assigned a BUD that does not exceed the BUD specified in the monograph?

No:

2.6.11) SOPs

1) Does the facility have SOPs on all aspects of the compounding operation?

Yes

Observation
USP 795 | Effective 11/01/2023
11. SOPS
Facilities preparing CNSPs must develop SOPs on all aspects of the compounding operation. All personnel who conduct or oversee compounding activities must be trained in the facility's SOPs and be responsible for ensuring that they are followed. One or more person(s) must be designated to ensure that the facility's SOPs are fully implemented. The designated person(s) must ensure that follow-up occurs if problems, deviations, or errors are identified.

3) Is an employee designated to ensure facility SOPs are fully implemented?

Yes

2.6.12) Quality Assurance and Quality Control

1) DEFINITIONS: Quality Assurance and Quality Control

Observation
USP 795 | Effective 11/01/2023
Quality assurance (QA) is a system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

Quality control (QC) is the sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CNSP. See Quality Assurance in Pharmaceutical

2) Are QA and QC programs formally established?

No

Observation
Discussed this policy will be formalized and implemented

USP 795 | Effective 11/01/2023
Compounding □1163□.
A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (□795□) and the laws and regulations of the applicable regulatory jurisdiction.

4) Do facility SOPs describe each aspect of the QA program?

Other: See Observation Below

Observation
FYI:
USP 795 | Effective 11/01/2023
The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program. Designated person(s) responsible for the QA program must have the training, experience, responsibility, and authority to perform these duties. The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed.

5) Is the QA and QC program reviewed annually by the designated person?

Other: See Observation Below

Observation
FYI:
USP 795 | Effective 11/01/2023
The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed.

6) RECALL PROCEDURES: Does the facility have recall procedures in place?

Other: See Observation Below

Observation
FYI:

USP 795 | Effective 11/01/2023
The facility must have procedures in place to
Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., strength, purity, or other quality attributes)
Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy
Investigate if other lots are affected and recall if necessary

7) RECALL PROCEDURES: Do SOPs for recalls of dispensed CNSPs contain all elements required by USP 795?

Other: See Observation Below

Observation
USP 795 | Effective 11/01/2023
An SOP for recall of dispensed CNSPs must contain
Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall
Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution
Procedures to identify patients who have received the CNSP
Procedures for disposal and documentation of the recalled CNSP
Procedures to investigate and document the reason for recall

8) RECALL PROCEDURES: Do SOPs for recalls require documentation and notification to the appropriate regulatory bodies?

Other: See Observation Below

Observation

USP 795| Effective 11/01/2023
The nonsterile compounding facility must document the implementation of the recall procedures. The recall must be reported to appropriate regulatory bodies as required by the laws and regulations of the applicable regulatory jurisdiction.

OAC 4729:7-2-03 | Effective 7/1/2021
(P) A pharmacy shall report to the state board of pharmacy within seventy-two hours upon discovery, and in a manner determined by the board, any product quality issue attributed to a compounded drug preparation dispensed by the pharmacy.

(1) As used in this paragraph, a product quality issue means any of the following:

(a) Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;

(b) Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or

(c) Any significant chemical, physical, or other change or deterioration of the dispensed compounded drug preparation within the compounded drug preparation's assigned beyond-use date.

(2) A product quality issue does not include an isolated allergic reaction to a substance included in a compounded drug preparation.

(Q) A pharmacy shall report to the state board of pharmacy within seventy-two hours of issuance or receipt, and in a manner determined by the board, any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration.

9) COMPLAINT HANDLING: Does the facility have a SOP for handling complaints?

Other: See Observation Below

Observation

USP 795 | Effective 11/01/2023
Compounding facilities must develop and implement SOPs for handling complaints. Complaints may include but are not limited to concerns or reports on the quality, labeling, or possible adverse reactions related to a specific CNSP.

10) COMPLAINT HANDLING: Are complaints reviewed to identify potential quality problems and actions taken?

Other: See Observation Below

Observation
USP 795 | Effective 11/01/2023
A designated person(s) must review all complaints to determine whether the complaint indicates a potential quality problem with the CNSP. If it does, a thorough investigation into the cause of the problem must be initiated and completed. The investigation must consider whether the quality problem extends to other CNSPs. Corrective action, if necessary, must be implemented for all potentially affected CNSPs.
Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected.

11) COMPLAINT HANDLING: Are records of complaints readily retrievable and complete?

Other: See Observation Below

Observation
USP 795 | Effective 11/01/223
A readily retrievable written or electronic record of each complaint must be kept by the facility, regardless of the source of the complaint (e.g., email, telephone, or mail). The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number).

12) COMPLAINT HANDLING: Do complaint records include the findings of investigation?

Other: See Observation Below

Observation

USP 795 | Effective 11/01/2023
The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the record-keeping requirements in 14. Documentation. A CNSP that is returned in connection with a complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with laws and regulations of the applicable regulatory jurisdiction.

13) COMPLAINT HANDLING: Are CNSPs returned in connection with a complaint quarantined and destroyed?

Other: See Observation Below

Observation
USP 795 | Effective 11/01/2023
A CNSP that is returned in connection with a complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with laws and regulations of the applicable regulatory jurisdiction.

14) ADVERSE EVENT REPORTING: Are adverse events properly reported?

Other: See Observation Below

Observation

USP 795 | Effective 11/01/2023
Adverse events potentially associated with the quality of CNSPs must be reported in accordance with the facility's SOPs and all laws and regulations of the applicable regulatory jurisdiction. If the investigation into an adverse event reveals a quality problem with a CNSP that is likely to affect other patients, those patients and prescribers potentially affected must be informed.

2.6.13) CNSP Packaging and Transporting

1) Do facility SOPs include CNSP packaging requirements?

Yes

Observation
Observed: As described in MFR
USP 795 | Effective 11/01/2023
13.1 Packaging of CNSPs
The facility's SOPs must describe packaging of CNSPs. Personnel should select and use packaging materials that will maintain the physical and chemical integrity and stability of the CNSPs. Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure.

2) Do SOPs describe CNSP transport?

Other: See Observation Below

Observation
Unable to observe corresponding policy

USP 795 | Effective 11/01/2023
If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed.

2.6.14) Documentation

1) Does the facility maintain written or electronic documentation demonstrating compliance with USP 795?

Yes: Includes documentation of personnel training, competency assessments, and qualification records including corrective actions for any failures.

Yes: Includes equipment records (e.g., calibration, verification, maintenance reports).

Yes: Includes COAs and all documentation required for components not conventionally manufactured.

Yes: Includes records of receipt for all components.

Yes: Includes SOPs, master formula records, and compounding records.

Yes: Includes release inspection and testing records.

Yes: Includes information related to complaints and adverse events including corrective actions taken.

Yes: Includes results of all investigations and corrective actions.

Yes: Includes records of cleaning and sanitizing the designated compounding area.

Yes: Includes temperature logs.

Yes: Includes accommodations to personnel compounding CNSPs.

Yes: Includes required routine reviews (e.g., yearly review of QA and QC programs, yearly review of chemical hazard and disposal information, etc.)

2) Does the facility maintain required documentation in a readily retrievable manner for at least 3 years?

Yes

8) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient. These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (The resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

9) Inspection Affirmation

1) Inspection Affirmation

Observation
*This document only addresses compliance with the rules or laws specifically identified above.

As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:
(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to WRITTENRESPONSE@PHARMACY.OHIO.GOV or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Lisa Hartig-Mawhorr, R.Ph. _____
(signature)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA3701871	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-02-2024

ADEGEN PHARMACY LLC
D.B.A ADEGEN PHARMACY
1620 GATEWAY CIR
GROVE CITY, OH 431238650

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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Form DEA-223 (9/2016)

eLicense Ohio
Professional Licensure

License Look Up

5/18/2025 3:18 PM

Adegen Pharmacy LLC

License Number	0232000435
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 3
License Issue Date	12/01/2023
License Expiration Date	03/31/2027
License Effective Date	04/01/2025
Street Address	1620 Gateway Cir
City	Grove City
State	OH
Zipcode	43123-8650
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
LISA HARTIG-MAWHORR	03319816	Active	Wed Oct 11 00:00:00 GMT 2023	

Current date & time: **5/18/2025 3:18 PM**

4JJJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $S00.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FA8019083
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other: Mail Order	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH PH04031		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Alto Pharmacy

Physical Address: 929 Broadway

City: Denver State: CO Zip: 80203-2705

Mailing Address (if different from physical address): 929 Broadway

City: Denver State: CO Zip: 80203-2705

Telephone: (800) 874-5881 Toll Free # (NAC 639.708, NRS 639.23286): (800) 874-5881

Fax: (415) 484-7058 Contact Email: pharmacycompliance@alto.com

Website: www.alto.com

Nevada Business License # (if applicable) NV20212001945

Supervising/Managing Pharmacist Name (NRS 639.220): Nimita N. Davis

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23322

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Nimita N. Davis	NV Pharmacist Registration #: 23322
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A-Not Applicable

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Alto Pharmacy Investments, LLC

Corporation/Organization Name: Alto Pharmacy LLC

Mailing Address: 645 Harrison Street, Suite 200

City: San Francisco State: CA Zip: 94107

Telephone: (800) 874-5881 Email: pharmacycompliance@alto.com

Contact Person Name: Lisa M. Jurinka

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A-Not Applicable

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A-Not Applicable

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Secretary (title) for Alto Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Lisa M. Jurinka

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

5/24/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Lisa M. Jurinka hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary (title) for Alto Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 24th day of May, 2025

Notary Public

OFFICIAL STAMP
TYLER DYE
NOTARY PUBLIC - OREGON
COMMISSION NO. 1055222
MY COMMISSION EXPIRES JANUARY 21, 2029

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lisa M. Jurinka, Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

5/24/25
Date

Board Use Only	Date Received: 6/18/25	Amount: $500 CC

Section 3: History of Company

Please be advised, the information provided relates to the Applicant's affiliate pharmacies located in San Francisco and Los Angeles, CA.

As the Applicant and affiliate locations operate under the same legal name and ownership, we are providing this information with transparency in mind, to ensure are aware of these matters.

Further be advised, the Applicant has not had a license investigated, disciplined nor are any investigations or disciplinary actions pending.

By:
Name: Lisa M. Jurinka
Title: Secretary

Date: 05/09/2025

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - San Francisco (Harrison Street), California				
		FACILITY	09/26/2024	Texas Board of Pharmacy (Case #: 2024-01512) On July 19, 2024, the Texas Board of Pharmacy ("Board of Pharmacy") issued an Agreed Board Order ("ABO") in which the Board of Pharmacy alleges, from about September 28, 2023, through on or about November 29, 2023, Alto Pharmacy, located at 645 Harrison Street, Suite 200, San Francisco, CA 94107, Texas Non-Resident Pharmacy Permit #: 34204, operated without a Texas licensed pharmacist named on the Texas Non-Resident Pharmacy Permit. Alto Pharmacy acknowledges operating without the required Texas licensed pharmacist, Alto Pharmacy further acknowledges contact, and correspondence was made with the Board of Pharmacy, requesting guidance and direction on operating without a Texas licensed pharmacist. The Board of Pharmacy and Alto Pharmacy finalized the ABO on November 5, 2024, and a fine of $1,000 was paid. Alto Pharmacy's Texas Non-Resident Pharmacy Permit remains active, in good standing and unrestricted. The Board of Pharmacy considered the matter closed and took no further action.

TEXAS STATE BOARD OF PHARMACY

November 7, 2024

ALTO PHARMACY
C/O TSAI LING JIANG
PHARMACIST-IN-CHARGE
645 HARRISON ST STE 200
SAN FRANCISCO, CALIFORNIA 94107

RE: In the Matter of Alto Pharmacy

Dear Tsai Ling Jiang:

Enclosed is a copy of Agreed Board Order (ABO) #2024-01512 that was entered by the Texas State Board of Pharmacy (Board) concerning the above-referenced matter. The Board entered this Order on November 5, 2024. The requirements and conditions of the enclosed Order and matters relating to the Order are discussed below.

ADMINISTRATIVE PENALTY (FINE)

Under the terms of this Order, Alto Pharmacy (pharmacy license #34204) must pay an administrative penalty (fine) of $1,000. **This fine is due on or before March 5, 2025.** Please make your cashier's check or money order payable to the "Texas State Board of Pharmacy" and submit to the Board's office by the due date. Please include your ABO number (#2024-01512) on the cashier's check or money order. **Note:** The Board will **not** accept partial payments. You must submit payment for the full amount by the due date.

LICENSE RENEWAL APPLICATIONS

Prior to the next expiration date of pharmacy license #34204, the pharmacy will complete a license renewal application for the Texas State Board of Pharmacy. This application will require a pharmacy representative to answer the question:

> "Has the pharmacy, the pharmacy's owner or any officer or partner (if the pharmacy is owned by a corporation or partnership) been the subject of any professional disciplinary action or are any such actions pending against you by a regulatory authority within the last 36 months?..."

As a result of the entry of ABO #2024-01512, Alto Pharmacy must answer "yes" to this question for 36 months from the date of the termination of all sanctions. Consequently, an Alto Pharmacy representative must answer "yes" to this question on any renewal applications submitted beginning November 5, 2024 and ending 36 months following the termination of all sanctions.

If you have any questions about this Order, please contact Knijiah Samuel, Monitoring Specialist, at (512) 305-8054 or via monitoring@pharmacy.texas.gov.

Sincerely,

Robert Rivera
Enforcement Manager

RR:ks

Enclosure: Agreed Board Order #2024-01512

c: Lisa Jurinka
Managing Officer, Alto Pharmacy LLC
On behalf of Alto Pharmacy
pharmacycompliance@alto.com

Kianna L. Sitarski
Legal Counsel for Alto Pharmacy
Brown & Fortunato, P.C.
7557 Rambler Road, Suite 510
Dallas, Texas 75231
ksitarski@bf-law.com

AGREED BOARD ORDER #2024-01512

RE: IN THE MATTER OF
ALTO PHARMACY
(PHARMACY LICENSE #34204)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 34204 issued to Alto Pharmacy (Respondent), 645 Harrison Street, Suite 200, San Francisco, California 94107.

By letter dated July 19, 2024, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 562.101(f); and 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2023); and

Section 291.103 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2023), in that allegedly:

COUNT

From on or about September 28, 2023, through on or about November 29, 2023, Alto Pharmacy, 645 Harrison Street, Suite 200, San Francisco, California 94107, was engaged in the operation of a non-resident pharmacy in violation of Texas State Board of Pharmacy Rules, in that the pharmacy was not under the supervision of a pharmacist-in-charge licensed as a pharmacist in Texas.

By letter dated July 19, 2024, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Lisa Jurinka, Managing Officer, Alto Pharmacy LLC, on behalf of Respondent, and Kianna L. Sitarski, Legal Counsel for Respondent, neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to an informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(3) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2023), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2024).

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 5th day of November, 2024.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Daniel Carroll, Pharm.D.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Lisa Jurinka

Lisa Jurinka, Managing Officer, Alto Pharmacy LLC
On behalf of Alto Pharmacy

Kianna L. Sitarski, Legal Counsel for Alto Pharmacy
Brown & Fortunato, P.C.
7557 Rambler Road, Suite 510
Dallas, Texas 75231

APPROVED AS TO FORM:

Megan G. Holloway, General Counsel
Texas State Board of Pharmacy

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - San Francisco, California				
		FACILITY	03/22/2023	California Board of Pharmacy (Case #: CI2022 96563) On March 22, 2023, the California Board of Pharmacy ("Board of Pharmacy")issued a Modified Citation and Fine ("Citation"), in which the Board of Pharmacy alleges, on or about July 2, 2022, the Licensee dispensed and delivered prescription drugs to a wrong address. On or about July 6, 2022, the prescription drugs were returned to the Licensee and afterwards placed into the Licensee's inventory. Further, Board of Pharmacy alleges the Licensee failed to quarantine and prepare the returned prescription drugs for destruction pursuant to Board of Pharmacy rules and regulations. Licensee acknowledges the returned prescription drugs were placed into inventory, not quarantined and prepared for destruction as required by Board of Pharmacy rules and regulations. Licensee agreed to pay the Board of Pharmacy's fine of $1,000 as indicated in the attached Citation. To ensure correct practices are followed, the Licensee's Compliance and Pharmacy Operations Departments have reviewed their Policies and Procedures, which address the handling of returned prescription drugs, with the staff at the pharmacy location. Staff has acknowledged the review, training and the proper procedures to follow when previously dispensed prescription drugs are returned to the pharmacy location. The Licensee's California Pharmacy Permit remains active, in good standing and unrestricted. Upon receipt of the fine, the Board of Pharmacy considered the matter closed and took no further action.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 22, 2023

CERTIFIED MAIL

ALTO PHARMACY
ATTN: MATTIEU GAMACHE-ASSELIN, CEO
1400 TENNESSEE ST UNIT 2
SAN FRANCISCO, CA 94107

Natalia Mazina
100 Pine St Ste 1250
San Francisco, cA 94111-5235

RE: CI 2022 96563
ALTO PHARMACY
PHY 54523

As a result of the explanation and information you provided at the office conference, the amount of the fines assessed in Citation and Fine, CI 2022 98558 have been reduced.

The modified Citation is attached and is hereby issued pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (d).

If you desire a hearing to appeal the attached Citation, you must submit a written request for a hearing to the Board of Pharmacy ("Board") within 30 days of the date this Citation was issued. (See Bus. Prof. Code sec. 125.9, subd. (b)(4), and C.C.R., title 16, sec. 1775.4, subd. (d).). Unless the Board receives a written request within the 30 days, you will be deemed to have waived your right to a hearing in this matter and the Citation shall become the final order of the Board. If a hearing is not requested, the timely payment of the imposed fine(s) shall not constitute an admission of the violation(s) charged in the Citation.

Failure to pay any imposed fine(s) within 30 days of the date the Citation was issued may result in disciplinary action being taken.

If any fine(s) are not timely paid, then the full amount of the unpaid fine(s) shall be added to the fee for the renewal of your license. Your license shall not then be renewed without full payment of the renewal fee and the assessed fine(s).

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

Attachments

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check | | I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: ALTO PHARMACY PHY 54523 Respondent	Citation Case No : CI 2022 96563 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED

(Respondent)

Mailing Address of Respondent:

_____

(Street Address)

( )

(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

(Attorney's Name

_____

(Street Address)

( )

(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: ALTO PHARMACY, PHY 54523
Citation and Fine CI 2022 96563

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On March 22, 2023, I served the attached:

Cover Letter, Citation, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: MATTIEU GAMACHE-ASSELIN, CEO 1400 TENNESSEE ST UNIT 2 SAN FRANCISCO, CA 94107	7020 2450 0000 3084 4580
Natalia Mazina 100 Pine St Ste 1250 San Francisco, CA 94111-5235	7020 2450 0000 3084 4573

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 22, 2023, at Sacramento, California.

DECLARANT
Suelynn Yee
Citation and Fine Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2022 96563	ALTO PHARMACY, PHY 54523

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4342 subd. (a)/Health & Safety Code § 111295	**Prevent sale of drugs lacking quality/It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated**	**$1,000.00**

CONDUCT:

Actions by the Board to prevent sales of preparations or Drugs lacking quality of strength; Penalties for knowing or willful violation of Regulations governing those sales: Business and Professions Code (BPC) 4342(a), states in pertinent part: (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code), as it relates to Health and Safety Code (HSC) 111295, which states, It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. Specifically, Alto Pharmacy, PHY54523, located at 1400 Tennessee St., Unit 2, San Francisco, CA 94107, on or around 7/2/2022, dispensed and delivered prescription numbers: 883850002 and 883850003, to an unknown person and location and held at an unknown tempterature, the chain of custody was broken. The prescriptions showed up at the reception desk of the correct address around 7/6/2022 and were then handed to the correct patient. They were subsequently retrieved by Alto Pharmacy. Alto Pharmacy was in violation when they determined the drugs once returned, would be returned to stock, meaning they would be held and offered for sale/re-dispensed to another patient. Those drugs are considered adulterated and should have been quarantined and then sent for destrucation as they were out of Alto Pharmacy's control between dates: 7/2/2022 and 7/6/2022. It was unknown how they were stored and if they had been tampered with in any way. Holding or offering for sale, prescription drugs which where out of Alto Pharmacy's control between dates 7/2/2022 to 7/6/2022, which should be considered adulterated, was a violation according to BPC 4342(a) as it relates to HSC 111295.

CITATION ISSUED ON: March 22, 2023 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: April 21, 2023

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

COPY

Citation Number	Name, License No
CI 2022 96563	ALTO PHARMACY, PHY 54523

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4342 subd. (a)/Health & Safety Code § 111295	Prevent sale of drugs lacking quality/It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	$1,000.00

CONDUCT:

Actions by the Board to prevent sales of preparations or Drugs lacking quality of strength; Penalties for knowing or willful violation of Regulations governing those sales: Business and Professions Code (BPC) 4342(a), states in pertinent part: (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code), as it relates to Health and Safety Code (HSC) 111295, which states, It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. Specifically, Alto Pharmacy, PHY54523, located at 1400 Tennessee St., Unit 2, San Francisco, CA 94107, on or around 7/2/2022, dispensed and delivered prescription numbers: 883850002 and 883850003, to an unknown person and location and held at an unknown tempterature, the chain of custody was broken. The prescriptions showed up at the reception desk of the correct address around 7/6/2022 and were then handed to the correct patient. They were subsequently retrieved by Alto Pharmacy. Alto Pharmacy was in violation when they determined the drugs once returned, would be returned to stock, meaning they would be held and offered for sale/re-dispensed to another patient. Those drugs are considered adulterated and should have been quarantined and then sent for destrucation as they were out of Alto Pharmacy's control between dates: 7/2/2022 and 7/6/2022. It was unknown how they were stored and if they had been tampered with in any way. Holding or offering for sale, prescription drugs which where out of Alto Pharmacy's control between dates 7/2/2022 to 7/6/2022, which should be considered adulterated, was a violation according to BPC 4342(a) as it relates to HSC 111295.

CITATION ISSUED ON: March 22, 2023

TOTAL AMOUNT OF FINE(S): $1,000.00

PAYMENT OF FINE(S) DUE BY: April 21, 2023

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - Los Angeles, California				
		FACILITY	07/14/2023	California Board of Pharmacy (Case #: CI 2021 95943) On December 28, 2023, the California Board of Pharmacy ("Board of Pharmacy") issued a dismissal of the Citation and Fine, in which the Board of Pharmacy alleged, on or about July 14, 2023, the Licensee failed to update their pharmacy systems and inventory indicating a certain prescription drug was not available for dispensing to a patient requesting the medication, thus delaying the receipt of the prescription medication for the patient. Alto Pharmacy's California Resident Pharmacy Permit remains active, in good standing and unrestricted.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

December 28, 2023

CERTIFIED MAIL

ALTO PHARMACY
ATTN: ALICIA DAVIS, CEO
5916 BOWCROFT ST
LOS ANGELES, CA 90016

Sweta Patel
1255 Treat Blvd., Suite 300
Walnut Creek, CA 94597

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

After thorough and careful consideration of the explanation and information you provided at the office conference, it was decided to dismiss Citation and Fine. CI 2021 95943 as originally issued. Effective immediately the fines assessed in Citation CI 2021 95943, have been dismissed.

This decision is the final administrative order regarding the Citation.

Please contact Associate Enforcement Analyst Suelynn Yee at (916) 518-3013, if you have any questions.

Sincerely

Julia G. Ansel
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY FIRST CLASS CERTIFIED MAIL

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and no party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suit 100, Sacramento, California 95833.

On December 28, 2023, I served the attached:

in said cause, by placing a true copy thereof enclosed in two separate sealed envelopes w postage thereon fully prepaid by Certified Mail and First Class Mail, in the United States m at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: ALICIA DAVIS, CEO 5916 BOWCROFT ST LOS ANGELES, CA 90016	7017 0530 0000 3305 3269
Sweta Patel 1255 Treat Blvd., Suite 300 Walnut Creek, CA 94597	7017 0530 0000 3305 3252

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 28, 2023, at Sacramento, California.

DECLARANT
Suelynn Yee
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 14, 2023

DATED MATERIAL ENCLOSED

ALTO PHARMACY
ATTN: ALICIA DAVIS, CEO
5916 BOWCROFT ST
LOS ANGELES, CA 90016

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

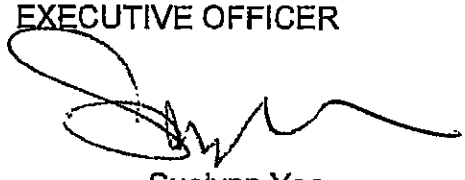
- August 13, 2023: Unless the Citation is contested payment of fine(s) must be received by the Board.
- July 28, 2023: Any contest of the Citation by request for an Informal Office Conference must be received by the Board.
- August 13, 2023: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By: 

Suelynn Yee
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **August 13, 2023.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than July 28, 2023 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than August 13, 2023 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2021 95943	ALTO PHARMACY, PHY 58642

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 733 subd. (a)	Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	$1,500.00

CONDUCT:

Unprofessional conduct: Business and Professions Code section 733, subsection (a) states, a licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency. Subsection (b) states notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exist subsection (2) (A) states, immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner. Alto Pharmacy, PHY58642, failed to comply. Specifically, on 5/18/2022, Dr. Shammas sent a prescription for EW for 30 tablets of Paxlovid 150 – 100 mg to Alto Pharmacy. On 5/18/2022, the prescription was processed under Rx774057005, and the data entry was verified by pharmacist Cynetha Lee at Alto Pharmacy Plano Texas, NRP2529, located at 6201 W Plano PKWY, Suite 400, Plano, TX. On 5/18/2022, upon completion of the data entry verification, the prescription was placed in the fulfillment queue at Alto Pharmacy Los Angeles, PHY58642, located at 5916 Bowcroft Street, Los Angeles, CA to fill the prescription. Two days later, on 5/20/2022, the pharmacists at Alto Pharmacy Los Angeles contacted Alto Pharmacy Clinical Care Specialist to inform EW that Alto Pharmacy Los Angeles cannot fill the prescription because Alto Pharmacy Los Angeles was a site not allocated to dispense Paxlovid thereby unable to obtain the medication to fill the prescription.

Alto Pharmacy failed to establish procedures or failed to update their computer software such that Alto Pharmacy staff are alerted that California Alto Pharmacy facilities do not dispense Paxlovid. Consequently, Alto Pharmacy obstructed EW from obtaining her prescription for Paxlovid in a timely manner.

oOn 5/18/2022, Alto Pharmacy's Clinical Care Specialist informed EW that Alto Pharmacy had Paxlovid in stock instead of informing EW on 5/20/2022 that Alto Pharmacy California facilities do not dispense Paxlovid.

oOn 5/18/2022, EW's prescription for Paxlovid was processed at Alto Pharmacy Plano Texas. The technician who processed the prescription and Pharmacist Cynetha Lee who verified the data entry of the prescription on 5/18/2022 should have informed the Care

Specialist to inform EW that California Alto Pharmacy facilities do not dispense Paxlovid.
oOn 5/18/2022, EW's Paxlovid prescription was placed in queue at Alto Pharmacy Los Angeles for filling. On 5/18/2022, the staff at Alto Pharmacy Los Angeles should have alerted the Care team to inform EW that Alto Pharmacy Los Angles cannot fill her prescription for Paxlovid because the pharmacy was not allocated to dispense Paxlovid.

Had Alto Pharmacy established procedures or updated their computer software, the staff at Alto Pharmacy could have informed EW on 5/18/2022 that her prescription for Paxlovid cannot be filled at Alto Pharmacy Los Angeles.
On 5/20/2022, EW contacted Dr. Shammas to send another prescription for Paxlovid to CVS Pharmacy 9660. The prescription was filled but was not delivered until 5/21/2022. Alto Pharmacy obstructed EW from obtaining from obtaining her prescription for Paxlovid, a medication which needed to be started within five days from the onset of COVID-19 symptoms, a violation of Business and Professions Code 733 (a).

CITATION ISSUED ON: July 14, 2023	TOTAL AMOUNT OF FINE(S): $1,500.00
PAYMENT OF FINE(S) DUE BY: August 13, 2023	

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2021 95943	ALTO PHARMACY, PHY 58642

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 733 subd. (a)	Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	$1,500.00

CONDUCT:

Unprofessional conduct: Business and Professions Code section 733, subsection (a) states, a licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency. Subsection (b) states notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exist subsection (2) (A) states, immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner. Alto Pharmacy, PHY58642, failed to comply. Specifically, on 5/18/2022, Dr. Shammas sent a prescription for EW for 30 tablets of Paxlovid 150 – 100 mg to Alto Pharmacy. On 5/18/2022, the prescription was processed under Rx774057005, and the data entry was verified by pharmacist Cynetha Lee at Alto Pharmacy Plano Texas, NRP2529, located at 6201 W Plano PKWY, Suite 400, Plano, TX. On 5/18/2022, upon completion of the data entry verification, the prescription was placed in the fulfillment queue at Alto Pharmacy Los Angeles, PHY58642, located at 5916 Bowcroft Street, Los Angeles, CA to fill the prescription. Two days later, on 5/20/2022, the pharmacists at Alto Pharmacy Los Angeles contacted Alto Pharmacy Clinical Care Specialist to inform EW that Alto Pharmacy Los Angeles cannot fill the prescription because Alto Pharmacy Los Angeles was a site not allocated to dispense Paxlovid thereby unable to obtain the medication to fill the prescription.

Alto Pharmacy failed to establish procedures or failed to update their computer software such that Alto Pharmacy staff are alerted that California Alto Pharmacy facilities do not dispense Paxlovid. Consequently, Alto Pharmacy obstructed EW from obtaining her prescription for Paxlovid in a timely manner.

oOn 5/18/2022, Alto Pharmacy's Clinical Care Specialist informed EW that Alto Pharmacy had Paxlovid in stock instead of informing EW on 5/20/2022 that Alto Pharmacy California facilities do not dispense Paxlovid.

oOn 5/18/2022, EW's prescription for Paxlovid was processed at Alto Pharmacy Plano Texas. The technician who processed the prescription and Pharmacist Cynetha Lee who verified the data entry of the prescription on 5/18/2022 should have informed the Care

Specialist to inform EW that California Alto Pharmacy facilities do not dispense Paxlovid. oOn 5/18/2022, EW's Paxlovid prescription was placed in queue at Alto Pharmacy Los Angeles for filling. On 5/18/2022, the staff at Alto Pharmacy Los Angeles should have alerted the Care team to inform EW that Alto Pharmacy Los Angles cannot fill her prescription for Paxlovid because the pharmacy was not allocated to dispense Paxlovid.

Had Alto Pharmacy established procedures or updated their computer software, the staff at Alto Pharmacy could have informed EW on 5/18/2022 that her prescription for Paxlovid cannot be filled at Alto Pharmacy Los Angeles.
On 5/20/2022, EW contacted Dr. Shammas to send another prescription for Paxlovid to CVS Pharmacy 9660. The prescription was filled but was not delivered until 5/21/2022. Alto Pharmacy obstructed EW from obtaining from obtaining her prescription for Paxlovid, a medication which needed to be started within five days from the onset of COVID-19 symptoms, a violation of Business and Professions Code 733 (a).

CITATION ISSUED ON: July 14, 2023	TOTAL AMOUNT OF FINE(S): $1,500.00
PAYMENT OF FINE(S) DUE BY: August 13, 2023	

COPY

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: ALTO PHARMACY

License No: PHY 58642

Citation Number : CI 2021 95943

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

_____

_____

_____

_____

_____

_____

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Daytime Number: (___) _____ Email Address: (___) _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: ALTO PHARMACY PHY 58642 Respondent	Citation Case No : CI 2021 95943 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: ALTO PHARMACY, PHY 58642
Citation and Fine CI 2021 95943

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On July 14, 2023, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: ALICIA DAVIS, CEO 5916 BOWCROFT ST LOS ANGELES, CA 90016	7021 1970 0001 5375 5542

I declare under penalty of perjury that the forgoing is true and correct.

Executed on July 14, 2023, at Sacramento, California.

DECLARANT

Suelynn Yee
Citation and Fine Analyst

Alto Pharmacy LLC

Owners and Officers

Name and Title	Work Address, Telephone and Email	Home Address and Telephone	Date of Birth	SSN or FEIN	Ownership %
Alto Pharmacy Investments, LLC Parent / Sole Member	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 pharmacycompliance@alto.com	[redacted]			100%
Alicia Boler Davis President and CEO	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 alicia.bolerdavis@alto.com				0%
Jamie E. Cohen CFO and Treasurer	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 jamie.cohen@alto.com				0%
Lisa M. Jurinka Secretary	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 lisa.jurinka@alto.com				0%

Managers

Name and Tile	Work Address, Telephone and Email	Home Address and Telephone	Date of Birth	SSN	Ownership %
Alicia Boler Davis Manager	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 alicia.bolerdavis@alto.com	[redacted]			0%

November 1, 2023

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Alto Pharmacy LLC

is an entity formed or registered under the law of Delaware has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 20181626884 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 06/10/2025 that have been posted, and by documents delivered to this office electronically through 06/11/2025 @ 10:35:46 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 06/11/2025 @ 10:35:46 in accordance with applicable law. This certificate is assigned Confirmation Number 17390652 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

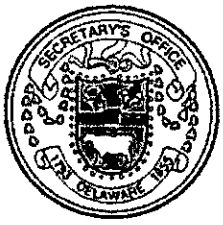
Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

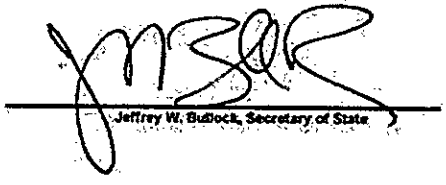
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALTO PHARMACY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





5763030 8300

SR# 20250175196

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202724830

Date: 01-17-25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Alto Pharmacy

Pharmacy/Wholesaler License # (if applicable): PH04031

Physical Address: 929 Broadway

City: Denver State: CO Zip: 80203-2705

Mailing Address (if different from physical address): 929 Broadway

City: Denver State: CO Zip: 80203-2705

Telephone: (800) 874-5881 Website: www.alto.com

Licensing Company Email: erik.heikkenen@adeiaservices.com

Section 2: Personal Information

First: Nimita Middle: N. Last: Davis

Alias(es, nicknames, name changes, etc.):

Date of Birth: 9/12/1975 SSN or ITIN: 346-78-0390 Sex: ☐ M ☒ F ☐ X

Mailing Address: 3540 Quivas Steet

City: Denver State: CO Zip: 08211

Telephone: (303) 888-0815 Email: nimita.davis@alto.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Colorado Anschutz Medical Campus		09/97-05/00	
Address	**City**	**State**	**Zip**
12850 E Montview BLVD	Aurora	CO	80045
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY)	
East Leyden High School		09/90-05/94	
Address	**City**	**State**	**Zip**
3400 Rose ST	Franklin Park	IL	60131
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
10/14-Present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Alto Pharmacy			05/21-Present	
Business Address		**City**	**State**	**Zip**
929 Broadway		Denver	CO	80203-2705
Phone	**Title**		**Number of Employed Hours**	
(800) 874-5881	Pharmacy Manager		8,320	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			06/15-05/21	
Business Address		**City**	**State**	**Zip**
612 Raymond DR		Naperville	IL	60563
Phone	**Title**		**Number of Employed Hours**	
	Pharmacy Manager		12,480	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			07/11-05/15	
Business Address		**City**	**State**	**Zip**
2005 FL-19		Eustis	FL	32726
Phone	**Title**		**Number of Employed Hours**	
	Pharmacy Manager		8,320	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			07/08-07/11	
Business Address		**City**	**State**	**Zip**
63 87th Ave		Naperville	IL	60565
Phone	**Title**		**Number of Employed Hours**	
	Pharmacist		6,240	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Nimita Davis, **certify that as the designated representative for**

Alto Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. NM I am at least 21 years of age;
3. NM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. NM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. NM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. NM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. NM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Nimita Davis

Print Name (First, Last)

Nimita Davis

Original Signature (electronic, copies or stamps not accepted)

5/19/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nimita Davis

Print Name (First, Last)

Nimita Davis — 5/19/2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Colorado, ss. County of Denver

I, NIMITA DAVIS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Nimita Davis — 5/20/25

Original Signature — **Date**

ANTWON SCOTT
Notary Public
State of Colorado
Notary ID # 20254007497
My Commission Expires 02-26-2029

Subscribed and Sworn to before me this 20th day of May 2025

Notary Public Signature

ANTWON SCOTT
Notary Public
State of Colorado
Notary ID # 20254007497
My Commission Expires 02-26-2029

(Seal)

Nevada State Board of Pharmacy

For licensing inquires please send an email to, pharmacylicensing@pharmacy.nv.gov (mailto:pharmacylicensing@pharmacy.nv.gov).

For current information on **disciplinary actions taken against licensees**, please send an email to teambc@pharmacy.nv.gov (mailto:teambc@pharmacy.nv.gov).

VERIFY LICENSE

Last Name	First Name	License#	License Status	License Expiration Date	City	State	Discipline	Action
Davis	Nimita	23322	Active	10/31/2025	Denver	CO	N	

License Number : 23322
Name : Davis, Nimita
License Type : Pharmacist
License Status : Active
License Date : 12/06/2022
Discipline : None
Expiration Date : 10/31/2025



Drop file(s) here to upload or click here to browse and select file(s) to upload. ()

Complete Upload Reset

Document Type	Upload Date	Name	Other Name	Is Public?	Status	Uploaded By	Link	Actions

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Personal History Record Application

N/A - Not Applicable. Applicant Alto Pharmacy LLC dba Alto Pharmacy is a 100% wholly owned subsidiary of Alto Pharmacy Investments, LLC. There are no individual owners.

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

THE COLORADO STATE BOARD OF PHARMACY
1560 Broadway, Suite 1300, Denver, CO 80202-5146
303-894-7800 FAX 303-894-7692 V/TDD 303-894-7880

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

Date of Inspection: 8/16/24 Time In/Out: ____/____

PDO Name Alto Registration No 168-176 Expiration Date 10/24

Address 929 Broadway City Denver Zip 80203

Pharmacist Manager ____ Lic No ____ Email ____

RPH on Duty ____ Lic No ____ Email ____

Physical/Postings	Compliant?
5.01.31b&c: Clean, sanitary, adequate space	NO
5.01.31d,f&g: Hot & cold water, frig & freezer	NO
5.01.50: Pharmacy security	YES
CRS 12-280-122:RPH/tech ratio____ nametags	YES
CRS 12-280-118:Licenses and registrations posted	YES
11.08.00, 7.00.30b: Employee list, tech posting	NO
5.01.31l: Prior inspection _____# deficiencies	YES
3.00.51: Initial interpretation and final evaluation	NO
23.00.60: PDMP notice, 20.00.70; CPP notice	YES
5.01.31h: Professional reference library	YES
Recordkeeping	
11.03.00: CS Inventory date 5/1/24 Open	YES
11.06.00: CII, CIII-V, RX drug receipts dated	YES
11.06.05: Receipts from registered sources	YES
11.07.20: Casual Sale records	N/A
11.07.10: Floor stock distribution	N/A
11.04.20: Daily printouts	NO
3.00.90b: RTS records	YES
25.00.16: SPDO: CS inv., distribution, use records	N/A
27.00.30: HSP: CS inv., records of distribution	N/A
Dispensing	
11.04.10: Hardcopy of order filed appropriately	YES
CII orders reviewed:_____	YES
CIII-V orders reviewed:_____	N/A
RX orders reviewed:_____	YES
2.01.53: Required order transfer information	NO
2.01.10: Information to appear on each order	YES
3.00.55: Prescription flavoring	N/A
Dispensing errors/valid prescription orders	NO
Prescription labeling	YES

Immunizations	Compliant?
19.01.10: Authorization, ACPE training, CPR	N/A
19.01.40: Administration records	N/A
19.01.50: Off-site administration	N/A
Non-Sterile Compounding	
21.10.10: P&P Manual annual review_____	N/A
21.10.20: Training of personnel	N/A
21.10.60: Components-expiration dating	N/A
21.10.90: Formulation records	N/A
21.11.00: Compounding records/labeling	N/A
21.10.80: Beyond use dating, studies on site	N/A
Central Prescription Processing/Remote Pharmacy Practice	
20.01.20 &26.00.20: Policy and procedure manual, written agreements _____	NO
20.00.90: Records of receipt/delivery	N/A
3.00.90e: Return to stock records	N/A
	N/A
Prepackaging/Labeling/Return Drug	N/A
3.01.20: Prepack labeling and records	N/A
3.01.22: Automated cassette labeling & records	N/A
3.03.00: Customized medication packages	N/A
3.00.80: Return for dispensing or donation	N/A
21.00.20: Casual sale of compounded products	N/A
Drug Therapy Management	
6.00.40: General authorization plan/protocols	N/A
6.00.30: Pharmacist qualifications	N/A
6.00.60: Recordkeeping	N/A
E-kits	
10.00.40: Labeling & contents of kit	N/A
10.00.71: Removal and replacement of med	N/A

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

PDO Name Alto **Pharmacist Manager**

1. Daily printouts shall include the strength of drug dispensed and should otherwise be legible.
REPEAT DEFICIENCY ✓

2. The pharmacist manager shall review, date and sign the remote pharmacy practice policy and procedure manual at least once annually. Last done 11/17/21.
REPEAT DEFICIENCY ✓

3. Please obtain running hot and cold water in the compounding dispensing area.
REPEAT DEFICIENCY ✓

4. Please assure that transferred orders comply with Rule 2.01.53. See controlled substance example.
REPEAT DEFICIENCY Care notified

5. Electronically-signed practitioner controlled substance orders are not acceptable. See examples.

6. The pharmacist manager shall review, date and sign the central prescription processing policy and procedure manual at least once annually. Last done 11/17/21.

7. The pharmacist manager shall review, date and sign the notice of initial interpretation and final evaluation within 72 hours of assuming the duty on or around 5/1/24.

8. Invoices detailing the receipt of prescription drugs and controlled substances shall be marked with a date of receipt. See examples.

9. Invoices shall be filed in one of three separate sets of files (C-II, C-III-V and Rx). See examples.

10. Please place a sign on the door facing the pharmacy which separates the pharmacy from an adjacent room where drug stocks and the sink are stored in accordance with Rule 5.01.31.

Tier 1 ☑ Tier 2 ☐

Pursuant to CRS 12-280-108, the Colorado State Board of Pharmacy has the authority to inspect all registered outlets and investigate violations of the Board's Rules and Regulations, CRS Title 12, 280 of the Pharmacists, Pharmacy Business, and Pharmaceuticals Act; and the CRS Title 18, Article 18 of the Uniform Controlled Substance Act of 1992

I ACKNOWLEDGE THAT THE CONTENTS OF THIS INSPECTION REPORT HAVE BEEN EXPLAINED TO ME.	INSPECTOR'S SIGNATURE
8/16/24	E Garcia, R.P.
PHARMACIST'S SIGNATURE DATE	OTHER INSPECTORS PRESENT:

Rev SEPT 2019

Alto Pharmacy | 929 Broadway | Denver, CO 80203-2705 | 1 (800) 874-5881

Please be advised the deficiencies noted in the Colorado Board of Pharmacy ("Board of Pharmacy") Inspection Report, dated August 6, 2024 (attached) did not require Alto Pharmacy to submit an official Plan of Correction to the Board of Pharmacy.

To ensure compliance with all Board of Pharmacy rules and regulations, and industry standards, Alto Pharmacy made the following corrections identified in the Inspection Report.

1. RECORDKEEPING_Colorado Code of Regulations, 11.04.20: Daily Printouts

Issue	*Daily printouts shall include the strength of drug dispensed and should otherwise be legible.*
Plan of Correction:	Pharmacist-in-Charge reviewed the Daily Dispense Log and found that the report did include the strength of the drug dispensed, however the font size was very small. The Pharmacy Compliance Department and Pharmacist-in-Charge collaborated with IT to ensure the font used for the Daily Printout was of sufficient size to be legible.

2. CENTRAL PRESCRIPTION PROCESSING/REMOTE PHARMACY PRACTICE_ Colorado Code of Regulations, 20.01.20 & 26.00.20: Policy and procedure manual, written agreements

Issue	*The pharmacist manager shall review, date and sign the remote pharmacy practice policy and procedure manual at least once annually. Last done 11/17/2021.*
Plan of Correction:	The Shared Services/Remote Practice policy document was reviewed and found that the previous Pharmacist-in-Charge signed and dated the document in 2024. The Pharmacy Compliance Department has established a process to provide the Shared Services/Remote Practice policy to the Pharmacist-in-Charge for signature and date on an annual basis.

3. PHYSICAL/POSTINGS_ Colorado Code of Regulations, 5.01.31d, f&g: Hot & cold water, frig & freezer

Issue — *Please obtain running hot and cold water in the compounding/ dispensing area.*

Plan of Correction: Pharmacist-in-Charge observed both running hot and cold water to be available at the sink in the pharmacy. A checklist has been implemented to review the status of the hot and cold running water availability at the sink in the pharmacy on a monthly basis.

4. DISPENSING_ Colorado Code of Regulations, 2.01.53: Required order transfer information

Issue — *Please assure that transferred orders comply with Rule 2.01.53. See controlled substance example.*

Plan of Correction: The Pharmacy Compliance Department met with the Pharmacist-in-Charge for the Shared Services site and the Pharmacist-in-Charge for the Remote Processing site jointly to review the process for verbal transfers and for facsimile transfers. The process for facsimile transfers was found to include all required elements. The process for verbal transfers was found to be missing one required element. The process for verbal transfers was corrected to include the missing element and the Pharmacist-in-Charge reviewed the process with the Patient Care Pharmacist team.

5. RECORDKEEPING_ Colorado Code of Regulations, 1304.06: Records and reports for electronic prescriptions.

Issue — *Electronically-signed practitioner-controlled substance orders are not acceptable.*

Plan of Correction: The Pharmacy Compliance Department met with the Pharmacist-in-Charge for the Remote Processing site to review the process to validate the controlled substance prescriptions received via facsimile. An audit report was created which identifies all controlled substance prescriptions which were received via facsimile. Additionally, Back tags include annotations to identify if the prescription was electronically signed by the practitioner which

is a flag to obtain alternate means of validation for the controlled substance prescription.

6. CENTRAL PRESCRIPTION PROCESSING/REMOTE PHARMACY PRACTICE_ Colorado Code of Regulations, 20.01.20 & 26.00.20: Policy and procedure manual, written agreements

Issue — *The pharmacist manager shall review, date and sign the central prescription processing policy and procedure manual at least once annually. Last done 11/17/2021.*

Plan of Correction: The Shared Services/Remote Practice policy document was reviewed and found that the current Pharmacist-in-Charge did not sign the document at the time of the change in Pharmacist-in-Charge. The document was then signed by the Pharmacist-in-Charge and dated 11/12/2024. The Pharmacy Compliance Department has established a checklist to be followed in the event of a change of Pharmacist-in-Charge, and annually thereafter, which includes obtaining a signature and date from the Pharmacist-in-Charge for the policy document.

7. PHYSICAL/POSTINGS_ Colorado Code of Regulations, 3.00.51: Initial interpretation and final evaluation

Issue — *The pharmacist manager shall review, date and sign the notice of initial interpretation and final evaluation within 72 hours of assuming the duty on or around 5/1/24.*

Plan of Correction: The notice of initial interpretation and final evaluation document was reviewed and it was found that the current Pharmacist-in-Charge did not sign the document at the time of the change in Pharmacist-in-Charge. The document was then signed by the Pharmacist-in-Charge and dated 11/12/2024. The Pharmacy Compliance Department has established a checklist to be followed in the event of a change of Pharmacist-in-Charge, and annually thereafter, which includes obtaining a signature and date from the Pharmacist-in-Charge for the policy document.

8. RECORDS AND REPORTS OF REGISTRANTS_Regulation 21 C.F.R. § 1304.21: General requirements for continuing records

Issue — *Invoices detailing the receipt of prescription drugs and controlled substances shall be marked with a date of receipt.*

Plan of Correction: Policy *SOP 302_Receiving Inventory* was reviewed and it was determined that the process is appropriately defined to properly receive and file invoices. The Pharmacist-in-Charge reviewed the procedure in place and found that an extern staff member did not fully follow the established policy. The policy was reviewed with the staff member for ongoing compliance. The Pharmacist-in-Charge conducts an audit of these files on a monthly basis and reviews the invoices for completeness, changes, and any variances; however, the pharmacy has increased the frequency of this review to twice monthly and has established a process to include a Pharmacist-in-Charge signature to ensure the audit has occurred.

9. RECORDS AND REPORTS OF REGISTRANTS_Regulation 21 C.F.R. § 1304.21: General requirements for continuing records

Issue — *Invoices shall be filed in one of three separate sets of files (CII, C-III-V and Rx).*

Plan of Correction: Policy *SOP 302_Receiving Inventory* was reviewed and it was determined that the process is appropriately defined to properly receive and file invoices. The Pharmacist-in-Charge reviewed the procedure in place and found that an extern staff member did not fully follow the established policy. The policy was reviewed with the staff member for ongoing compliance. The Pharmacist-in-Charge conducts an audit of these files on a monthly basis and reviews the invoices for completeness, changes, and any variances; however, the pharmacy has increased the frequency of this review to weekly and has established a process to include a Pharmacist-in-Charge signature to ensure the audit has occurred.

10. PHYSICAL/POSTINGS_ Colorado Code of Regulations, 5.01.31.d (2)

Issue	*Please place a sign on the door facing the pharmacy which separates the pharmacy from an adjacent room where drug stocks and the sink are stored in accordance with Rule 5.01.31.*
Plan of Correction:	It was found that the sign was present but not prominently placed. The sign was placed on the door facing the pharmacy which separates the pharmacy from the adjacent room and the sign states "This room is part of the Board-approved designated principal compounding/dispensing area."

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

Below are your electronic wallet cards to use as proof of your license. You can also print your license at any time by visiting www.colorado.gov/dora/DPO_Print_License and following the instructions listed.

If you would like a more durable wallet card option, you can order one for a fee by visiting www.nasbastore.org and selecting the "Colorado License Cards" link on the left hand side of the page. If you prefer, you can also contact NASBA by phone at 1-888-925-5237 or by email at nasbastore@nasba.org.

Should you have questions about your credential, or need other information please contact our Customer Service Team at 303-894-7800 or dora_dpo_licensing@state.co.us.

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy

Alto Pharmacy

Prescription Drug Outlet- In-State

PDO.1680000176	11/01/2024
Number	**Issue Date**
Active	10/31/2026
Credential Status	**Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy

Alto Pharmacy

Prescription Drug Outlet- In-State

PDO.1680000176	11/01/2024
Number	**Issue Date**
Active	10/31/2026
Credential Status	**Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

Lookup Detail View

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	DBA	Public Address
Alto Pharmacy		929 Broadway Denver, CO 80203

Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
PDO.1680000176	Original	Prescription Drug Outlet- In-State	Active	10/30/2018	11/01/2024	10/31/2026

Supervision

Relationship	Supervisor/Supervisee	License	Start Date	Relationship Type
Supervised By	Nimita Niranjan Davis	PHA.0015903	05/01/2024	Manager

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

Generated on: 5/5/2025 10:26:40 AM

Lookup Detail View

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	Public Address
Nimita Niranjan Davis	Denver, CO 80234

Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
PHA.0015903	Examination	Pharmacist	Active	08/09/2000	11/01/2023	10/31/2025

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

Other Colorado License Records

The below license records are also on file with the Division of Professions and Occupations. For additional information, use our License Verification Search Screen (https://apps.colorado.gov/dora/licensing/Lookup/LicenseLookup.aspx) and enter the License Type and Number below in the search criteria.

License Number	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
IN.0000098048	Pharmacist Intern	Cancelled	09/17/1997	09/01/1999	08/31/2000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA8019083	06-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-15-2024

ALTO PHARMACY, LLC
DBA ALTO PHARMACY
929 N BROADWAY
DENVER, CO 802032705

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA8019083	06-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-15-2024

ALTO PHARMACY, LLC
DBA ALTO PHARMACY
929 N BROADWAY
DENVER, CO 802032705

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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Form DEA-223 (9/2016)

NABP ACCREDITED
DIGITAL PHARMACY

Alto Pharmacy LLC

with headquarters located at

1400 Tennessee Street, Unit 2, San Francisco, CA 97107

This business has met all the digital pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accredited locations may also be verified by visiting the digital pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

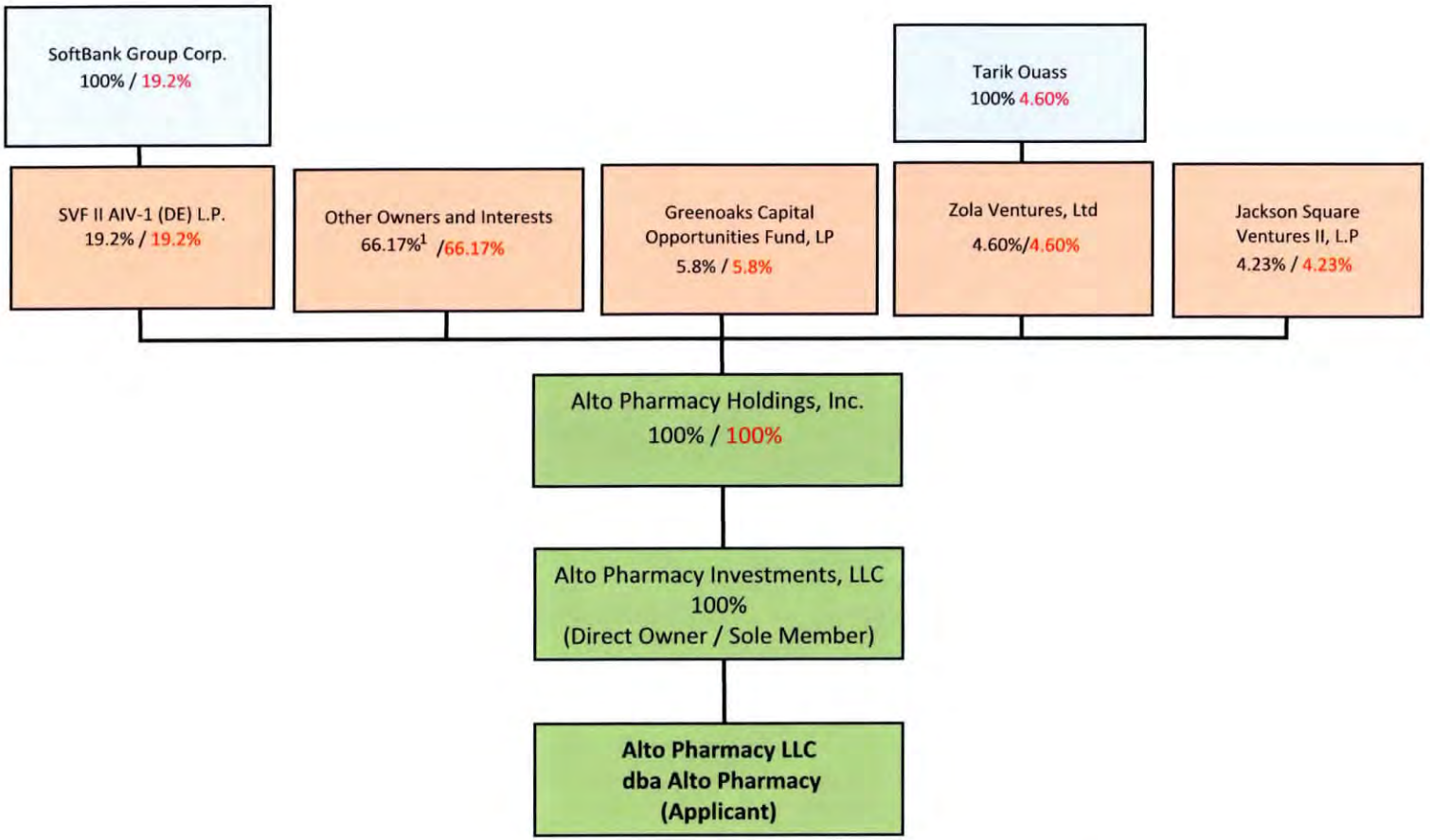
04/25/2024 - 04/24/2027
Period of Accreditation

List of 1 NABP-Accredited Digital Pharmacies

Accreditation is valid for 3 years

Business Name Pharmacy Name	Website	End Date Membership Type
Alto Pharmacy 1400 Tennessee Street San Francisco, CA 97107 [-] 15 Stores	https://alto.com	04/24/27 Open to all
Alto Specialty Pharmacy	4175 Freidrich Lane, Suite 202 Austin, TX 78744	
Alto Pharmacy	4950 Terminal St , Suite 200 Bellaire, TX 77401-6013	
Alto Pharmacy	13010 NE 20th Street, Suite 200 Bellevue, WA 98005	
Alto Pharmacy	929 N Broadway Denver, CO 80203	
Alto Pharmacy	20 Fairbanks, Suite 187 Irvine, CA 92618	
Alto Pharmacy	600 Pilot Road, Suite A Las Vegas, NV 98119	
Alto Pharmacy	475 State Highway 121 Bypass, Suite 150 Lewisville, TX 75067	
Alto Pharmacy	5916 Bowcroft Street Los Angeles, CA 90016	
Alto Pharmacy	100 Park Ave, Front E New York, NY 10017	
Alto Pharmacy	245 Newtown Road, Suite 300 Plainview, NY 11803	
Alto Pharmacy	6201 W. Plano Parkway, Suite 400 Plano, TX 75093	
Alto Pharmacy	4240 Kearny Mesa Rd, Suite 107 San Diego, CA 92111	
Alto Pharmacy	1400 Tennessee St San Francisco, CA 94107	
Alto Pharmacy	645 Harrison St San Francisco, CA 97107	
Alto Pharmacy	2360 Qume Dr, Suite A San Jose, CA 95131-1838	

Alto Pharmacy, LLC dba Alto Pharmacy
Pre-Close Organizational Chart

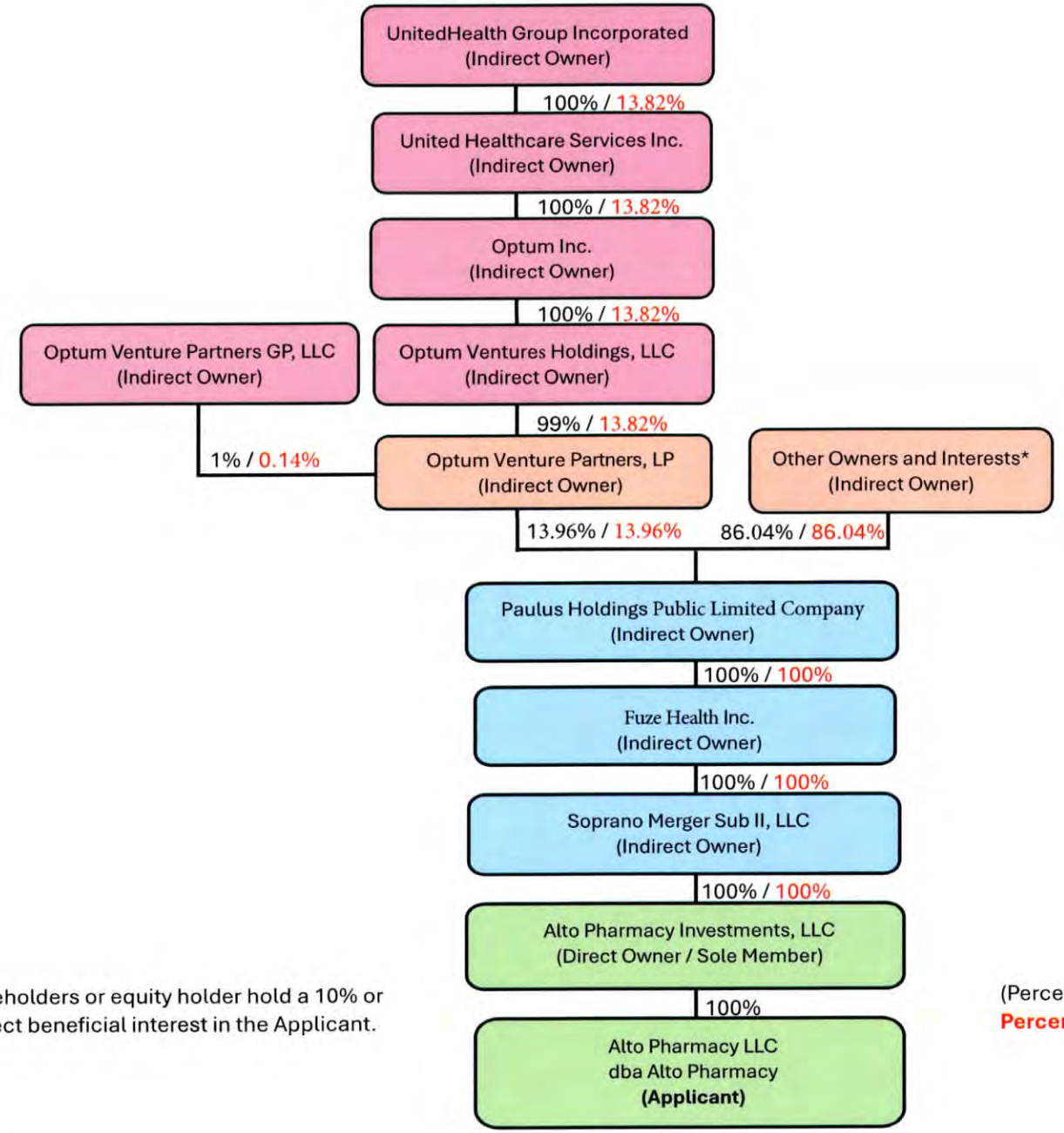


(Percentage is Direct Ownership in Owned Entity /
Percentage is Indirect Ownership of Applicant)

[1]Approximately 900+ Individual owners or interests.
No individual or interest holding 5% or more direct or indirect ownership

May 20, 2025

Alto Pharmacy, LLC dba Alto Pharmacy
Post-Close Organizational Chart



*No individual shareholders or equity holder hold a 10% or more direct or indirect beneficial interest in the Applicant.

(Percentage is Direct Ownership in Owned Entity / **Percentage is Indirect Ownership of Applicant)**

May 20, 2025

4KKK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH PH04285	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Prescription processing pharmacy	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Prescription processing pharmacy

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Alto Pharmacy

Physical Address: 6201 West Plano Parkway, Suite 400

City: Plano State: TX Zip: 75093-4907

Mailing Address (if different from physical address): 6201 West Plano Parkway, Suite 400

City: Plano State: TX Zip: 75093-4907

Telephone: (800) 874-5881 Toll Free # (NAC 639.708, NRS 639.23286): (800) 874-5881

Fax: (415) 484-7058 Contact Email: pharmacycompliance@alto.com

Website: www.alto.com

Nevada Business License # (if applicable) NV20212001945

Supervising/Managing Pharmacist Name (NRS 639.220): Rina P. Soni

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20804

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Rina P. Soni	NV Pharmacist Registration #: 20804
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A-Not Applicable

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Alto Pharmacy Investments, LLC

Corporation/Organization Name: Alto Pharmacy LLC

Mailing Address: 645 Harrison Street, Suite 200

City: San Francisco State: CA Zip: 94107

Telephone: (800) 874-5881 Email: pharmacycompliance@alto.com

Contact Person Name: Lisa M. Jurinka

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A-Not Applicable

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A-Not Applicable

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Secretary (title) for Alto Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Lisa M. Jurinka

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

5/24/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Lisa M. Jurinka hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary (title) for Alto Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request; and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 24th day of May, 2025

Notary Public

OFFICIAL STAMP
TYLER DYE
NOTARY PUBLIC - OREGON
COMMISSION NO. 1055222
MY COMMISSION EXPIRES JANUARY 21, 2029

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lisa M. Jurinka, Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

5/24/25

Date

Board Use Only	Date Received: 6/18/25	Amount: $500-cc

Section 3: History of Company

Please be advised, the information provided relates to the Applicant's affiliate pharmacies located in San Francisco and Los Angeles, CA.

As the Applicant and affiliate locations operate under the same legal name and ownership, we are providing this information with transparency in mind, to ensure are aware of these matters.

Further be advised, the Applicant has not had a license investigated, disciplined nor are any investigations or disciplinary actions pending.

By:
Name: Lisa M. Jurinka
Title: Secretary

Date: 05/09/2025

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - San Francisco (Harrison Street), California				
		FACILITY	09/26/2024	Texas Board of Pharmacy (Case #: 2024-01512) On July 19, 2024, the Texas Board of Pharmacy ("Board of Pharmacy") issued an Agreed Board Order ("ABO") in which the Board of Pharmacy alleges, from about September 28, 2023, through on or about November 29, 2023, Alto Pharmacy, located at 645 Harrison Street, Suite 200, San Francisco, CA 94107, Texas Non-Resident Pharmacy Permit #: 34204, operated without a Texas licensed pharmacist named on the Texas Non-Resident Pharmacy Permit. Alto Pharmacy acknowledges operating without the required Texas licensed pharmacist, Alto Pharmacy further acknowledges contact, and correspondence was made with the Board of Pharmacy, requesting guidance and direction on operating without a Texas licensed pharmacist. The Board of Pharmacy and Alto Pharmacy finalized the ABO on November 5, 2024, and a fine of $1,000 was paid. Alto Pharmacy's Texas Non-Resident Pharmacy Permit remains active, in good standing and unrestricted. The Board of Pharmacy considered the matter closed and took no further action.

TEXAS STATE BOARD OF PHARMACY

November 7, 2024

ALTO PHARMACY
C/O TSAI LING JIANG
PHARMACIST-IN-CHARGE
645 HARRISON ST STE 200
SAN FRANCISCO, CALIFORNIA 94107

RE: In the Matter of Alto Pharmacy

Dear Tsai Ling Jiang:

Enclosed is a copy of Agreed Board Order (ABO) #2024-01512 that was entered by the Texas State Board of Pharmacy (Board) concerning the above-referenced matter. The Board entered this Order on November 5, 2024. The requirements and conditions of the enclosed Order and matters relating to the Order are discussed below.

ADMINISTRATIVE PENALTY (FINE)

Under the terms of this Order, Alto Pharmacy (pharmacy license #34204) must pay an administrative penalty (fine) of $1,000. **This fine is due on or before March 5, 2025.** Please make your cashier's check or money order payable to the "Texas State Board of Pharmacy" and submit to the Board's office by the due date. Please include your ABO number (#2024-01512) on the cashier's check or money order. **Note:** The Board will **not** accept partial payments. You must submit payment for the full amount by the due date.

LICENSE RENEWAL APPLICATIONS

Prior to the next expiration date of pharmacy license #34204, the pharmacy will complete a license renewal application for the Texas State Board of Pharmacy. This application will require a pharmacy representative to answer the question:

> "Has the pharmacy, the pharmacy's owner or any officer or partner (if the pharmacy is owned by a corporation or partnership) been the subject of any professional disciplinary action or are any such actions pending against you by a regulatory authority within the last 36 months?..."

As a result of the entry of ABO #2024-01512, Alto Pharmacy must answer "yes" to this question for 36 months from the date of the termination of all sanctions. Consequently, an Alto Pharmacy representative must answer "yes" to this question on any renewal applications submitted beginning November 5, 2024 and ending 36 months following the termination of all sanctions.

If you have any questions about this Order, please contact Knijiah Samuel, Monitoring Specialist, at (512) 305-8054 or via monitoring@pharmacy.texas.gov.

Sincerely,

Robert Rivera
Enforcement Manager

RR:ks

Enclosure: Agreed Board Order #2024-01512

c: Lisa Jurinka
Managing Officer, Alto Pharmacy LLC
On behalf of Alto Pharmacy
pharmacycompliance@alto.com

Kianna L. Sitarski
Legal Counsel for Alto Pharmacy
Brown & Fortunato, P.C.
7557 Rambler Road, Suite 510
Dallas, Texas 75231
ksitarski@bf-law.com

AGREED BOARD ORDER #2024-01512

RE: IN THE MATTER OF
ALTO PHARMACY
(PHARMACY LICENSE #34204)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 34204 issued to Alto Pharmacy (Respondent), 645 Harrison Street, Suite 200, San Francisco, California 94107.

By letter dated July 19, 2024, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 562.101(f); and 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2023); and

Section 291.103 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2023), in that allegedly:

COUNT

From on or about September 28, 2023, through on or about November 29, 2023, Alto Pharmacy, 645 Harrison Street, Suite 200, San Francisco, California 94107, was engaged in the operation of a non-resident pharmacy in violation of Texas State Board of Pharmacy Rules, in that the pharmacy was not under the supervision of a pharmacist-in-charge licensed as a pharmacist in Texas.

By letter dated July 19, 2024, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Lisa Jurinka, Managing Officer, Alto Pharmacy LLC, on behalf of Respondent, and Kianna L. Sitarski, Legal Counsel for Respondent, neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to an informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(3) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2023), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2024).

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 5th day of November, 2024.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Daniel Carroll, Pharm.D.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Lisa Jurinka, Managing Officer, Alto Pharmacy LLC
On behalf of Alto Pharmacy

Kianna L. Sitarski, Legal Counsel for Alto Pharmacy
Brown & Fortunato, P.C.
7557 Rambler Road, Suite 510
Dallas, Texas 75231

APPROVED AS TO FORM:

Megan G. Holloway, General Counsel
Texas State Board of Pharmacy

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - San Francisco, California				
		FACILITY	03/22/2023	California Board of Pharmacy (Case #: CI2022 96563) On March 22, 2023, the California Board of Pharmacy ("Board of Pharmacy")issued a Modified Citation and Fine ("Citation"), in which the Board of Pharmacy alleges, on or about July 2, 2022, the Licensee dispensed and delivered prescription drugs to a wrong address. On or about July 6, 2022, the prescription drugs were returned to the Licensee and afterwards placed into the Licensee's inventory. Further, Board of Pharmacy alleges the Licensee failed to quarantine and prepare the returned prescription drugs for destruction pursuant to Board of Pharmacy rules and regulations. Licensee acknowledges the returned prescription drugs were placed into inventory, not quarantined and prepared for destruction as required by Board of Pharmacy rules and regulations. Licensee agreed to pay the Board of Pharmacy's fine of $1,000 as indicated in the attached Citation. To ensure correct practices are followed, the Licensee's Compliance and Pharmacy Operations Departments have reviewed their Policies and Procedures, which address the handling of returned prescription drugs, with the staff at the pharmacy location. Staff has acknowledged the review, training and the proper procedures to follow when previously dispensed prescription drugs are returned to the pharmacy location. The Licensee's California Pharmacy Permit remains active, in good standing and unrestricted. Upon receipt of the fine, the Board of Pharmacy considered the matter closed and took no further action.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 22, 2023

CERTIFIED MAIL

ALTO PHARMACY
ATTN: MATTIEU GAMACHE-ASSELIN, CEO
1400 TENNESSEE ST UNIT 2
SAN FRANCISCO, CA 94107

Natalia Mazina
100 Pine St Ste 1250
San Francisco, cA 94111-5235

RE: CI 2022 96563
ALTO PHARMACY
PHY 54523

As a result of the explanation and information you provided at the office conference, the amount of the fines assessed in Citation and Fine, CI 2022 98558 have been reduced.

The modified Citation is attached and is hereby issued pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (d).

If you desire a hearing to appeal the attached Citation, you must submit a written request for a hearing to the Board of Pharmacy ("Board") within 30 days of the date this Citation was issued. (See Bus. Prof. Code sec. 125.9, subd. (b)(4), and C.C.R., title 16, sec. 1775.4, subd. (d).). Unless the Board receives a written request within the 30 days, you will be deemed to have waived your right to a hearing in this matter and the Citation shall become the final order of the Board. If a hearing is not requested, the timely payment of the imposed fine(s) shall not constitute an admission of the violation(s) charged in the Citation.

Failure to pay any imposed fine(s) within 30 days of the date the Citation was issued may result in disciplinary action being taken.

If any fine(s) are not timely paid, then the full amount of the unpaid fine(s) shall be added to the fee for the renewal of your license. Your license shall not then be renewed without full payment of the renewal fee and the assessed fine(s).

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

Attachments

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check | | I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: ALTO PHARMACY PHY 54523 Respondent	Citation Case No : CI 2022 96563 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED

(Respondent)

Mailing Address of Respondent:

_____

(Street Address)

(City (State) (Zip) ( ) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

(Attorney's Name

_____

(Street Address)

(City (State) (Zip) ( ) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: ALTO PHARMACY, PHY 54523
Citation and Fine CI 2022 96563

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On March 22, 2023, I served the attached:

Cover Letter, Citation, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: MATTIEU GAMACHE-ASSELIN, CEO 1400 TENNESSEE ST UNIT 2 SAN FRANCISCO, CA 94107	7020 2450 0000 3084 4580
Natalia Mazina 100 Pine St Ste 1250 San Francisco, CA 94111-5235	7020 2450 0000 3084 4573

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 22, 2023, at Sacramento, California.

DECLARANT

Suelynn Yee

Citation and Fine Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2022 96563	ALTO PHARMACY, PHY 54523

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4342 subd. (a)/Health & Safety Code § 111295	**Prevent sale of drugs lacking quality/It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated**	**$1,000.00**

CONDUCT:

Actions by the Board to prevent sales of preparations or Drugs lacking quality of strength; Penalties for knowing or willful violation of Regulations governing those sales: Business and Professions Code (BPC) 4342(a), states in pertinent part: (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code), as it relates to Health and Safety Code (HSC) 111295, which states, It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. Specifically, Alto Pharmacy, PHY54523, located at 1400 Tennessee St., Unit 2, San Francisco, CA 94107, on or around 7/2/2022, dispensed and delivered prescription numbers: 883850002 and 883850003, to an unknown person and location and held at an unknown tempterature, the chain of custody was broken. The prescriptions showed up at the reception desk of the correct address around 7/6/2022 and were then handed to the correct patient. They were subsequently retrieved by Alto Pharmacy. Alto Pharmacy was in violation when they determined the drugs once returned, would be returned to stock, meaning they would be held and offered for sale/re-dispensed to another patient. Those drugs are considered adulterated and should have been quarantined and then sent for destrucation as they were out of Alto Pharmacy's control between dates: 7/2/2022 and 7/6/2022. It was unknown how they were stored and if they had been tampered with in any way. Holding or offering for sale, prescription drugs which where out of Alto Pharmacy's control between dates 7/2/2022 to 7/6/2022, which should be considered adulterated, was a violation according to BPC 4342(a) as it relates to HSC 111295.

CITATION ISSUED ON: March 22, 2023 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: April 21, 2023

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE COPY

Citation Number	Name, License No
CI 2022 96563	ALTO PHARMACY, PHY 54523

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4342 subd. (a)/Health & Safety Code § 111295	Prevent sale of drugs lacking quality/It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	$1,000.00

CONDUCT:

Actions by the Board to prevent sales of preparations or Drugs lacking quality of strength; Penalties for knowing or willful violation of Regulations governing those sales: Business and Professions Code (BPC) 4342(a), states in pertinent part: (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code), as it relates to Health and Safety Code (HSC) 111295, which states, It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. Specifically, Alto Pharmacy, PHY54523, located at 1400 Tennessee St., Unit 2, San Francisco, CA 94107, on or around 7/2/2022, dispensed and delivered prescription numbers: 883850002 and 883850003, to an unknown person and location and held at an unknown tempterature, the chain of custody was broken. The prescriptions showed up at the reception desk of the correct address around 7/6/2022 and were then handed to the correct patient. They were subsequently retrieved by Alto Pharmacy. Alto Pharmacy was in violation when they determined the drugs once returned, would be returned to stock, meaning they would be held and offered for sale/re-dispensed to another patient. Those drugs are considered adulterated and should have been quarantined and then sent for destrucation as they were out of Alto Pharmacy's control between dates: 7/2/2022 and 7/6/2022. It was unknown how they were stored and if they had been tampered with in any way. Holding or offering for sale, prescription drugs which where out of Alto Pharmacy's control between dates 7/2/2022 to 7/6/2022, which should be considered adulterated, was a violation according to BPC 4342(a) as it relates to HSC 111295.

CITATION ISSUED ON: March 22, 2023 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: April 21, 2023

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - Los Angeles, California				
		FACILITY	07/14/2023	California Board of Pharmacy (Case #: CI 2021 95943) On December 28, 2023, the California Board of Pharmacy ("Board of Pharmacy") issued a dismissal of the Citation and Fine, in which the Board of Pharmacy alleged, on or about July 14, 2023, the Licensee failed to update their pharmacy systems and inventory indicating a certain prescription drug was not available for dispensing to a patient requesting the medication, thus delaying the receipt of the prescription medication for the patient. Alto Pharmacy's California Resident Pharmacy Permit remains active, in good standing and unrestricted.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

December 28, 2023

CERTIFIED MAIL

ALTO PHARMACY
ATTN: ALICIA DAVIS, CEO
5916 BOWCROFT ST
LOS ANGELES, CA 90016

Sweta Patel
1255 Treat Blvd., Suite 300
Walnut Creek, CA 94597

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

After thorough and careful consideration of the explanation and information you provided at the office conference, it was decided to dismiss Citation and Fine. CI 2021 95943 as originally issued. Effective immediately the fines assessed in Citation CI 2021 95943, have been dismissed.

This decision is the final administrative order regarding the Citation.

Please contact Associate Enforcement Analyst Suelynn Yee at (916) 518-3013, if you have any questions.

Sincerely

Julia G. Ansel
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY FIRST CLASS CERTIFIED MAIL

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and no party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suit 100, Sacramento, California 95833.

On December 28, 2023, I served the attached:

in said cause, by placing a true copy thereof enclosed in two separate sealed envelopes w postage thereon fully prepaid by Certified Mail and First Class Mail, in the United States m at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: ALICIA DAVIS, CEO 5916 BOWCROFT ST LOS ANGELES, CA 90016	7017 0530 0000 3305 3269
Sweta Patel 1255 Treat Blvd., Suite 300 Walnut Creek, CA 94597	7017 0530 0000 3305 3252

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 28, 2023, at Sacramento, California.

DECLARANT
Suelynn Yee
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 14, 2023

DATED MATERIAL ENCLOSED

ALTO PHARMACY
ATTN: ALICIA DAVIS, CEO
5916 BOWCROFT ST
LOS ANGELES, CA 90016

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- August 13, 2023: Unless the Citation is contested payment of fine(s) must be received by the Board.
- July 28, 2023: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- August 13, 2023: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By:

Suelynn Yee
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **August 13, 2023.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than July 28, 2023 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than August 13, 2023 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2021 95943	ALTO PHARMACY, PHY 58642

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 733 subd. (a)	**Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription**	**$1,500.00**

CONDUCT:

Unprofessional conduct: Business and Professions Code section 733, subsection (a) states, a licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency. Subsection (b) states notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exist subsection (2) (A) states, immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner. Alto Pharmacy, PHY58642, failed to comply. Specifically, on 5/18/2022, Dr. Shammas sent a prescription for EW for 30 tablets of Paxlovid 150 – 100 mg to Alto Pharmacy. On 5/18/2022, the prescription was processed under Rx774057005, and the data entry was verified by pharmacist Cynetha Lee at Alto Pharmacy Plano Texas, NRP2529, located at 6201 W Plano PKWY, Suite 400, Plano, TX. On 5/18/2022, upon completion of the data entry verification, the prescription was placed in the fulfillment queue at Alto Pharmacy Los Angeles, PHY58642, located at 5916 Bowcroft Street, Los Angeles, CA to fill the prescription. Two days later, on 5/20/2022, the pharmacists at Alto Pharmacy Los Angeles contacted Alto Pharmacy Clinical Care Specialist to inform EW that Alto Pharmacy Los Angeles cannot fill the prescription because Alto Pharmacy Los Angeles was a site not allocated to dispense Paxlovid thereby unable to obtain the medication to fill the prescription.

Alto Pharmacy failed to establish procedures or failed to update their computer software such that Alto Pharmacy staff are alerted that California Alto Pharmacy facilities do not dispense Paxlovid. Consequently, Alto Pharmacy obstructed EW from obtaining her prescription for Paxlovid in a timely manner.
oOn 5/18/2022, Alto Pharmacy's Clinical Care Specialist informed EW that Alto Pharmacy had Paxlovid in stock instead of informing EW on 5/20/2022 that Alto Pharmacy California facilities do not dispense Paxlovid.
oOn 5/18/2022, EW's prescription for Paxlovid was processed at Alto Pharmacy Plano Texas. The technician who processed the prescription and Pharmacist Cynetha Lee who verified the data entry of the prescription on 5/18/2022 should have informed the Care

Specialist to inform EW that California Alto Pharmacy facilities do not dispense Paxlovid. oOn 5/18/2022, EW's Paxlovid prescription was placed in queue at Alto Pharmacy Los Angeles for filling. On 5/18/2022, the staff at Alto Pharmacy Los Angeles should have alerted the Care team to inform EW that Alto Pharmacy Los Angles cannot fill her prescription for Paxlovid because the pharmacy was not allocated to dispense Paxlovid.

Had Alto Pharmacy established procedures or updated their computer software, the staff at Alto Pharmacy could have informed EW on 5/18/2022 that her prescription for Paxlovid cannot be filled at Alto Pharmacy Los Angeles.
On 5/20/2022, EW contacted Dr. Shammas to send another prescription for Paxlovid to CVS Pharmacy 9660. The prescription was filled but was not delivered until 5/21/2022. Alto Pharmacy obstructed EW from obtaining from obtaining her prescription for Paxlovid, a medication which needed to be started within five days from the onset of COVID-19 symptoms, a violation of Business and Professions Code 733 (a).

CITATION ISSUED ON: July 14, 2023	TOTAL AMOUNT OF FINE(S): $1,500.00
PAYMENT OF FINE(S) DUE BY: August 13, 2023	

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2021 95943	ALTO PHARMACY, PHY 58642

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 733 subd. (a)	Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	$1,500.00

CONDUCT:

Unprofessional conduct: Business and Professions Code section 733, subsection (a) states, a licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency. Subsection (b) states notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exist subsection (2) (A) states, immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner. Alto Pharmacy, PHY58642, failed to comply. Specifically, on 5/18/2022, Dr. Shammas sent a prescription for EW for 30 tablets of Paxlovid 150 – 100 mg to Alto Pharmacy. On 5/18/2022, the prescription was processed under Rx774057005, and the data entry was verified by pharmacist Cynetha Lee at Alto Pharmacy Plano Texas, NRP2529, located at 6201 W Plano PKWY, Suite 400, Plano, TX. On 5/18/2022, upon completion of the data entry verification, the prescription was placed in the fulfillment queue at Alto Pharmacy Los Angeles, PHY58642, located at 5916 Bowcroft Street, Los Angeles, CA to fill the prescription. Two days later, on 5/20/2022, the pharmacists at Alto Pharmacy Los Angeles contacted Alto Pharmacy Clinical Care Specialist to inform EW that Alto Pharmacy Los Angeles cannot fill the prescription because Alto Pharmacy Los Angeles was a site not allocated to dispense Paxlovid thereby unable to obtain the medication to fill the prescription.

Alto Pharmacy failed to establish procedures or failed to update their computer software such that Alto Pharmacy staff are alerted that California Alto Pharmacy facilities do not dispense Paxlovid. Consequently, Alto Pharmacy obstructed EW from obtaining her prescription for Paxlovid in a timely manner.

oOn 5/18/2022, Alto Pharmacy's Clinical Care Specialist informed EW that Alto Pharmacy had Paxlovid in stock instead of informing EW on 5/20/2022 that Alto Pharmacy California facilities do not dispense Paxlovid.

oOn 5/18/2022, EW's prescription for Paxlovid was processed at Alto Pharmacy Plano Texas. The technician who processed the prescription and Pharmacist Cynetha Lee who verified the data entry of the prescription on 5/18/2022 should have informed the Care

Specialist to inform EW that California Alto Pharmacy facilities do not dispense Paxlovid. oOn 5/18/2022, EW's Paxlovid prescription was placed in queue at Alto Pharmacy Los Angeles for filling. On 5/18/2022, the staff at Alto Pharmacy Los Angeles should have alerted the Care team to inform EW that Alto Pharmacy Los Angles cannot fill her prescription for Paxlovid because the pharmacy was not allocated to dispense Paxlovid.

Had Alto Pharmacy established procedures or updated their computer software, the staff at Alto Pharmacy could have informed EW on 5/18/2022 that her prescription for Paxlovid cannot be filled at Alto Pharmacy Los Angeles.
On 5/20/2022, EW contacted Dr. Shammas to send another prescription for Paxlovid to CVS Pharmacy 9660. The prescription was filled but was not delivered until 5/21/2022. Alto Pharmacy obstructed EW from obtaining from obtaining her prescription for Paxlovid, a medication which needed to be started within five days from the onset of COVID-19 symptoms, a violation of Business and Professions Code 733 (a).

CITATION ISSUED ON: July 14, 2023	TOTAL AMOUNT OF FINE(S): $1,500.00
PAYMENT OF FINE(S) DUE BY: August 13, 2023	

COPY

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: ALTO PHARMACY

License No: PHY 58642

Citation Number : CI 2021 95943

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

_____

_____

_____

_____

_____

_____

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Daytime Number: (___) _____ Email Address: (___) _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: ALTO PHARMACY PHY 58642 Respondent	Citation Case No : CI 2021 95943 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: ALTO PHARMACY, PHY 58642
Citation and Fine CI 2021 95943

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On July 14, 2023, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: ALICIA DAVIS, CEO 5916 BOWCROFT ST LOS ANGELES, CA 90016	7021 1970 0001 5375 5542

I declare under penalty of perjury that the forgoing is true and correct.

Executed on July 14, 2023, at Sacramento, California.

DECLARANT

Suelynn Yee

Citation and Fine Analyst

Alto Pharmacy LLC

Owners and Officers

Name and Title	Work Address, Telephone and Email	Home Address and Telephone	Date of Birth	SSN or FEIN	Ownership %
Alto Pharmacy Investments, LLC Parent / Sole Member	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 pharmacycompliance@alto.com	[redacted]			100%
Alicia Boler Davis President and CEO	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 alicia.bolerdavis@alto.com				0%
Jamie E. Cohen CFO and Treasurer	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 jamie.cohen@alto.com				0%
Lisa M. Jurinka Secretary	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 lisa.jurinka@alto.com				0%

Managers

Name and Tile	Work Address, Telephone and Email	Home Address and Telephone	Date of Birth	SSN	Ownership %
Alicia Boler Davis Manager	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 alicia.bolerdavis@alto.com	[redacted]			0%

November 1, 2023

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Application for Registration for Alto Pharmacy LLC (file number 803494873), a DELAWARE, USA, Foreign Limited Liability Company (LLC), was filed in this office on December 17, 2019.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on June 11, 2025.

Jane Nelson
Secretary of State

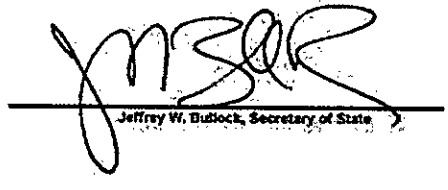
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALTO PHARMACY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





5763030 8300

SR# 20250175196

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202724830

Date: 01-17-25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Alto Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH04285

Physical Address 6201 West Plano Parkway, Suite 400

City Plano State TX Zip 75093-4907

Mailing Address (if different from physical address) 6201 West Plano Parkway, Suite 400

City Plano State TX Zip 75093-4907

Telephone (800) 874-5881 Website www.alto.com

Licensing Company Email erik.heikkenen@adeiaservices.com

Section 2: Personal Information

First Rina Middle P. Last Soni

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Butler University		08/99-05/01	
Address	City	State	Zip
4600 Sunset Ave	Indianapolis	IN	46208
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Mahatma Gandhi College of Pharmacy		08/93-05/97	
Address	City	State	Zip
Sankarankovil Taluk	Tenkasi District	India	627753
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Children's Academy Group of Schools		08/89-05/93	
Address	City	State	Zip
BL Murarka Marg. Bachani Nagar. Malad East	Mumbai	India	400097
Diploma/Degree obtained, if any			
Secondary education diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/20-present	[redacted]			
08/19-05/20				
09/17-08/19				
05/15-09/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Alto Pharmacy			06/20-Present	
Business Address		**City**	**State**	**Zip**
6201 West Plano Parkway, Suite 400		Plano	TX	75093-4907
Phone	**Title**		**Number of Employed Hours**	
(800) 874-5881	Pharmacy Manager		10,400	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			02/00-05/20	
Business Address		**City**	**State**	**Zip**
One CVS Drive		Woonsocket	RI	02895
Phone	**Title**		**Number of Employed Hours**	
401-765-1500	Pharmacy Manager		41,600	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Rina P. Soni, **certify that as the designated representative for**

Alto Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RS I am at least 21 years of age;
3. RS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Rina P. Soni

Print Name (First, Last)

Rina P. Soni

Original Signature (electronic, copies or stamps not accepted)

5/22/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rina P. Soni

Print Name (First, Last)

Rina P. Soni — 5/22/2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Colin

I, Rina P Soni, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Rina P. Soni — 5/22/2025

Original Signature — **Date**

Subscribed and Sworn to before me this 22nd day of May, 2025

Notary Public Signature

AKINADE F OLAOPA
MY COMMISSION EXPIRES
OCTOBER 20, 2025
NOTARY ID: 133403903

(Seal)

Nevada State Board of Pharmacy

For licensing inquires please send an email to, pharmacylicensing@pharmacy.nv.gov (mailto:pharmacylicensing@pharmacy.nv.gov).

For current information on **disciplinary actions taken against licensees**, please send an email to teambc@pharmacy.nv.gov (mailto:teambc@pharmacy.nv.gov).

VERIFY LICENSE

Last Name	First Name	License#	License Status	License Expiration Date	City	State	Discipline	Action
Soni	Rina	20804	Active	10/31/2025	Plano	TX	N	

License Number : 20804
Name : Soni, Rina
License Type : Pharmacist
License Status : Active
License Date : 03/11/2021
Discipline : None
Expiration Date : 10/31/2025



Drop file(s) here to upload or click here to browse and select file(s) to upload. ()

Complete Upload Reset

Document Type	Upload Date	Name	Other Name	Is Public?	Status	Uploaded By	Link	Actions

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Personal History Record Application

N/A - Not Applicable. Applicant Alto Pharmacy LLC dba Alto Pharmacy is a 100% wholly owned subsidiary of Alto Pharmacy Investments, LLC. There are no individual owners.

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *ALTO PHARMACY* **License Number:** *33338*

Class of License: *G*

Inspection Information

Type: *Compliance* **Purpose:** *Licensee Request*

Date: *03/05/2024* **Arrival Time:** *9:00 AM* **Departure Time:** *10:15 AM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Not Applicable*

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Satisfactory*
34. Notifications	*Satisfactory*
76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean	*Satisfactory*
05. Equipment Inspection	*Satisfactory*
07. Security	*Satisfactory*
08. Environment	*Satisfactory*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Satisfactory*
61. Supervision of supportive personnel	*Satisfactory*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*

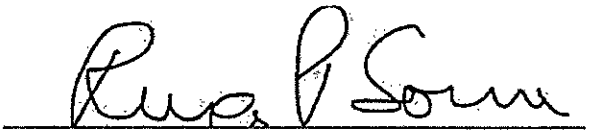
Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Satisfactory*
87. Quality Control/Assurance	*Satisfactory*

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Rina Soni PIC #54575



Terri Burrows

TEXAS STATE BOARD OF PHARMACY
1801 Congress Avenue, Suite 13.100
Austin, TX 78701-1319
(512) 305-8000

License Number: 33338

(Date PDF Version Generated: 12/30/2024)

HELPFUL PHARMACY INFORMATION

- Pharmacies are required to notify TSBP within 10 days of a discontinuance of service, change of location or closure. See the TSBP website here Pharmacy - Renew & Update (texas.gov) for changes.
- Renewals open about 60 days prior to your expiration date, renewal information can be found here Renew | Pharmacy (texas.gov).
- Change of Employment or Change of PIC information can be found here Update | Employment (texas.gov).
- Change of Ownership – Call (512) 305-8021 or see Apply | Change of Ownership (texas.gov).
- For questions or assistance regarding rules, contact TSBP Rules Queue line at (512) 305-8070 see www.pharmacy.texas.gov.
- Non-Resident Pharmacy questions call (512) 305-9127 or email NonResPhcy@pharmacy.texas.gov.

An up-to-date License Verification is always available on the Board's website: http://www.pharmacy.texas.gov/

This certifies that the pharmacy named below is hereby licensed to operate as a Class **G** pharmacy.

License No. **33338** Expiration Date: **07/31/2026**

Balances: **0**

ALTO PHARMACY
6201 W PLANO PKWY STE 400
PLANO, TX 75093

Daniel R. Carroll, Pharm.D.,
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 33338

ALTO PHARMACY

License Information

License Status Active
License # 33338
Expiration Date 07/31/2026
Date License Issued 07/17/2020

Address

6201 W PLANO PKWY STE 400
PLANO, TX 75093
County COLLIN
Phone (800) 874-5881

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Central Processing Pharmacy
Type of Ownership Corporation
Type of Pharmacy Other
# of Hospital beds

Employment Information

Pharmacist in Charge
SONI, RINA

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	No

Translating services (Listed Below If Available)

Spanish
Vietnamese
Telecomm. for the deaf (TDD)

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 1105382 33338 ALTOPHARMACY 2023-01 01-2028.pdf
- 1105382 33338 ALTOPHARMACY 2020-09 09-2025.pdf
- 1105382 33338 ALTOPHARMACY 2020-12 12-2025.pdf
- 1105382 33338 ALTOPHARMACY 2024-03 03-2029.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	No
Ship Prescription Out of State	No
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	No
24 Hour Service	No
Closed Door	No
Compounding, Office Use	No
Home Delivery	No
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No

Other Services Yes

Texas Pharmacist Employment Information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
ALLISON, TRAVIS	62666	07/05/2018	08/31/2026	Staff	Active
DEWOOLKAR, ANUYA VINAYAK	70365	04/28/2022	09/30/2026	Staff	Active
HO, NHI	58820	07/21/2016	08/31/2026	Staff	Active
HOOK, ROBERT	66489	03/19/2020	05/31/2026	Staff	Active
LANIER, ELIZABETH	56487	06/04/2015	03/31/2027	Staff	Active
LEE, SYLVIA	68815	07/22/2021	01/31/2027	Staff	Active
LEE, CYNETHA LEE	37873	07/17/1998	08/31/2025	Staff	Active
LEE, EUN JI	57512	09/17/2015	03/31/2027	Staff	Active
LOONEY, SHARON RANEE	64277	02/21/2019	07/31/2025	Staff	Active
NDUGWA, TIMOTHY	56926	07/30/2015	09/30/2025	Staff	Active
SADEK, ROSHDY ALY	60685	07/06/2017	11/30/2025	Staff	Active
SONI, RINA	54575	04/10/2014	01/31/2026	PIC	Active
TRAN, MY LINH MAI	64006	11/30/2018	04/30/2027	Staff	Active
WASHINGTON, TERRI C	45754	09/26/2007	07/31/2025	Staff	Active

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Texas Registered Technicians/Trainees Employment Information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
ALEXANDER, JORDYN	259914	08/31/2016	07/31/2025	Staff	Active
BATCH, COURTNEY MELISSA	243386	05/25/2015	09/30/2026	Staff	Active
BENSON, BRIGETTE NICOLE	189766	02/07/2011	04/30/2026	Staff	Active
BILAL, BEATRICE MICHEL	275617	10/16/2017	08/31/2026	Staff	Active
BROOKS, SHATORI	204758	01/17/2012	02/28/2027	Staff	Active
BUCHANAN, KENNEDY ANNE	282414	04/19/2018	02/28/2026	Staff	Active
BUI, THOMAS	338174	04/05/2022	12/31/2026	Staff	Active
CORNELL, NICOLE	292062	01/07/2019	01/31/2027	Staff	Active
DAVIS, CONSQUELA	231473	06/05/2014	06/30/2026	Staff	Active
DAVIS, SHARELL	273955	09/07/2017	09/30/2025	Staff	Active
DIGGS, SANDRA ANN	143134	09/07/2010	11/30/2026	Staff	Active
DUNCAN, KRISTIE LYNN	230947	05/21/2014	05/31/2026	Staff	Active
DURAN, DANTE JACE	303599	12/10/2019	12/31/2025	Staff	Active
EVANS, INDIA	313123	10/15/2020	10/31/2026	Staff	Active
FLORES, VANESSA IDETTE	246199	08/13/2015	09/30/2025	Staff	Active
FREEBAIRN, AMY LYN	322476	06/03/2021	06/30/2025	Staff	Active
FREMGEN, SHANNON CONWAY	314109	11/06/2020	07/31/2025	Staff	Active
GONZALEZ, BRIAN	254727	04/12/2016	05/31/2026	Staff	Active
GUILLEN, VANESSA MARIE	146537	04/13/2007	04/30/2027	Staff	Active
HERRERA, JASMINE	294470	03/25/2019	02/28/2027	Staff	Active

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Texas Remote Pharmacy Information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner Information

Owner Name	Owner Title	Address	City	State	Zipcode
ALTO PHARMACY LLC	OWNER	1400 TENNESSEE ST UNIT	SAN FRANCISCO	CA	94107
DAVIS, ALICIA BOLER	OFFICER	,			
COHEN, JAMIE E	OFFICER	,			
JURINKA, LISA	OFFICER	,			

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The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

NABP ACCREDITED

DIGITAL PHARMACY

Alto Pharmacy LLC

with headquarters located at

1400 Tennessee Street, Unit 2, San Francisco, CA 97107

This business has met all the digital pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accredited locations may also be verified by visiting the digital pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/25/2024 - 04/24/2027
Period of Accreditation

List of 1 NABP-Accredited Digital Pharmacies

Accreditation is valid for 3 years

Business Name Pharmacy Name	Website	End Date Membership Type
Alto Pharmacy 1400 Tennessee Street San Francisco, CA 97107 [-] 15 Stores	https://alto.com	04/24/27 Open to all
Alto Specialty Pharmacy	4175 Freidrich Lane, Suite 202 Austin, TX 78744	
Alto Pharmacy	4950 Terminal St , Suite 200 Bellaire, TX 77401-6013	
Alto Pharmacy	13010 NE 20th Street, Suite 200 Bellevue, WA 98005	
Alto Pharmacy	929 N Broadway Denver, CO 80203	
Alto Pharmacy	20 Fairbanks, Suite 187 Irvine, CA 92618	
Alto Pharmacy	600 Pilot Road, Suite A Las Vegas, NV 98119	
Alto Pharmacy	475 State Highway 121 Bypass, Suite 150 Lewisville, TX 75067	
Alto Pharmacy	5916 Bowcroft Street Los Angeles, CA 90016	
Alto Pharmacy	100 Park Ave, Front E New York, NY 10017	
Alto Pharmacy	245 Newtown Road, Suite 300 Plainview, NY 11803	
Alto Pharmacy	6201 W. Plano Parkway, Suite 400 Plano, TX 75093	
Alto Pharmacy	4240 Kearny Mesa Rd, Suite 107 San Diego, CA 92111	
Alto Pharmacy	1400 Tennessee St San Francisco, CA 94107	
Alto Pharmacy	645 Harrison St San Francisco, CA 97107	
Alto Pharmacy	2360 Qume Dr, Suite A San Jose, CA 95131-1838	

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacist License # 54575

License Information

SONI, RINA

License Status Active
License # 54575
Expiration Date 01/31/2026
Date License Issued 04/10/2014

Pharmacist Details

School Graduated
OTHER - FOREIGN COLLEGE OF PHARMACY
Graduation Year 1997
Degree at time of licensure BS
License Method Reciprocity
Preceptor No
Prior Disciplinary Order(s)* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Names

Last Name SONI
First Name RINA
Middle Name
Other Name
Certificate Name SONI, RINA

More Pharmacist Details

Specialty Board Certification ¥ Unknown

¥ Data regarding Specialty Board Certification is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder for clarification.

Remedial Plans and Drug Therapy Management

Remedial plans (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

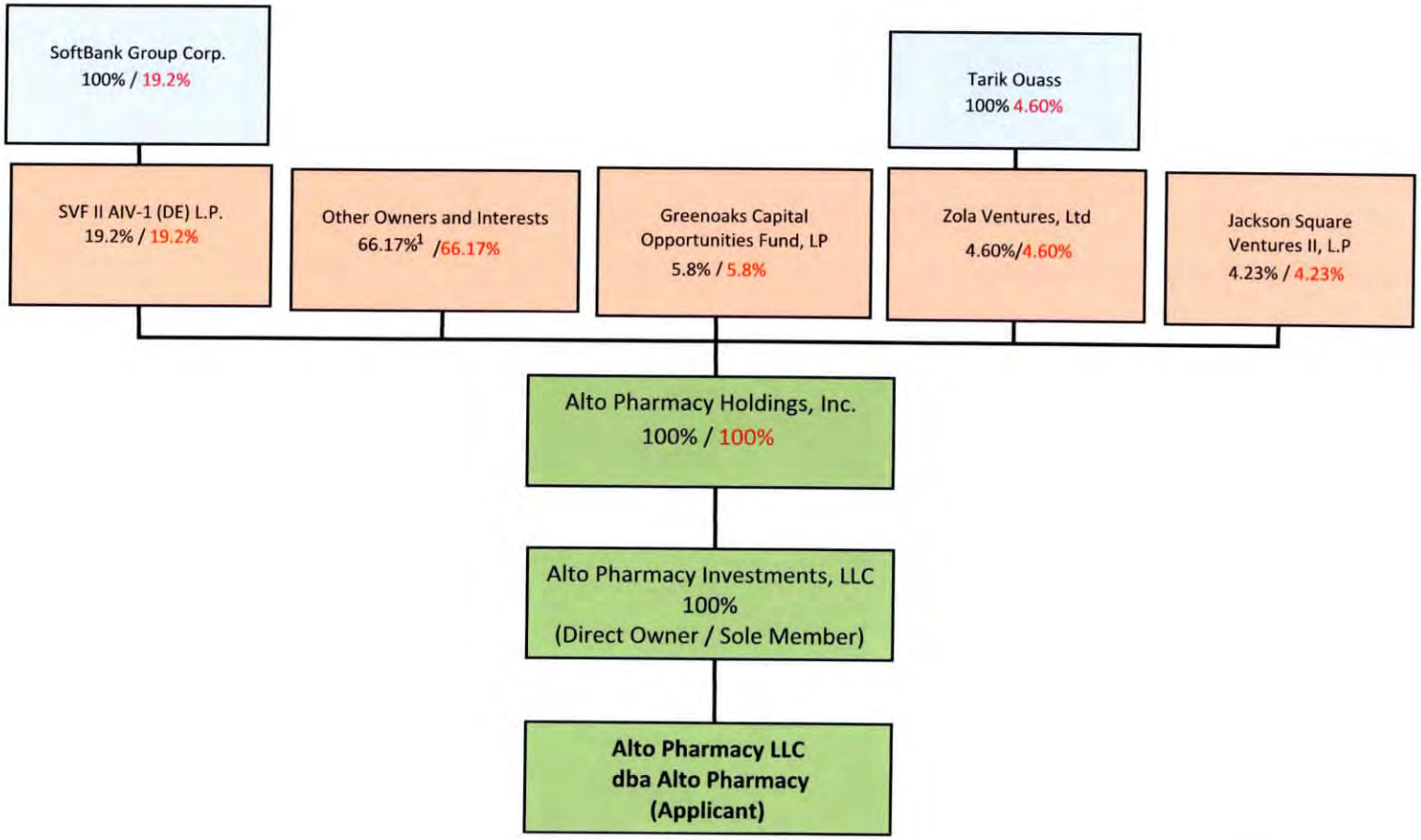
Texas Pharmacist Employment Information

Pharmacy Name	Pharmacy License #	Employment Status
ALTO PHARMACY	33338	PIC

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The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

Alto Pharmacy, LLC dba Alto Pharmacy
Pre-Close Organizational Chart

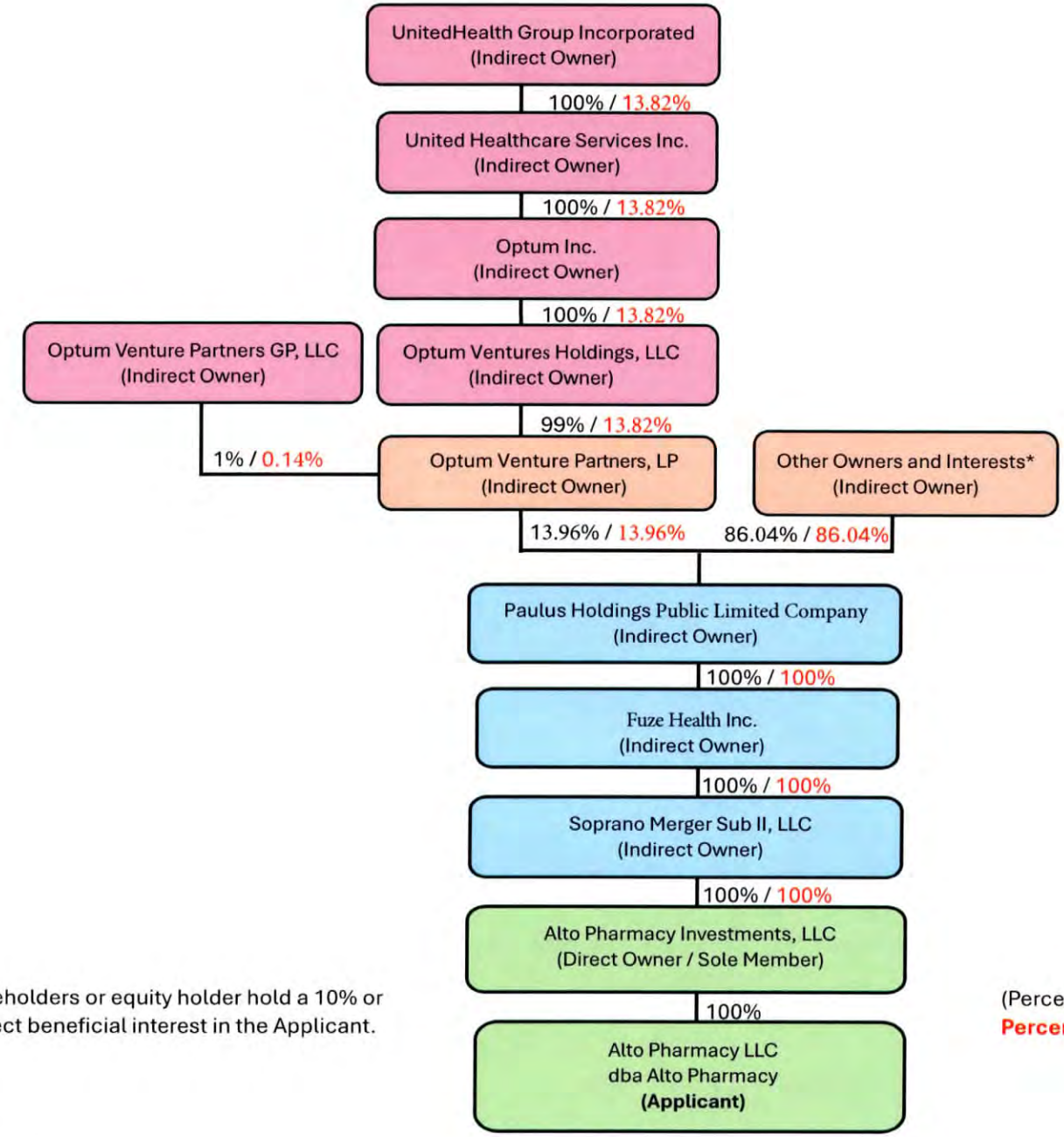


(Percentage is Direct Ownership in Owned Entity /
Percentage is Indirect Ownership of Applicant)

[1]Approximately 900+ Individual owners or interests.
No individual or interest holding 5% or more direct or indirect ownership

May 20, 2025

Alto Pharmacy, LLC dba Alto Pharmacy
Post-Close Organizational Chart



*No individual shareholders or equity holder hold a 10% or more direct or indirect beneficial interest in the Applicant.

(Percentage is Direct Ownership in Owned Entity / **Percentage is Indirect Ownership of Applicant)**

May 20, 2025

4LLL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Y

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH N/A	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other: Specialty, Mail Order	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Specialty, Mail Order

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Alto Specialty Pharmacy

Physical Address: 4175 Freidrich Lane, Suite 202

City: Austin State: TX Zip: 78744-1017

Mailing Address (if different from physical address): 4175 Freidrich Lane, Suite 202

City: Austin State: TX Zip: 78744-1017

Telephone: (800) 874-5881 Toll Free # (NAC 639.708, NRS 639.23286): (800) 874-5881

Fax: (415) 484-7058 Contact Email: pharmacycompliance@alto.com

Website: www.alto.com

Nevada Business License # (if applicable) NV20212001945

Supervising/Managing Pharmacist Name (NRS 639.220): Marissa J. Bradley

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24556

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Marissa J. Bradley	NV Pharmacist Registration #: 24556
Name: Caroline Cranwell-Calleros	NV Pharmacist Registration #: 24390
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Alto Pharmacy Investments, LLC

Corporation/Organization Name: Alto Pharmacy, LLC

Mailing Address: 645 Harrison Street, Suite 200

City: San Francisco State: CA Zip: 94107

Telephone: (800) 874-5881 Email: pharmacycompliance@alto.com

Contact Person Name: Lisa M. Jurinka

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Secretary (title) for Alto Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Lisa M. Jurinka

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/20/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Lisa M. Jurinka hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary (title) for Alto Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

STATE OF OREGON COUNTY OF MULTNOMAH

SUBSCRIBED AND SWORN TO
Before me, a notary public this 20th day of JUNE, 2025

Elena Heller

Notary Public

OFFICIAL STAMP
ELENA HELLER
NOTARY PUBLIC - OREGON
COMMISSION NO. 1013405
MY COMMISSION EXPIRES AUGUST 08, 2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lisa M. Jurinka, Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6/20/25
Date

Board Use Only	Date Received: 7/16/25	Amount: $800.00

Alto Pharmacy LLC

Owners and Officers

Name and Title	Work Address, Telephone and Email	Home Address and Telephone	Date of Birth	SSN or FEIN	Ownership %
Alto Pharmacy Investments, LLC Parent / Sole Member	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 pharmacycompliance@alto.com	[redacted]			100%
Alicia Boler Davis President and CEO	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 alicia.bolerdavis@alto.com				0%
Jamie E. Cohen CFO and Treasurer	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 jamie.cohen@alto.com				0%
Lisa M. Jurinka Secretary	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 lisa.jurinka@alto.com				0%

Managers

Name and Tile	Work Address, Telephone and Email	Home Address and Telephone	Date of Birth	SSN	Ownership %
Alicia Boler Davis Manager	645 Harrison Street, Suite 200 San Francisco, CA 94107-3624 (800) 874-5881 alicia.bolerdavis@alto.com	[redacted]			0%

November 1, 2023

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Application for Registration for Alto Pharmacy LLC (file number 803494873), a DELAWARE, USA, Foreign Limited Liability Company (LLC), was filed in this office on December 17, 2019.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on June 11, 2025.

Jane Nelson
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Alto Specialty Pharmacy

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 4175 Freidrich Lane, Suite 202

City: Austin State: TX Zip: 78744-1017

Mailing Address (if different from physical address): 4175 Freidrich Lane, Suite 202

City: Austin State: TX Zip: 78744-1017

Telephone: (800) 874-5881 Website: www.alto.com

Licensing Company Email: info@adeiaservices.com

Section 2: Personal Information

First: Marissa Middle: J Last: Bradley

Alias(es, nicknames, name changes, etc.): Marissa Glinton

[redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Florida		08/11 - 05/15	
Address	City	State	Zip
101 PO Box	Gainesville	FL	33441
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Florida		08/07 - 05/11	
Address	City	State	Zip
101 PO Box	Gainesville	FL	33441
Diploma/Degree obtained, if any			
Bachelor's degree- Food Science			

School Name		From - To (MM/YY – MM/YY)	
Deerfield Beach High School		08/03 - 05/07	
Address	City	State	Zip
910 Buckpride Way	Deerfield Beach	FL	33441
Diploma/Degree obtained, if any			
secondary education diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/22 - Present	[redacted]			
07/18 - 01/22				
08/16 - 10/20				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Alto Specialty Pharmacy			11/21 - Present	
Business Address		**City**	**State**	**Zip**
4175 Freidrich Lane, Suite 202		Austin	TX	78744-1017
Phone	**Title**		**Number of Employed Hours**	
(800) 874-5881	Pharmacist in Charge		6,720	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Westpark Springs Behavioral Hospital			12/18-11/21	
Business Address		**City**	**State**	**Zip**
6902 S Peek Rd		Richmond	TX	77407
Phone	**Title**		**Number of Employed Hours**	
	Director of Pharmacy		5,760	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Publix Super Markets			08/17-06/18	
Business Address		**City**	**State**	**Zip**
1601 GA-40		Kingsland	GA	31548
Phone	**Title**		**Number of Employed Hours**	
(912) 729-7878	Pharmacy Manager		1,760	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Publix Super Markets			09/15-08/17	
Business Address		**City**	**State**	**Zip**
13820 Old Saint Augustine Rd		Jacksonville	FL	32258
Phone	**Title**		**Number of Employed Hours**	
(904) 262-5415	Pharmacist		3,680	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Marissa J. Bradley, **certify that as the designated representative for**

Alto Specialty Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MB I am at least 21 years of age;
3. MB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Marissa J. Bradley
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-11-2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Marissa J. Bradley

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-11-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Hays

I, Marissa Bradley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-12-2025

Date

Subscribed and Sworn to before me this 12 day of June 2025.

AL BA

Notary Public Signature

AL BA
NOTARY PUBLIC
STATE OF TEXAS
MY COMM. EXP. 10/07/28
NOTARY ID 135119173

(Seal)

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *ALTO PHARMACY* License Number: *33893*

Class of License: *A*

Inspection Information

Type: *Compliance* Purpose: *Licensee Request*

Date: *03/27/2024* Arrival Time: *10:30 AM* Departure Time: *11:00 AM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Not Applicable*
17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Satisfactory*

Comment

Annual controlled substance inventory completed on: 4/29/2023

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Not Applicable*
34. Notifications	*Satisfactory*

76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean	*Satisfactory*
04. Balance inspection	*Not Applicable*
05. Equipment Inspection	*Satisfactory*
07. Security	*Satisfactory*
08. Environment	*Satisfactory*
48. Drugs (procurement, temperature, security, out-of-date, samples)	*Satisfactory*
90. TSBP complaint notification	*Satisfactory*

Controlled Substances

10. Prescriptions separated	*Satisfactory*
24. Theft/Loss	*Satisfactory*

Comment

No theft or loss has occurred.

26. Controlled substance prescription compliance	*Satisfactory*
30. Controlled substance invoices dated/initialed by pharmacist	*Satisfactory*
35. Controlled substance invoices separated	*Satisfactory*
46. Drug distribution	*Not Applicable*
53. Possession of controlled substances	*Satisfactory*
57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Satisfactory*
45. Proper dispensing/labeling	*Satisfactory*
54. Proper prepackaging procedures	*Not Applicable*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Satisfactory*

61. Supervision of supportive personnel	*Satisfactory*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Satisfactory*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Satisfactory*
56. Prescription transfers	*Satisfactory*
67. Written drug information provided	*Satisfactory*
80. Patient counseling	*Satisfactory*
82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*
86. Absence of pharmacist records	*Not Applicable*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Satisfactory*
92. Automated dispensing policy & procedures/SOPs	*Not Applicable*

Non-Sterile Compounding

38. Area for non-sterile compounding	*Not Applicable*
43. Records for non-sterile compounding	*Not Applicable*

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).

Marissa Bradley

Felicia Carrasco

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (Initial each statement below):

MB I am the Pharmacist-in-Charge (PIC) of *ALTO PHARMACY*, pharmacy license number *33893*, and I [✓] was/[ ] was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *03/27/2024*.

MB I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

MB I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

N/A If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

MB I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: [signature] Date: 3/27/2024

Printed Name: *Marissa Bradley* License No.(if applicable): *62698*

Texas State Board of Pharmacy
"Red Flags" Checklist for Pharmacies
YOU MIGHT BE A PILL MILL IF...

Check all that apply:

	(1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy
	(2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume.
	(3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs.
	(4) The prescriptions for controlled substances contain nonspecific or no diagnoses.
	(5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities.
	(6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions.
	(7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms.
	(8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy.
	(9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate.
	(10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants.
	(11) Drugs prescribed are inconsistent with the prescriber's area of practice.
	(12) The prescriber of the drugs is located a significant distance from your pharmacy.
	(13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action.
	(14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies.
	(15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office.
	(16) Multiple persons with the same address present prescriptions from the same prescriber.
	(17) Persons pay with cash or credit card more often than through insurance.
	(18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy).
	(19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies.
	(20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders.
	(21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday.
	(22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems.
	(23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility).

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

Updated 2/2018

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *ALTO PHARMACY*
License Number: *33893*
Address: *4175 FREIDRICH LN STE 202, AUSTIN, TX 78744*
Phone: *(800) 874-5881*
Email:
Class of License: *A*
License Expiration: *07/31/2025*
DEA #: *FA0608755*
DEA Expiration: *06/30/2024*

Inspection Information

Type: *Compliance*
Purpose: *Licensee Request*
Date: *03/27/2024*
Arrival Time: *10:30 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Marissa Janae Bradley *PIC* *62698*

Witness

Felicia Carrasco

TEXAS STATE BOARD OF PHARMACY
1801 Congress Avenue, Suite 13.100
Austin, TX 78701-1319
(512) 305-8000

License Number: 33893

(Date PDF Version Generated: 7/14/2025)

HELPFUL PHARMACY INFORMATION

- Pharmacies are required to notify TSBP within 10 days of a discontinuance of service, change of location or closure. See the TSBP website here Pharmacy - Renew & Update (texas.gov) for changes.
- Renewals open about 60 days prior to your expiration date, renewal information can be found here Renew | Pharmacy (texas.gov).
- Change of Employment or Change of PIC information can be found here Update | Employment (texas.gov).
- Change of Ownership – Call (512) 305-8021 or see Apply | Change of Ownership (texas.gov).
- For questions or assistance regarding rules, contact TSBP Rules Queue line at (512) 305-8070 see www.pharmacy.texas.gov.
- Non-Resident Pharmacy questions call (512) 305-9127 or email NonResPhcy@pharmacy.texas.gov.

An up-to-date License Verification is always available on the Board's website: http://www.pharmacy.texas.gov/

CERTIFICATE OF LICENSE
BOARD OF PHARMACY

This certifies that the pharmacy named below is hereby licensed to operate as a Class **A** pharmacy.

License No. **33893** Expiration Date: **07/31/2027**

Balances: **0**

ALTO SPECIALTY PHARMACY
4175 FREIDRICH LN STE 202
AUSTIN, TX 78744

Daniel R. Carroll, Pharm.D.,
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 33893

ALTO SPECIALTY PHARMACY

License Information

License Status Active
License # 33893
Expiration Date 07/31/2025
Date License Issued 07/22/2021

Address

4175 FREIDRICH LN STE 202
AUSTIN, TX 78744
County TRAVIS
Phone (800) 874-5881

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Community Pharmacy
Type of Ownership LLC
Type of Pharmacy Community Multi
# of Hospital beds

Employment Information

Pharmacist in Charge
BRADLEY, MARISSA JANAE

Pharmacy Profile ¥

Accessible to disabled persons? Yes

Participates in the Texas Medicaid program? Yes

Translating services (Listed Below If Available)

Spanish

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 3193138 33893 ALTOPHARMACY 2022-02 02-2027.pdf
- 3193138 33893 V ALTOPHARMACY 2024-03 03-2029.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	Yes
Ship Prescription Out of State	Yes
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	No
24 Hour Service	No
Closed Door	No
Compounding, Office Use	No
Home Delivery	Yes
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment Information

Pharmacist Name *	License #	Registr. Date	Expir. Date	Emp. Status	License Status

BRADLEY, MARISSA JANAE	62698	07/05/2018	01/31/2026	PIC	Active
CRANWELL CALLEROS, CAROLINE	68437	04/29/2021	12/31/2026	Relief	Active
LANDERS, CARRIE LYNNE	60127	02/02/2017	06/30/2025	Relief	Active

Page 1 of 1 20 View 1 - 3 of 3

Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
HUBBELL, MADISON ROSE	313077	10/13/2020	04/30/2026	Staff	Active

Page 1 of 0 20 View 1 - 1 of 1

Texas Remote Pharmacy Information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner Information

Owner Name	Owner Title	Address	City	State	Zipcode
ALTO PHARMACY LLC	OWNER	1400 TENNESSEE ST UNIT	SAN FRANCISCO	CA	94107
DAVIS, ALICIA BOLER	OFFICER	,			
JURINKA, LISA	OFFICER	,			
COHEN, JAMIE E	OFFICER	,			

Page 1 of 1 20 View 1 - 4 of 4

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA0608755	06-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-16-2024

ALTO SPECIALTY PHARMACY
ALTO PHARMACY, LLC
4175 FREIDRICH LN
STE 202
AUSTIN, TX 78744

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA0608755	06-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-16-2024

ALTO SPECIALTY PHARMACY
ALTO PHARMACY, LLC
4175 FREIDRICH LN
STE 202
AUSTIN, TX 78744

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NABP ACCREDITED
DIGITAL PHARMACY

Alto Pharmacy LLC

with headquarters located at

1400 Tennessee Street, Unit 2, San Francisco, CA 97107

This business has met all the digital pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accredited locations may also be verified by visiting the digital pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/25/2024 - 04/24/2027
Period of Accreditation

3073

List of 1 NABP-Accredited Digital Pharmacies

Accreditation is valid for 3 years

Business Name Pharmacy Name	Website	End Date Membership Type
Alto Pharmacy 1400 Tennessee Street San Francisco, CA 97107 [-] 15 Stores	https://alto.com	04/24/27 Open to all
Alto Specialty Pharmacy	4175 Freidrich Lane, Suite 202 Austin, TX 78744	
Alto Pharmacy	4950 Terminal St , Suite 200 Bellaire, TX 77401-6013	
Alto Pharmacy	13010 NE 20th Street, Suite 200 Bellevue, WA 98005	
Alto Pharmacy	929 N Broadway Denver, CO 80203	
Alto Pharmacy	20 Fairbanks, Suite 187 Irvine, CA 92618	
Alto Pharmacy	600 Pilot Road, Suite A Las Vegas, NV 98119	
Alto Pharmacy	475 State Highway 121 Bypass, Suite 150 Lewisville, TX 75067	
Alto Pharmacy	5916 Bowcroft Street Los Angeles, CA 90016	
Alto Pharmacy	100 Park Ave, Front E New York, NY 10017	
Alto Pharmacy	245 Newtown Road, Suite 300 Plainview, NY 11803	
Alto Pharmacy	6201 W. Plano Parkway, Suite 400 Plano, TX 75093	
Alto Pharmacy	4240 Kearny Mesa Rd, Suite 107 San Diego, CA 92111	
Alto Pharmacy	1400 Tennessee St San Francisco, CA 94107	
Alto Pharmacy	645 Harrison St San Francisco, CA 97107	
Alto Pharmacy	2360 Qume Dr, Suite A San Jose, CA 95131-1838	

ACHC

Company Name	Alto Pharmacy LLC
DBA Company Name	Alto Specialty Pharmacy
Address	4175 Freidrich Lane, Suite 202, Austin, TX 78744
Date	06/06/2024 Through 06/05/2027
Program	Pharmacy
Service	Specialty Pharmacy Services

urac®

Accreditation Details

Alto Pharmacy, LLC

Specialty Pharmacy Accreditation 5.0

ORGANIZATION

Alto Pharmacy, LLC
1400 Tennessee St Unit 2
San Francisco, CA 94107

ACCREDITED SITES

Alto Pharmacy, LLC
4175 Freidrich Lane
Suite 202
Austin, TX 78744

Alto Pharmacy
645 Harrison Street
San Francisco, CA 94107

Alto Pharmacy, LLC
1400 Tennessee Street Unit 2
San Francisco, CA 94107

ACCREDITATION INFORMATION

Accreditation Status: Full Accreditation
Expiration Date: 01/01/2028
Program: Specialty Pharmacy Accreditation 5.0

Section 3: History of Company

Please be advised, the information provided relates to the Applicant's affiliate pharmacies located in San Francisco and Los Angeles, CA.

As the Applicant and affiliate locations operate under the same legal name and ownership, we are providing this information with transparency in mind, to ensure are aware of these matters.

Further be advised, the Applicant has not had a license investigated, disciplined nor are any investigations or disciplinary actions pending.

By:
Name: Lisa M. Jurinka
Title: Secretary

Date: 06/04/2025

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - San Francisco (Harrison Street), California				
		FACILITY	09/26/2024	Texas Board of Pharmacy (Case #: 2024-01512) On July 19, 2024, the Texas Board of Pharmacy ("Board of Pharmacy") issued an Agreed Board Order ("ABO") in which the Board of Pharmacy alleges, from about September 28, 2023, through on or about November 29, 2023, Alto Pharmacy, located at 645 Harrison Street, Suite 200, San Francisco, CA 94107, Texas Non-Resident Pharmacy Permit #: 34204, operated without a Texas licensed pharmacist named on the Texas Non-Resident Pharmacy Permit. Alto Pharmacy acknowledges operating without the required Texas licensed pharmacist, Alto Pharmacy further acknowledges contact, and correspondence was made with the Board of Pharmacy, requesting guidance and direction on operating without a Texas licensed pharmacist. The Board of Pharmacy and Alto Pharmacy finalized the ABO on November 5, 2024, and a fine of $1,000 was paid. Alto Pharmacy's Texas Non-Resident Pharmacy Permit remains active, in good standing and unrestricted. The Board of Pharmacy considered the matter closed and took no further action.

TEXAS STATE BOARD OF PHARMACY

November 7, 2024

ALTO PHARMACY
C/O TSAI LING JIANG
PHARMACIST-IN-CHARGE
645 HARRISON ST STE 200
SAN FRANCISCO, CALIFORNIA 94107

RE: In the Matter of Alto Pharmacy

Dear Tsai Ling Jiang:

Enclosed is a copy of Agreed Board Order (ABO) #2024-01512 that was entered by the Texas State Board of Pharmacy (Board) concerning the above-referenced matter. The Board entered this Order on November 5, 2024. The requirements and conditions of the enclosed Order and matters relating to the Order are discussed below.

ADMINISTRATIVE PENALTY (FINE)

Under the terms of this Order, Alto Pharmacy (pharmacy license #34204) must pay an administrative penalty (fine) of $1,000. **This fine is due on or before March 5, 2025.** Please make your cashier's check or money order payable to the "Texas State Board of Pharmacy" and submit to the Board's office by the due date. Please include your ABO number (#2024-01512) on the cashier's check or money order. **Note:** The Board will **not** accept partial payments. You must submit payment for the full amount by the due date.

LICENSE RENEWAL APPLICATIONS

Prior to the next expiration date of pharmacy license #34204, the pharmacy will complete a license renewal application for the Texas State Board of Pharmacy. This application will require a pharmacy representative to answer the question:

> "Has the pharmacy, the pharmacy's owner or any officer or partner (if the pharmacy is owned by a corporation or partnership) been the subject of any professional disciplinary action or are any such actions pending against you by a regulatory authority within the last 36 months?..."

As a result of the entry of ABO #2024-01512, Alto Pharmacy must answer "yes" to this question for 36 months from the date of the termination of all sanctions. Consequently, an Alto Pharmacy representative must answer "yes" to this question on any renewal applications submitted beginning November 5, 2024 and ending 36 months following the termination of all sanctions.

If you have any questions about this Order, please contact Knijiah Samuel, Monitoring Specialist, at (512) 305-8054 or via monitoring@pharmacy.texas.gov.

Sincerely,

Robert Rivera
Enforcement Manager

RR:ks

Enclosure: Agreed Board Order #2024-01512

c: Lisa Jurinka
Managing Officer, Alto Pharmacy LLC
On behalf of Alto Pharmacy
pharmacycompliance@alto.com

Kianna L. Sitarski
Legal Counsel for Alto Pharmacy
Brown & Fortunato, P.C.
7557 Rambler Road, Suite 510
Dallas, Texas 75231
ksitarski@bf-law.com

AGREED BOARD ORDER #2024-01512

RE: IN THE MATTER OF
ALTO PHARMACY
(PHARMACY LICENSE #34204)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 34204 issued to Alto Pharmacy (Respondent), 645 Harrison Street, Suite 200, San Francisco, California 94107.

By letter dated July 19, 2024, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 562.101(f); and 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2023); and

Section 291.103 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2023), in that allegedly:

COUNT

From on or about September 28, 2023, through on or about November 29, 2023, Alto Pharmacy, 645 Harrison Street, Suite 200, San Francisco, California 94107, was engaged in the operation of a non-resident pharmacy in violation of Texas State Board of Pharmacy Rules, in that the pharmacy was not under the supervision of a pharmacist-in-charge licensed as a pharmacist in Texas.

By letter dated July 19, 2024, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Lisa Jurinka, Managing Officer, Alto Pharmacy LLC, on behalf of Respondent, and Kianna L. Sitarski, Legal Counsel for Respondent, neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to an informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(3) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2023), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2024).

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 5th day of November, 2024.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Daniel Carroll, Pharm.D.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Lisa Jurinka, Managing Officer, Alto Pharmacy LLC
On behalf of Alto Pharmacy

Kianna L. Sitarski, Legal Counsel for Alto Pharmacy
Brown & Fortunato, P.C.
7557 Rambler Road, Suite 510
Dallas, Texas 75231

APPROVED AS TO FORM:

Megan G. Holloway, General Counsel
Texas State Board of Pharmacy

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - San Francisco, California				
		FACILITY	03/22/2023	California Board of Pharmacy (Case #: CI2022 96563) On March 22, 2023, the California Board of Pharmacy ("Board of Pharmacy")issued a Modified Citation and Fine ("Citation"), in which the Board of Pharmacy alleges, on or about July 2, 2022, the Licensee dispensed and delivered prescription drugs to a wrong address. On or about July 6, 2022, the prescription drugs were returned to the Licensee and afterwards placed into the Licensee's inventory. Further, Board of Pharmacy alleges the Licensee failed to quarantine and prepare the returned prescription drugs for destruction pursuant to Board of Pharmacy rules and regulations. Licensee acknowledges the returned prescription drugs were placed into inventory, not quarantined and prepared for destruction as required by Board of Pharmacy rules and regulations. Licensee agreed to pay the Board of Pharmacy's fine of $1,000 as indicated in the attached Citation. To ensure correct practices are followed, the Licensee's Compliance and Pharmacy Operations Departments have reviewed their Policies and Procedures, which address the handling of returned prescription drugs, with the staff at the pharmacy location. Staff has acknowledged the review, training and the proper procedures to follow when previously dispensed prescription drugs are returned to the pharmacy location. The Licensee's California Pharmacy Permit remains active, in good standing and unrestricted. Upon receipt of the fine, the Board of Pharmacy considered the matter closed and took no further action.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 22, 2023

CERTIFIED MAIL

ALTO PHARMACY
ATTN: MATTIEU GAMACHE-ASSELIN, CEO
1400 TENNESSEE ST UNIT 2
SAN FRANCISCO, CA 94107

Natalia Mazina
100 Pine St Ste 1250
San Francisco, cA 94111-5235

RE: CI 2022 96563
ALTO PHARMACY
PHY 54523

As a result of the explanation and information you provided at the office conference, the amount of the fines assessed in Citation and Fine, CI 2022 98558 have been reduced.

The modified Citation is attached and is hereby issued pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (d).

If you desire a hearing to appeal the attached Citation, you must submit a written request for a hearing to the Board of Pharmacy ("Board") within 30 days of the date this Citation was issued. (See Bus. Prof. Code sec. 125.9, subd. (b)(4), and C.C.R., title 16, sec. 1775.4, subd. (d).). Unless the Board receives a written request within the 30 days, you will be deemed to have waived your right to a hearing in this matter and the Citation shall become the final order of the Board. If a hearing is not requested, the timely payment of the imposed fine(s) shall not constitute an admission of the violation(s) charged in the Citation.

Failure to pay any imposed fine(s) within 30 days of the date the Citation was issued may result in disciplinary action being taken.

If any fine(s) are not timely paid, then the full amount of the unpaid fine(s) shall be added to the fee for the renewal of your license. Your license shall not then be renewed without full payment of the renewal fee and the assessed fine(s).

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

Attachments

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check | | I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:	Citation Case No : CI 2022 96563
ALTO PHARMACY PHY 54523 Respondent	NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED

(Respondent)

Mailing Address of Respondent:

_____

(Street Address)

(City , (State) (Zip) ( ) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

(Attorney's Name

_____

(Street Address)

(City (State) (Zip) ( ) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: ALTO PHARMACY, PHY 54523
Citation and Fine CI 2022 96563

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On March 22, 2023, I served the attached:

Cover Letter, Citation, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: MATTIEU GAMACHE-ASSELIN, CEO 1400 TENNESSEE ST UNIT 2 SAN FRANCISCO, CA 94107	7020 2450 0000 3084 4580
Natalia Mazina 100 Pine St Ste 1250 San Francisco, CA 94111-5235	7020 2450 0000 3084 4573

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 22, 2023, at Sacramento, California.

DECLARANT

Suelynn Yee

Citation and Fine Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2022 96563	ALTO PHARMACY, PHY 54523

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4342 subd. (a)/Health & Safety Code § 111295	**Prevent sale of drugs lacking quality/It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated**	**$1,000.00**

CONDUCT:

Actions by the Board to prevent sales of preparations or Drugs lacking quality of strength; Penalties for knowing or willful violation of Regulations governing those sales: Business and Professions Code (BPC) 4342(a), states in pertinent part: (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code), as it relates to Health and Safety Code (HSC) 111295, which states, It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. Specifically, Alto Pharmacy, PHY54523, located at 1400 Tennessee St., Unit 2, San Francisco, CA 94107, on or around 7/2/2022, dispensed and delivered prescription numbers: 883850002 and 883850003, to an unknown person and location and held at an unknown tempterature, the chain of custody was broken. The prescriptions showed up at the reception desk of the correct address around 7/6/2022 and were then handed to the correct patient. They were subsequently retrieved by Alto Pharmacy. Alto Pharmacy was in violation when they determined the drugs once returned, would be returned to stock, meaning they would be held and offered for sale/re-dispensed to another patient. Those drugs are considered adulterated and should have been quarantined and then sent for destrucation as they were out of Alto Pharmacy's control between dates: 7/2/2022 and 7/6/2022. It was unknown how they were stored and if they had been tampered with in any way. Holding or offering for sale, prescription drugs which where out of Alto Pharmacy's control between dates 7/2/2022 to 7/6/2022, which should be considered adulterated, was a violation according to BPC 4342(a) as it relates to HSC 111295.

CITATION ISSUED ON: March 22, 2023 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: April 21, 2023

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE COPY

Citation Number	Name, License No
CI 2022 96563	ALTO PHARMACY, PHY 54523

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4342 subd. (a)/Health & Safety Code § 111295	Prevent sale of drugs lacking quality/It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	$1,000.00

CONDUCT:

Actions by the Board to prevent sales of preparations or Drugs lacking quality of strength; Penalties for knowing or willful violation of Regulations governing those sales: Business and Professions Code (BPC) 4342(a), states in pertinent part: (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code), as it relates to Health and Safety Code (HSC) 111295, which states, It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. Specifically, Alto Pharmacy, PHY54523, located at 1400 Tennessee St., Unit 2, San Francisco, CA 94107, on or around 7/2/2022, dispensed and delivered prescription numbers: 883850002 and 883850003, to an unknown person and location and held at an unknown tempterature, the chain of custody was broken. The prescriptions showed up at the reception desk of the correct address around 7/6/2022 and were then handed to the correct patient. They were subsequently retrieved by Alto Pharmacy. Alto Pharmacy was in violation when they determined the drugs once returned, would be returned to stock, meaning they would be held and offered for sale/re-dispensed to another patient. Those drugs are considered adulterated and should have been quarantined and then sent for destrucation as they were out of Alto Pharmacy's control between dates: 7/2/2022 and 7/6/2022. It was unknown how they were stored and if they had been tampered with in any way. Holding or offering for sale, prescription drugs which where out of Alto Pharmacy's control between dates 7/2/2022 to 7/6/2022, which should be considered adulterated, was a violation according to BPC 4342(a) as it relates to HSC 111295.

CITATION ISSUED ON: March 22, 2023 | **TOTAL AMOUNT OF FINE(S): $1,000.00**

PAYMENT OF FINE(S) DUE BY: April 21, 2023

Standard Report - Legal History and Actions

Client	Branch	Action Level	Date of Action	Notes
Alto Pharmacy LLC				
Alto Pharmacy LLC - Los Angeles, California				
		FACILITY	07/14/2023	California Board of Pharmacy (Case #: CI 2021 95943) On December 28, 2023, the California Board of Pharmacy ("Board of Pharmacy") issued a dismissal of the Citation and Fine, in which the Board of Pharmacy alleged, on or about July 14, 2023, the Licensee failed to update their pharmacy systems and inventory indicating a certain prescription drug was not available for dispensing to a patient requesting the medication, thus delaying the receipt of the prescription medication for the patient. Alto Pharmacy's California Resident Pharmacy Permit remains active, in good standing and unrestricted.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

December 28, 2023

CERTIFIED MAIL

ALTO PHARMACY
ATTN: ALICIA DAVIS, CEO
5916 BOWCROFT ST
LOS ANGELES, CA 90016

Sweta Patel
1255 Treat Blvd., Suite 300
Walnut Creek, CA 94597

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

After thorough and careful consideration of the explanation and information you provided at the office conference, it was decided to dismiss Citation and Fine. CI 2021 95943 as originally issued. Effective immediately the fines assessed in Citation CI 2021 95943, have been dismissed.

This decision is the final administrative order regarding the Citation.

Please contact Associate Enforcement Analyst Suelynn Yee at (916) 518-3013, if you have any questions.

Sincerely

Julia G. Ansel
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY FIRST CLASS CERTIFIED MAIL

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and no party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suit 100, Sacramento, California 95833.

On December 28, 2023, I served the attached:

in said cause, by placing a true copy thereof enclosed in two separate sealed envelopes w postage thereon fully prepaid by Certified Mail and First Class Mail, in the United States m at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: ALICIA DAVIS, CEO 5916 BOWCROFT ST LOS ANGELES, CA 90016	7017 0530 0000 3305 3269
Sweta Patel 1255 Treat Blvd., Suite 300 Walnut Creek, CA 94597	7017 0530 0000 3305 3252

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 28, 2023, at Sacramento, California.

DECLARANT
Suelynn Yee
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 14, 2023

DATED MATERIAL ENCLOSED

ALTO PHARMACY
ATTN: ALICIA DAVIS, CEO
5916 BOWCROFT ST
LOS ANGELES, CA 90016

RE: CI 2021 95943
ALTO PHARMACY
PHY 58642

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

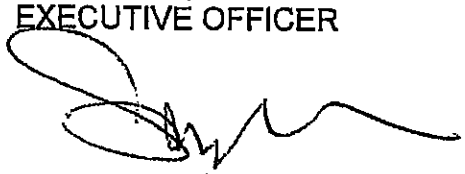
- August 13, 2023: Unless the Citation is contested payment of fine(s) must be received by the Board.
- July 28, 2023: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- August 13, 2023: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By: 

Suelynn Yee
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **August 13, 2023.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than July 28, 2023 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than August 13, 2023 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2021 95943	ALTO PHARMACY, PHY 58642

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 733 subd. (a)	**Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription**	**$1,500.00**

CONDUCT:

Unprofessional conduct: Business and Professions Code section 733, subsection (a) states, a licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency. Subsection (b) states notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exist subsection (2) (A) states, immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner. Alto Pharmacy, PHY58642, failed to comply. Specifically, on 5/18/2022, Dr. Shammas sent a prescription for EW for 30 tablets of Paxlovid 150 – 100 mg to Alto Pharmacy. On 5/18/2022, the prescription was processed under Rx774057005, and the data entry was verified by pharmacist Cynetha Lee at Alto Pharmacy Plano Texas, NRP2529, located at 6201 W Plano PKWY, Suite 400, Plano, TX. On 5/18/2022, upon completion of the data entry verification, the prescription was placed in the fulfillment queue at Alto Pharmacy Los Angeles, PHY58642, located at 5916 Bowcroft Street, Los Angeles, CA to fill the prescription. Two days later, on 5/20/2022, the pharmacists at Alto Pharmacy Los Angeles contacted Alto Pharmacy Clinical Care Specialist to inform EW that Alto Pharmacy Los Angeles cannot fill the prescription because Alto Pharmacy Los Angeles was a site not allocated to dispense Paxlovid thereby unable to obtain the medication to fill the prescription.

Alto Pharmacy failed to establish procedures or failed to update their computer software such that Alto Pharmacy staff are alerted that California Alto Pharmacy facilities do not dispense Paxlovid. Consequently, Alto Pharmacy obstructed EW from obtaining her prescription for Paxlovid in a timely manner.

oOn 5/18/2022, Alto Pharmacy's Clinical Care Specialist informed EW that Alto Pharmacy had Paxlovid in stock instead of informing EW on 5/20/2022 that Alto Pharmacy California facilities do not dispense Paxlovid.

oOn 5/18/2022, EW's prescription for Paxlovid was processed at Alto Pharmacy Plano Texas. The technician who processed the prescription and Pharmacist Cynetha Lee who verified the data entry of the prescription on 5/18/2022 should have informed the Care

Specialist to Inform EW that California Alto Pharmacy facilities do not dispense Paxlovid. oOn 5/18/2022, EW's Paxlovid prescription was placed in queue at Alto Pharmacy Los Angeles for filling. On 5/18/2022, the staff at Alto Pharmacy Los Angeles should have alerted the Care team to inform EW that Alto Pharmacy Los Angles cannot fill her prescription for Paxlovid because the pharmacy was not allocated to dispense Paxlovid.

Had Alto Pharmacy established procedures or updated their computer software, the staff at Alto Pharmacy could have informed EW on 5/18/2022 that her prescription for Paxlovid cannot be filled at Alto Pharmacy Los Angeles.
On 5/20/2022, EW contacted Dr. Shammas to send another prescription for Paxlovid to CVS Pharmacy 9660. The prescription was filled but was not delivered until 5/21/2022. Alto Pharmacy obstructed EW from obtaining from obtaining her prescription for Paxlovid, a medication which needed to be started within five days from the onset of COVID-19 symptoms, a violation of Business and Professions Code 733 (a).

CITATION ISSUED ON: July 14, 2023	TOTAL AMOUNT OF FINE(S): $1,500.00
PAYMENT OF FINE(S) DUE BY: August 13, 2023	

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2021 95943	ALTO PHARMACY, PHY 58642

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 733 subd. (a)	Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	$1,500.00

CONDUCT:

Unprofessional conduct: Business and Professions Code section 733, subsection (a) states, a licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency. Subsection (b) states notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exist subsection (2) (A) states, Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner. Alto Pharmacy, PHY58642, failed to comply. Specifically, on 5/18/2022, Dr. Shammas sent a prescription for EW for 30 tablets of Paxlovid 150 – 100 mg to Alto Pharmacy. On 5/18/2022, the prescription was processed under Rx774057005, and the data entry was verified by pharmacist Cynetha Lee at Alto Pharmacy Plano Texas, NRP2529, located at 6201 W Plano PKWY, Suite 400, Plano, TX. On 5/18/2022, upon completion of the data entry verification, the prescription was placed in the fulfillment queue at Alto Pharmacy Los Angeles, PHY58642, located at 5916 Bowcroft Street, Los Angeles, CA to fill the prescription. Two days later, on 5/20/2022, the pharmacists at Alto Pharmacy Los Angeles contacted Alto Pharmacy Clinical Care Specialist to inform EW that Alto Pharmacy Los Angeles cannot fill the prescription because Alto Pharmacy Los Angeles was a site not allocated to dispense Paxlovid thereby unable to obtain the medication to fill the prescription.

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Specialist to inform EW that California Alto Pharmacy facilities do not dispense Paxlovid. oOn 5/18/2022, EW's Paxlovid prescription was placed in queue at Alto Pharmacy Los Angeles for filling. On 5/18/2022, the staff at Alto Pharmacy Los Angeles should have alerted the Care team to inform EW that Alto Pharmacy Los Angles cannot fill her prescription for Paxlovid because the pharmacy was not allocated to dispense Paxlovid.

Had Alto Pharmacy established procedures or updated their computer software, the staff at Alto Pharmacy could have informed EW on 5/18/2022 that her prescription for Paxlovid cannot be filled at Alto Pharmacy Los Angeles.
On 5/20/2022, EW contacted Dr. Shammas to send another prescription for Paxlovid to CVS Pharmacy 9660. The prescription was filled but was not delivered until 5/21/2022. Alto Pharmacy obstructed EW from obtaining from obtaining her prescription for Paxlovid, a medication which needed to be started within five days from the onset of COVID-19 symptoms, a violation of Business and Professions Code 733 (a).

CITATION ISSUED ON: July 14, 2023	TOTAL AMOUNT OF FINE(S): $1,500.00
PAYMENT OF FINE(S) DUE BY: August 13, 2023	

COPY

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: ALTO PHARMACY

License No: PHY 58642

Citation Number : CI 2021 95943

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

_____

_____

_____

_____

_____

_____

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Daytime Number: (___) _____ Email Address: (___) _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:	Citation Case No : CI 2021 95943
ALTO PHARMACY PHY 58642 Respondent	NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: ALTO PHARMACY, PHY 58642
Citation and Fine CI 2021 95943

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On July 14, 2023, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
ALTO PHARMACY ATTN: ALICIA DAVIS, CEO 5916 BOWCROFT ST LOS ANGELES, CA 90016	7021 1970 0001 5375 5542

I declare under penalty of perjury that the forgoing is true and correct.

Executed on July 14, 2023, at Sacramento, California.

DECLARANT

Suelynn Yee
Citation and Fine Analyst

4MMM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: E-Rxhub

Physical Address: 13940 North Dale Mabry Hwy

City: Tampa State: FL Zip: 33618

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-311-5805 Toll Free # (NAC 639.708, NRS 639.23286): 800-311-5805

Fax: 800-798-7589 Contact Email: partners@e-rxhub.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Kitrina Woloschek

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21277

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kitrina Woloschek	NV Pharmacist Registration #: 21277
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: WYOMING

Parent Company (if any): _____

Corporation/Organization Name: E-RXHUB LLC

Mailing Address: 13940 North Dale Mabry Hwy

City: Tampa State: FL Zip: 33618

Telephone: 800-311-5805 Email: partners@e-rxhub.com

Contact Person Name: Meriam Ibrahim

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for E-Rxhub (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Meriam Ibrahim

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/17/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Meriam Ibrahim hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner (title) for E-Rxhub (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

_____
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

pertaining to the practice of pharmacy.

5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

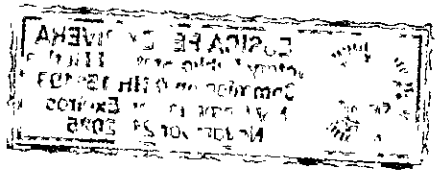
Meriam Ibrahim

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/17/25

Date



Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Meriam Ibrahim hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner (title) for E-Rxhub (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18 day of July, 2025

Notary Public

JESSICA PEREZ RIVERA
Notary Public-State of Florida
Commission # HH 159199
My Commission Expires
November 21, 2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Meriam Ibrahim

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7/17/2025

Date

Board Use Only	Date Received: 7/21/25	Amount: $500 CK 0916

E-RxHub

13940 N Dale Mabry Hwy

Tampa, FL 33618

Phone: (800) 311-5805

Email: partners@e-rxhub.com

Date: July 18, 2025

To:

Nevada State Board of Pharmacy

985 Damonte Ranch Pkwy, Suite 206

Reno, NV 89521

Subject: Ownership Statement for E-RxHub

Dear Members of the Nevada State Board of Pharmacy,

This letter is to formally declare that I, Meriam Ibrahim, am the sole owner of E-RxHub, a licensed pharmacy operating at 13940 N Dale Mabry Hwy, Tampa, Florida 33618.

There are no other individuals or entities with ownership interest, financial stake, or decision-making authority in the business. I serve as the Chief Executive Officer and have full authority over the operations, financials, and compliance matters of the pharmacy.

Please feel free to contact me should you require any additional documentation or clarification regarding this matter. I appreciate your attention to this submission as part of our application for non-resident pharmacy licensure in the State of Nevada.

Sincerely,

Meriam Ibrahim
Chief Executive Officer
E-RxHub

State of Florida
Department of State

I certify from the records of this office that E-RXHUB LLC is a limited liability company organized under the laws of the State of Florida, filed on September 17, 2024, effective September 12, 2024.

The document number of this limited liability company is L24000405322.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on March 2, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Thirteenth day of June, 2025

Secretary of State

Tracking Number: 2431421711CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler E-Rxhub

Pharmacy/Wholesaler License # (if applicable) Florida, PH

Physical Address 13940 North Dale Mabry Hwy

City Tampa State FL Zip 33618

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-311-5805 Website N/A

Licensing Company Email Partners@e-rxhub.com

Section 2: Personal Information

First Kitrina Middle A. Last Woloschek

Alias(es, nicknames, name changes, etc.) Trina Stewart ; Kitrina Stewart

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Florida Agricultural and Mechanical University			08-1994 - 05/98	
Address	City	State	Zip	
1601 S Martin Luther King Jr Blvd	Tallahassee	FL	32307	
Diploma/Degree obtained, if any				
Doctor of Pharmacy				

School Name			From - To (MM/YY – MM/YY)	
Dixie Hollins High			8/83 - 6/87	
Address	City	State	Zip	
4940 62nd St. N.	St. Petersburg	FL	33709	
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
3/17 – Present	[redacted]			
10/15 - 3/17				
01/99 - 10/15				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
TelyRx Mail Order Pharmacy			12/2024-Current
Business Address	**City**	**State**	**Zip**
24761 US Hwy 19 North	Clearwater	FL	33763
Phone	**Title**	**Number of Employed Hours**	
800-878-1660	Pharmacist in Charge	40 hours weekly	

Description of Duties
Supervise pharmacist and pharmacy technicians, maintain prescirption records, ensure adherence to SOP as well as state and federal regulations. Renew pharmacy permits and PIC licenses before expiration date. Conduct quaterly CQI.

Business Name			From - To (MM/YY – MM/YY)
LinCare dba Reliant Pharmacy Service Mail Order Pharmacy			09/17-12/24
Business Address	**City**	**State**	**Zip**
3985 Gateway Centre Blvd STE 200	Pinellas Park	FL	33782
Phone	**Title**	**Number of Employed Hours**	
727-523-8232	Pharmacist in Charge	40 hours weekly	

Description of Duties
Supervise pharmacist and pharmacy technicians, maintain prescription records, ensure adherence to SOP and state and federal regulations. Conduct qauterly CQI.

Business Name			From - To (MM/YY – MM/YY)
Walmart Pharmacy			10/15-08/17
Business Address	**City**	**State**	**Zip**
10237 Bay Pines Blvd	Seminole	Florida	33708
Phone	**Title**	**Number of Employed Hours**	
727-345-8319	Pharmacist in Charge	40 hours weekly	

Description of Duties
Filling prescriptions, couseling patients and monitoring profiles for drug interations. Web forms are completed monthly per SOP. Ordering medications and supplies. Preparing Technicains schedules and reviewing vacation requests.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Kitrina Woloschek, **certify that as the designated representative for**

E-Rxhub,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KW I am at least 21 years of age;
3. KW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kitrina Woloschek

Print Name (First, Last)

Kitrina Woloschek

Original Signature (electronic, copies or stamps not accepted)

07/17/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kitrina Woloschek

Print Name (First, Last)

Kitrina Woloschek

Original Signature (electronic, copies or stamps not accepted)

07/17/2025

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of HILLSBOROUGH

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Kitrina Woloschek

Original Signature

7/18/25

Date

Subscribed and Sworn to before me this 18 day of July.

JESSICA PEREZ RIVERA
Notary Public-State of Florida
Commission # HH 159199
My Commission Expires
November 21, 2025

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site E-Rxhub

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH35276 Florida

Physical Address 13940 North Dale Mabry Hwy

City Tampa State Florida Zip 33618

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-311-5805 Website N/A

Licensing Company Email Partners@e-rxhub.com

Section 2: Personal Information

First Meriam Middle _____ Last Ibrahim

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: ~~Diamond Bar High School~~ / CSUF		From - To (MM/YY – MM/YY): 2/00 - 6/05	
Address: 800 N. State College Blvd	City: Fullerton	State: CA	Zip: 92831
Diploma/Degree obtained, if any: Psychology			
School Name: Diamond Bar High School		From - To (MM/YY – MM/YY): 9/1997 - 6/01	
Address: 21400 Pathfinder Rd	City: Diamond Bar	State: CA	Zip: 91765
Diploma/Degree obtained, if any: general			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 2/2014 - Pres	[redacted]			
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
E-Rxhub			06/24 - Current
Business Address	**City**	**State**	**Zip**
13940 North Dale Mabry Hwy	Tampa	FL	33618
Phone	**Title**		
800-311-5805	Pharmacy Owner		
Description of Duties			
Pharmacy owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Meriam Ibrahim

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/17/2025

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of HILLSBOROUGH

I, MERIAM IBRAHIM, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/17/25

Date

Subscribed and Sworn to before me this 17 day of July, 2025

Notary Public Signature

JESSICA PEREZ RIVERA
Notary Public-State of Florida
Commission # HH 159199
My Commission Expires
November 21, 2025

(Seal)

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 30144
Insp # 200380

NAME	PERMIT NUMBER	DATE OF INSPECTION
E-RxHub	35276	06/02/2025
DOING BUSINESS AS		
E-RXHUB		
STREET ADDRESS	**TELEPHONE #**	**EXT**
13490 N Dale Mabry	714-356-8759	
CITY	**COUNTY**	**STATE/ZIP**
TAMPA	HILLSBOROUGH	FL/33618

Additional Information

Business Operation Hours

M-T-W-TH-F N	Weekly Hours
Monday Y	Monday Hours 5:00 PM - 8:30 PM
Tuesday N	Tuesday Hours
Wednesday Y	Wednesday Hours 8:00 AM - 1:00 PM
Thursday Y	Thursday Hours 5:00 PM - 8:30 PM
Friday N	Friday Hours
Saturday Y	Saturday Hours 9:00 AM - 5:00 PM
Sunday N	Sunday Hours

Registered Pharmacist / Intern / Tech

License # PS 48584	Licensee Name Lalichan George
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # N/A	

License Relations

Pharmacy Affiliate

IBRAHIM, MERIAM EZZAT	License #

RX DPT MGR/COR/POR

GEORGE, LALICHAN PERNICHERIL	License # 48584

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	N/A

INV359 - Community Requirements

Insp # 200380 | E-RxHub | File # 30144

Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	N/A
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.] *Still looking for a return solutions company to contract with.*	N/A
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.] *Has only been operating for 1 month at the time of inspection.*	N/A
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	N/A
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.] *CarePMS*	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	N/A
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.] *Safechain*	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] *No controlled substances stored or administered at this facility.*	N/A
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	N/A
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	N/A
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

INV359 - Community Requirements

Insp # 200380 E-RxHub File # 30144

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

Routine inspection completed with Meriam Ibrahim. Operating requirements met.

I heve read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

HODGES, PETER

Date:6/2/2025

Representative:

Meriam Ibrahim

Date:6/2/2025

Your license number is PH 35276.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
JANUARY 28, 2025	**PH 35276**	**150183**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy

EXPIRATION DATE: **FEBRUARY 28, 2027**

E-RXHUB
E-RxHub
13940 N DALE MABRY
TAMPA, FL - 33618

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
JANUARY 28, 2025	PH 35276	150183

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date: **FEBRUARY 28, 2027**

E-RXHUB
E-RxHub

REGISTRANT SIGNATURE

Department of Health

E-RxHub

E-RxHub

License Number: PH35276

Data As Of 6/17/2025

Profession	Pharmacy
License	PH35276
License Status	CLEAR/
Qualifications	Community Pharmacy
License Expiration Date	2/28/2027
License Original Issue Date	08/27/2024
Address of Record	13940 N Dale Mabry TAMPA, FL 33618
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
GEORGE, LALICHAN PERNICHERIL	RX DPT MGR/COR/POR	PHARMACIST	48584	03/20/2025
IBRAHIM, MERIAM EZZAT	PHARMACY AFFILIATE	PHARMACY AFFILIATE		08/27/2024

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

4NNN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Foundation Pharmacy LLC

Physical Address: 10204 NW 47th St.

City: Sunrise State: FL Zip: 33351

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 1(888)857-1984 Toll Free # (NAC 639.708, NRS 639.23286): 1(888)857-1984

Fax: 1(888)857-1984 Contact Email: info@foundationhealthrx.com

Website: N/A

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Joshua Heiblum

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24586

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Joshua Heiblum	NV Pharmacist Registration #: 24586
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): _____

Corporation/Organization Name: Foundation Pharmacy LLC

Mailing Address: 10204 NW 47th St.

City: Sunrise State: FL Zip: 33351

Telephone: 1(888)857-1984 Email: info@foundationhealthrx.com

Contact Person Name: Joshua Heiblum

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PIC and Owner (title) for Foundation Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Joshua Heiblum

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

5/22/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Joshua Heiblum hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PIC and Owner (title) for Foundation Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 22 day of May, 2025.

Notary Public

ANDRES GARCIA
Notary Public - State of Florida
Commission # HH 416405
My Comm. Expires May 24, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joshua Heiblum

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

05/22/25

Date

Board Use Only	Date Received: 6/24/25	Amount: $500-ck 583

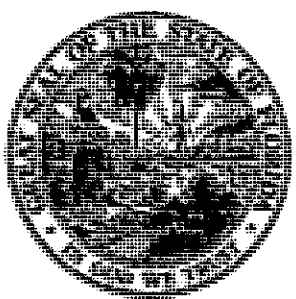
State of Florida
Department of State

I certify from the records of this office that FOUNDATION PHARMACY LLC is a limited liability company organized under the laws of the State of Florida, filed on November 12, 2024, effective November 11, 2024.

The document number of this limited liability company is L24000478111.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on April 24, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-fourth day of April, 2025



Secretary of State

Tracking Number: 0814065737CC

To authenticate this certificate,visit the following site,enter this number, and tben follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Foundation Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 10204 NW 47th St.

City Sunrise State FL Zip 33351

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 1(888)857-1984 Website N/A

Licensing Company Email info@foundationhealthrx.com

Section 2: Personal Information

First Joshua Middle _____ Last Heiblum

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University - CPG		06/10-06/13	
Address	City	State	Zip
19555 N 59th Ave	Glendal	AZ	85308
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Florida International University		08/02-06/07	
Address	City	State	Zip
11200 SW 8th St	Miami	FL	33199
Diploma/Degree obtained, if any			
B.S. Biology, Minor in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Scheck Hillel Community School		08/98-06/02	
Address	City	State	Zip
19000 NE 25th Ave	Miami	FL	33180
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20-Current	[redacted]			
07/14-08/20				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Cue Health, Inc				From - To (MM/YY – MM/YY): 08/22-07/24
Business Address: San Diego (Bankrupt)		City	State	Zip
Phone	Title: Senior Director of Pharmacy Services			
Description of Duties: Responsible for pharmacy services for the diagnostic based company				

Business Name: Amazon Pharmacy/ PillPack Miami				From - To (MM/YY – MM/YY): 11/15-07/20
Business Address: 8725 NW 13th Terrace		City: Doral	State: FL	Zip: 33172
Phone: 855-745-5725	Title: PIC and Site Leader			
Description of Duties: PIC and all operational services				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joshua,Heiblum

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/23/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Joshua Heiblum, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/23/25

Date

Subscribed and Sworn to before me this 23rd day of July.

Alexis Thompson

Notary Public Signature



STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV355 - Community Pharmacy (New Business / Change of Owner)

File # 30601
Insp # 204707

NAME	PERMIT NUMBER	DATE OF INSPECTION	
Foundation Pharmacy LLC		04/17/2025	
DOING BUSINESS AS			
STREET ADDRESS 10204 NW 47th St.		**TELEPHONE #** 305-586-6302	**EXT**
CITY SUNRISE	**COUNTY** BROWARD	**STATE/ZIP** FL/33351	

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9am to 5pm
Monday Y	Monday Hours 9am to 5pm
Tuesday Y	Tuesday Hours 9am to 5pm
Wednesday Y	Wednesday Hours 9am to 5pm
Thursday Y	Thursday Hours 9am to 5pm
Friday Y	Friday Hours 9am to 5pm
Saturday N	Saturday Hours Closed
Sunday N	Sunday Hours Closed

Registered Pharmacist / Intern / Tech

License # PS51133	Licensee Name Josh Heiblum
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # N/A	

License Relations

RX DPT MGR/COR/POR

HEIBLUM, JOSHUA REUVEN	License # 51133

INV355 - Community Pharmacy (New Business / Change of Owner)

COMMUNITY REQUIREMENTS GENERAL SECTION

Rx Department is open for a minimum of 20 hours per week and signage stating the hours the pharmacy department is open. [64B16-28.1081, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-28.1035, F.A.C]	Yes
Private Consultation Area available. [64B16-28.1035, F.A.C]	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes
Prescription department is clean and safe, has a sink with running water convenient to the prescription department, and references and equipment necessary for the practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy has a designated Prescription Department manager with a current and active Florida license. [465.018, F.S.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16 -27.410(2)(a) F.A.C.]	Yes
Continuous Quality Improvement Program described in Policy and Procedure manual [64B16-27.300 F.A.C.] [766.101(1)(a)(l) F.S.]	Yes
Policy and Procedure to prevent the fraudulent dispensing or controlled substances. [465.022 (4) F.S]	Yes
Prescription Department is securable from unauthorized access. [64B16-28.109 F.A.C.]	Yes

INV355 - Community Pharmacy (New Business / Change of Owner)

Insp # 204707 | Foundation Pharmacy LLC | File # 30801

All medications to be purchased from a Florida licensed wholesaler [499-F.S.] *Wholesaler: TBD*	Yes
The following rules have been reviewed with the applicant: 64B16-30.003, F.A.C. (Citations), 64B16-28.140(4) F.A.C. (Compounding Records), 64B16-28.1081, F.A.C. (Regulation of Daily Operating Hours; Commencement of Operation-s), 64B16-28.202, F.A.C (Closing of a Pharmacy)	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Remarks:

Inspection completed with PDM Josh Heiblum PharmD.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature
MENDEZ, JUAN CARLOS

Date:4/17/2025

Representative:
Josh Heiblum

Date:4/17/2025

Your license number is PS 51133.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO	CONTROL NO.
AUGUST 10, 2023	PS 51133	383496

THE PHARMACIST
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

EXPIRATION DATE: SEPTEMBER 30, 2025

JOSHUA REUVEN HEIBLUM
636 NANDINA DR
WESTON, FL - 33327

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
AUGUST 10, 2023	PS 51133	383496

THE PHARMACIST
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

JOSHUA REUVEN HEIBLUM

Expiration Date: SEPTEMBER 30, 2025

LICENSEE SIGNATURE

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
04232025	PH 35707	155404

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Modules II & III
Community Pharmacy

EXPIRATION DATE FEBRUARY 28, 2027

FOUNDATION PHARMACY LLC
10204 NW 47TH ST.
SUNRISE, FL 33351

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

Department of Health

JOSHUA REUVEN HEIBLUM

License Number: PS51133

Data As Of 11/25/2024

Profession	Pharmacist
License	PS51133
License Status	CLEAR/Active
License Expiration Date	9/30/2025
License Original Issue Date	09/04/2013
Address of Record	636 Nandina Dr WESTON, FL 33327
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 06/05/2025
Amount:
License #: 24586

Joshua R. Heiblum

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:06/05/2025
Expires:10/31/2025

Joshua R. Heiblum

License #
24586
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Pharmacist

Expires: 10/31/2025
STATUS: Active

License Type: Pharmacist
License #: 24586
Effective Date:06/05/2025

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Joshua R. Heiblum

NONTRANSFERABLE

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

Department of Health

Foundation Pharmacy LLC

License Number: PH35707

Data As Of 4/22/2025

Profession	Pharmacy
License	PH35707
License Status	CLEAR/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2027
License Original Issue Date	04/22/2025
Address of Record	10204 NW 47th St. SUNRISE, FL 33351
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

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Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
HEIBLUM, JOSHUA REUVEN	RX DPT MGR/COR/POR	PHARMACIST	51133	04/22/2025

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

4000

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Medico Pharmacy

Physical Address: 11779 Santa Monica Blvd

City: LA State: CA Zip: 90025

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 310-444-9011 Toll Free # (NAC 639.708, NRS 639.23286): 833-452-3450

Fax: 310-444-0418 Contact Email: everpharmrx@gmail.com

Website: https://medicopharmacyrx.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Mikhail Granin

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24530

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Mikhail Granin	NV Pharmacist Registration #: 24530
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Yury Akopyan

Business Name: Evergreen Rx dba Medico Pharmacy

Business Address: 11799 Santa Monica Blvd

City: Los Angeles State: CA Zip: 90025

Telephone: (310) 266-4745 Email: yuryako@yahoo.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Medico Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Yury Akopyan

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/10/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Yury Akopyan hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for Medico Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

See attached

Notary Public

CALIFORNIA
JURAT CERTIFICATE

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 19th day of May, 2025, by Yury AYopyan,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

WITNESS MY HAND AND OFFICIAL SEAL.

BKnerr

Signature of Notary Public

BRIGITTE KNERR
Notary Public - California
Los Angeles County
Commission # 2488312
My Comm. Expires May 24, 2028

(Notary Seal)

OPTIONAL INFORMATION

The jurat contained within this document is in accordance with California law. Any affidavit subscribed and sworn to before a notary shall use the preceding wording or substantially similar wording pursuant to Civil Code sections 1189 and 8202. A jurat certificate cannot be affixed to a document sent by mail or otherwise delivered to a notary public, including electronic means, whereby the signer did not personally appear before the notary public, even if the signer is known by the notary public. The seal and signature cannot be affixed to a document without the correct notarial wording. As an additional option an affiant can produce an affidavit on the same document as the notarial certificate wording to eliminate the use of additional documentation.

DESCRIPTION OF ATTACHED DOCUMENT

_____
(Title of document)

Number of Pages _____(Including jurat)

Document Date _____

_____
(Additional Information)

CAPACITY CLAIMED BY THE SIGNER

- ☐ Individual
- ☐ Corporate Officer
- ☐ Partner
- ☐ Attorney-In-Fact
- ☐ Trustee
- ☐ Other: _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yury Akopyan

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4/10/25

Date

Board Use Only	Date Received: 7/23/25	Amount $500 ck. 1324

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	EVERGREEN RX, INC.
Entity No.:	3604234
Registration Date:	09/18/2013
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of July 01, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 343631426

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medico Pharmacy

Pharmacy/Wholesaler License # (if applicable): PHY 51906

Physical Address: 11779 Santa Monica Blvd

City: Los Angeles State: CA Zip: 90025

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 310-444-9011 Website: medicopharmacyrx.com

Licensing Company Email: everpharmrx@gmail.com

Section 2: Personal Information

First: Mikhail Middle: Last: Granin

Alias(es, nicknames, name changes, etc.):

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LECOM School of Pharmacy		08/13-06/17	
Address	**City**	**State**	**Zip**
5000 Lakewood Ranch Blvd	Bradenton	FL	34211
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
AJU		08/11-06/13	
Address	**City**	**State**	**Zip**
15600 Mulholland Dr	Los Angeles	CA	90077
Diploma/Degree obtained, if any			
B.A. Bioethics and Natural Sciences			

School Name		From - To (MM/YY – MM/YY)	
Santa Monica College		08/08-06/11	
Address	**City**	**State**	**Zip**
1900 Pico Blvd	Santa Monica	CA	90405
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Palisades Charter High School		09/04-06/08	
Address	**City**	**State**	**Zip**
15777 Bowdoin St	Pacific Palisades	CA	90727
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/21-current	[redacted]			
03/18-07/21				
04/02-03/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Medico Pharmacy			09/24-Current	
Business Address		**City**	**State**	**Zip**
11779 Santa Monica Blvd		Los Angeles	CA	90025
Phone	**Title**		**Number of Employed Hours**	
310-444-9011	PIC		1280+	
Description of Duties				
All duties required for operation of pharmacy, including filling, checking, and consultation on all prescriptions within the pharmacy.				

Business Name			From - To (MM/YY – MM/YY)	
Elements Pharmacy			01/24-09/24	
Business Address		**City**	**State**	**Zip**
12602 Ventura Blvd		Studio City	CA	91604
Phone	**Title**		**Number of Employed Hours**	
818-762-2055	Compound Pharmacist		1440	
Description of Duties				
All duties required for compounding and dispensing of prescriptions.				

Business Name			From - To (MM/YY – MM/YY)	
RX Unlimited Pharmacy			05/24-12/24	
Business Address		**City**	**State**	**Zip**
16673 Roscoe Blvd		North Hills	CA	91343
Phone	**Title**		**Number of Employed Hours**	
818-781-2400	PIC		840	
Description of Duties				
All duties required for compounding and dispensing of prescriptions.				

Business Name			From - To (MM/YY – MM/YY)	
Rancho Park Compounding Pharmacy			09/21-05/23	
Business Address		**City**	**State**	**Zip**
10587 W Pico Blvd		Los Angeles	CA	90064
Phone	**Title**		**Number of Employed Hours**	
310-475-3040	Sterile Compound Pharmacist		3360	
Description of Duties				
All duties required for compounding and dispensing of prescriptions.				

Business Name			From - To (MM/YY – MM/YY)	
Kindred Care Pharmacy			12/20-09/21	
Business Address		**City**	**State**	**Zip**
26500 Agoura Rd #111		Calabasas	CA	91302
Phone	**Title**		**Number of Employed Hours**	
818-880-8816	Staff Pharmacist		1440	
Description of Duties				
All duties required for operation of pharmacy, including filling, checking, and consultation on all prescriptions within the pharmacy.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Brentwood Plaza Pharmacy			01/18-09/24
Business Address	**City**	**State**	**Zip**
11980 San Vicente Blvd #104	Los Angeles	CA	90049
Phone	**Title**		**Number of Employed Hours**
310-820-1496	Staff Pharmacist		300
Description of Duties			
All duties required for operation of pharmacy, including filling, checking, and consultation on all prescriptions within the pharmacy.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Mikhail Granin, **certify that as the designated representative for**

Medico Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MG I am at least 21 years of age;
3. MG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Mikhail Granin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/13/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mikhail Granin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/13/2025

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

See attached

Notary Public Signature

(Seal)

CALIFORNIA ALL-PURPOSE CERTIFICATE OF ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los angeles

On June 13, 2025 before me, Brigitte Knerr, Notary Public
(Here insert name and title of the officer)

personally appeared Mikhail Granin

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature of Notary Public

(Notary Seal)

BRIGITTE KNERR
Notary Public - California
Los Angeles County
Commission # 2488312
My Comm. Expires May 24, 2028

ADDITIONAL OPTIONAL INFORMATION

DESCRIPTION OF THE ATTACHED DOCUMENT

Designated Representative Application
(Title or description of attached document)

(Title or description of attached document continued)

Number of Pages _____ Document Date _____

(Additional information)

CAPACITY CLAIMED BY THE SIGNER

- ☐ Individual (s)
- ☐ Corporate Officer

(Title)

- ☐ Partner(s)
- ☐ Attorney-in-Fact
- ☐ Trustee(s)
- ☐ Other _____

INSTRUCTIONS FOR COMPLETING THIS FORM

Any acknowledgment completed in California must contain verbiage exactly as appears above in the notary section or a separate acknowledgment form must be properly completed and attached to that document. The only exception is if a document is to be recorded outside of California. In such instances, any alternative acknowledgment verbiage as may be printed on such a document so long as the verbiage does not require the notary to do something that is illegal for a notary in California (i.e. certifying the authorized capacity of the signer). Please check the document carefully for proper notarial wording and attach this form if required.

- State and County information must be the State and County where the document signer(s) personally appeared before the notary public for acknowledgment.
- Date of notarization must be the date that the signer(s) personally appeared which must also be the same date the acknowledgment is completed.
- The notary public must print his or her name as it appears within his or her commission followed by a comma and then your title (notary public).
- Print the name(s) of document signer(s) who personally appear at the time of notarization.
- Indicate the correct singular or plural forms by crossing off incorrect forms (i.e. ~~he~~/she/~~they,~~ is /~~are~~) or circling the correct forms. Failure to correctly indicate this information may lead to rejection of document recording.
- The notary seal impression must be clear and photographically reproducible. Impression must not cover text or lines. If seal impression smudges, re-seal if a sufficient area permits, otherwise complete a different acknowledgment form.
- Signature of the notary public must match the signature on file with the office of the county clerk.
  - Additional information is not required but could help to ensure this acknowledgment is not misused or attached to a different document.
  - Indicate title or type of attached document, number of pages and date.
  - Indicate the capacity claimed by the signer. If the claimed capacity is a corporate officer, indicate the title (i.e. CEO, CFO, Secretary).
- Securely attach this document to the signed document

2008 Version CAPA v12.10.07 800-873-9865 www.NotaryClasses.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Evergreen Rx, dba Medico Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PHY 51906

Physical Address 11779 Santa Monica Blvd.

City Los Angeles State CA Zip 90025

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone (310)444-9011 Website www.medicopharmacyrx.com

Licensing Company Email www.pharmacy.ca.gov and BOPstewardship@dca.ca.gov

Section 2: Personal Information

First Yury Middle _____ Last Akopyan

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: West Coast University		From - To (MM/YY – MM/YY): 9/2017 - 5/2019	
Address: 1080 Marina Village Parkway Suite 500 CA	City	State: CA	Zip: 94501
Diploma/Degree obtained, if any: Masters in Healthcare Administration			
School Name: University of Oil and Gas		From - To (MM/YY – MM/YY): 1969 through 1974	
Address: Baku, Azerbajan	City	State	Zip
Diploma/Degree obtained, if any: Masters in Oil Drilling Engineering			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 01/2001 - Present	[redacted]			
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Evergreen Rx dba Medico Pharmacy			05/15 - present	
Business Address		**City**	**State**	**Zip**
11779 Santa Monica Blvd.		Los Angeles	CA	90025
Phone	**Title**			
(310)444-9011	Owner			
Description of Duties				
Oversee all business operations				

Business Name			From - To (MM/YY – MM/YY)	
Complete Care Community Health Center, Inc.			2007n - present	
Business Address		**City**	**State**	**Zip**
3000 S. Robertson Blvd., Suite 280		Los Angeles	CA	90034
Phone	**Title**			
(310)730 - 6362	CEO			
Description of Duties				
Oversee provision of healthcare services to an under served population.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yury Akopyan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/14/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Yury Akopyan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/14/2025

Date

Subscribed and Sworn to before me this ____ day of _____.

Notary Public Signature

See attached

(Seal)

CALIFORNIA
JURAT CERTIFICATE

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 15th day of July,

2025, by Yury Akopyan,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

WITNESS MY HAND AND OFFICIAL SEAL.

BRIGITTE KNERR
Notary Public - California
Los Angeles County
Commission # 2488312
My Comm. Expires May 24, 2028

BKnerr

Signature of Notary Public

(Notary Seal)

OPTIONAL INFORMATION

The jurat contained within this document is in accordance with California law. Any affidavit subscribed and sworn to before a notary shall use the preceding wording or substantially similar wording pursuant to Civil Code sections 1189 and 8202. A jurat certificate cannot be affixed to a document sent by mail or otherwise delivered to a notary public, including electronic means, whereby the signer did not personally appear before the notary public, even if the signer is known by the notary public. The seal and signature cannot be affixed to a document without the correct notarial wording. As an additional option an affiant can produce an affidavit on the same document as the notarial certificate wording to eliminate the use of additional documentation.

DESCRIPTION OF ATTACHED DOCUMENT

(Title of document)

Number of Pages _____ (Including jurat)

Document Date _____

(Additional Information)

CAPACITY CLAIMED BY THE SIGNER

- ☐ Individual
- ☐ Corporate Officer
- ☐ Partner
- ☐ Attorney-In-Fact
- ☐ Trustee
- ☐ Other: _____

MMX V. BAN2 510.409.1334 www.BayAreaNotary.com

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy **X** Hospital Pharmacy Clinic Outsourcing Facility Wholesaler Hypodermic

Date: 5/8/2025 Inspector: Gloria Saldana

Firm: MEDICO PHARMACY Phone:

Address: 11779 SANTA MONICA BLVD City: LOS ANGELES Zip: 90025

Ownership: CORPORATION

Permit #: PHY51906 Permit Exp: 5/1/2026 DEA#: FE5222029 DEA Exp: 8/3/2027

Date of Self Assessment Form: 9/27/2024 Other Permit #: N/A Date of DEA Inventory: 12/12/2024

Hours M-F: 9AM to 5:30PM Hours Saturday: CLOSED Hours Sunday: CLOSED

PIC **MIKHAIL GRANIN** RPH77946 Administrator

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
SANAM NOURIESFAHANI	RPH81104	**DINA LENCHITSKY (CHIEF**	CORP OFFICER
		DREYSY L GIRON	TCH140744
		ERIC D CHISM	TCH67845
		GAYANE CHINARYAN	TCH145701
		STELLA J DUA	TCH47334

Inspector Remarks:

Here today to follow-up with Medico Pharmacy. New PIC Mikhail Granin assisted with the inspection.
PIC Granin completed self-assessment on 9/27/2024 and DEA Inventory and Quarterly with reconciliation on 12/24/2024.

PIC Granin showed me the attic, which is accessible only with a latter. Files and invoices are stored here.
I reviewed Cardinal Health invoices dated 4/21.2021 to 7/1/2021.
Pharma Logistics was reverse distributor.
SA completed 1/27/2025 gs
I am requesting the following items:
1. 2021 Self-Assessment to be emailed to gloria.saldana@dca.ca.gov, by 5/9/2025
2. Email regarding student from Granada Hills, staff verifying vaccine information by 5/16/2025.

Topics to Educate

1. BPC 4052.04 – Pharmacist may furnish COVID-19 oral therapeutics following a positive test.
   - "COVID-19 oral therapeutics" means drugs that are approved or authorized by the FDA for the treatment of COVID-19 and administered orally.
   - Prior to furnishing COVID-19 oral therapeutics, a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by FDA in providing these patient care services.
   - A pharmacist who furnishes COVID-19 oral therapeutics shall notify patient's PCP or enter appropriate information into patient record system shared with PCP, as permitted by that PCP. If the patient does not have a PCP, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.
   - Document the kind and amounts of COVID-19 oral therapeutics furnished, as well as any information regarding testing services

INSPECTION REPORT

provided, in the patient's record in the record system maintained by the pharmacy.

- Retain records for 3 years.

2. BPC 4113 – PIC authority to make staffing decisions
   - PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely.
   - If PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed.
   - PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or RPH on duty shall ensure the BOP is timely notified. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff include, but are not limited to:
     - Workplace safety and health hazards that present an immediate risk of death, illness or irreparable harm to patients, personnel, or pharmacy staff.
     - Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
     - Vermin infestation that poses a risk to the safety or efficacy of medicine.
3. BPC 4113.1 – Reporting medication errors within 14 days from discovery.
   - Applies to "community pharmacies" – *i.e.*, any pharmacy that dispenses medication to an outpatient (but not including facilities of CDCR).
   - Per the BOP's AB 1286 Implementation Statement, the reporting of medication errors under BPC 4113.1 will not be required until the BOP approves an entity to receive the reports.
4. BPC 4113.6 – Chain community pharmacy subject to BPC 4113.5 must be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The BOP will not take action against a pharmacy for violation of this staffing requirement if any of the following conditions apply:
   - RPH on duty waives the requirement in writing during specified hours based on workload need.
   - The pharmacy is open beyond normal business hours (*i.e.*, before 8am, after 7pm). During the hours before 8am and after 7pm, the staffing requirement shall not apply.
   - The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services (such as immunizations or CLIA-waived tests) this exception does not apply.

   When staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted, and included on the outgoing telephone message.
5. BPC 4115 – Pharmacy technician may, under the direct supervision and control of a pharmacy, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are CLIA waived, receive prescription transfers, and accept clarification on prescriptions under certain specified conditions.
6. BPC 4231 – CE required for pharmacists to renew their pharmacist license must now include at least one hour of participation in a cultural competency course which meets specified requirements.
7. The Board has posted on its website the FAQ's to address the changes in pharmacy law related AB1286, dated 12/21/2023. Here's the link: https://pharmacy.ca.gov/publications/ab1286_faqs.pdf

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

Compounding

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
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INSPECTION REPORT

November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated USP compounding standards.

The Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of federal law and USP General Chapters.

During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the Board's website.

Licensees are reminded to also ensure continuing compliance with other laws, regulations, and requirements that may apply to their activities, including, without limitation: the Federal Food, Drug, and Cosmetic Act (21 USC §§ 321–399i), including Section 503A thereof (21 USC § 353a); provisions of California's Sherman Food, Drug, and Cosmetic Law (Health and Safety Code §§ 109875–111929.4); and laws, regulations, and requirements related to radiopharmaceuticals and/or the handling of hazardous drugs, including requirements established by Cal/OSHA.

Educational Links and References:

1. Revisions to USP Compounding General Chapters <795> and <797> https://go.usp.org/2022_Revisions_795_797
   - BUD Scientific Rationale for the 2021 Proposed Revisions to <795>
   - BUD Reference for the 2021 Proposed Revisions to <795>
   - BUD Scientific Rationale for the 2021 Proposed Revisions to <797>
   - BUD Reference for the 2021 Proposed Revisions to <797>
2. 9/29/23, Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
   https://www.fda.gov/media/94155/download
3. FDA Drug Establishments Current Registration Site:
   https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
4. FDA to Compounders: Know Your Bulks and Excipients Suppliers https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers

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INSPECTION REPORT

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Mikhail Granin

Inspector (sign) _____

Inspector (print) G. Saldana

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 51906

NAME: MEDICO PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

11779 SANTA MONICA BLVD
LOS ANGELES CA 90025
LOS ANGELES COUNTY

ISSUANCE DATE

MAY 1, 2015

EXPIRATION DATE

MAY 1, 2026

CURRENT DATE / TIME

JULY 29, 2025
11:8:40 AM

LICENSE RELATIONSHIPS

NAME: GRANIN, MIKHAIL

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 77946 **PRIMARY STATUS:** CLEAR



CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

License No. PHY 51906
Receipt No. 50690324

Valid Until: 5/1/2026

MEDICO PHARMACY
11779 SANTA MONICA BLVD
LOS ANGELES, CA 90025

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change), administrator or pharmacist-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov.

--- NON-TRANSFERABLE --- POST IN PUBLIC VIEW ---

FORM WPHPHY (09/30/19) PHY

4PPP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FP4937679
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH03204		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Praxis Specialty Pharmacy, LLC

Physical Address: 5455 West Waters Avenue Suite 214

City: Tampa State: FL Zip: 33634

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888.903.7453 Toll Free # (NAC 639.708, NRS 639.23286): 888.903.7453

Fax: 888.958.2831 Contact Email: licensing@praxisrx.com

Website: www.praxisrx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Harold (Tom) Shilling

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22633

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Harold (Tom) Shilling	NV Pharmacist Registration #: 22633
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Brand Direct Health, LLC

Corporation/Organization Name: _____

Mailing Address: 550 Hills Drive

City: Bedminster State: NJ Zip: 07921

Telephone: 888.903.7453 Email: cj.rothacher@alfasigma.com

Contact Person Name: CJ Rothacher

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for Praxis Specialty Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Harold Thomas Shilling

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

July 10, 2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Harold Thomas Shilling hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for Praxis Specialty Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

Notary Public

Clear Form

Jurat Certificate

WELLS FARGO

State of Florida

County of **Seminole**

Sworn to (or affirmed) and subscribed before me this **10th** day of **July**, 20 **25**, by means of ☒ physical presence or ☐ online notarization **Harold Thomas Shilling** (name of person making statement).

☐ Personally known to me

☒ Produced Identification

Type of Identification Produced **FL Drivers License**

Notary Signature

Title **Notary**

My appointment expires **11/02/2028**

Place Seal Here

MARC ROMANO
Notary Public - State of Florida
Commission # HH 597741
My Comm. Expires Nov 2, 2028

Description of Attached document

Type or Title of Document

Nevada State Board of Pharmacy - Pharmacy Application - Affidavit for Pharmacy License

Document Date

07/10/2025

Number of Pages

10

Signer(s) Other Than Named Above

n/a

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DSG3018FL/595500 (Rev 04 - 09/24)

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Harold Thomas Shilling

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

July 10, 2025

Date

Board Use Only	Date Received: 7/28/25	Amount: $500 - CK0000253760

Praxis Rx Pharmacy Ownership

- **Old Owner:** CitizensRx Holdings, LLC
- **New Owner:** Brand Direct Health, LLC
    - Officer of Brand Direct Health, LLC: Monica Wahba, Secretary
- **Officers of Praxis Rx Pharmacy:** None

State of Florida
Department of State

I certify from the records of this office that PRAXIS SPECIALTY PHARMACY, LLC is a Delaware limited liability company authorized to transact business in the State of Florida, qualified on November 18, 2013.

The document number of this limited liability company is M13000007284.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on March 28, 2025, and that its status is active.

I further certify that said limited liability company has not filed a Certificate of Withdrawal.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-first day of July, 2025

Secretary of State

Tracking Number: 1145705970CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **PRAXIS SPECIALTY PHARMACY, LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 05/30/2014, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/21/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507215918971
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PRAXISRX PHARMACY

Pharmacy/Wholesaler License # (if applicable) PH03204

Physical Address 5455 W WATERS AVE SUITE 214

City TAMPA State FL Zip 33634

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First HAROLD Middle THOMAS Last SHILLING

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF FLORIDA		08/13-05/17	
Address	**City**	**State**	**Zip**
1225 CENTER DRIVE	GAINESVILLE	FL	32610
Diploma/Degree obtained, if any			
PHARM D			

School Name		From - To (MM/YY – MM/YY)	
MIAMI DADE COLLEGE		01/05-05/10	
Address	**City**	**State**	**Zip**
11011 SW 104TH ST	MIAMI	FL	33176
Diploma/Degree obtained, if any			
AA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/15-07/25	[redacted]			
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: PRAXISRX PHARMACY				From - To (MM/YY – MM/YY): 08/22-7/25
Business Address: 5455 W WATERS AVE SUITE 214		City: TAMPA	State: FL	Zip: 33634
Phone: 888-903-7453	Title: PHARMACY DIRECTOR			Number of Employed Hours: 5894
Description of Duties: OVERSEE THE DAILY OPERATIONS OF THE PHARMACY				

Business Name: PRAXISRX PHARMACY				From - To (MM/YY – MM/YY): 09/20-08/22
Business Address: 100 TECHNOLOGY PARK		City: LAKE MARY	State: FL	Zip: 32746
Phone: 866-842-2147	Title: PHARMACY MANAGER			Number of Employed Hours: 4160
Description of Duties: OVERSEE THE DAILY OPERATIONS OF THE PHARMACY				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, HAROLD SHILLING, **certify that as the designated representative for**

PRAXISRX PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

HAROLD SHILLING
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 10, 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HAROLD SHILLING

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 10, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

Clear Form

Jurat Certificate

WELLS FARGO

State of Florida

County of **Seminole**

Sworn to (or affirmed) and subscribed before me this **10th** day of **July**, 20 **25**, by means of ☒ physical presence or ☐ online notarization **Harold Thomas Shilling** (name of person making statement).

☐ Personally known to me

☒ Produced Identification

Type of Identification Produced **FL Drivers License**

Notary Signature

Title **Notary**

My appointment expires **11/02/2028**

Place Seal Here

MARC ROMANO
Notary Public - State of Florida
Commission # HH 597741
My Comm. Expires Nov 2, 2028

Description of Attached document

Type or Title of Document

Nevada State Board of Pharmacy - Designated Representative Application

Document Date

07/10/2025

Number of Pages

9

Signer(s) Other Than Named Above

n/a

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DSG3018FL/595500 (Rev 04 - 09/24)

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 20810
Insp # 185864

NAME	PERMIT NUMBER	DATE OF INSPECTION
PRAXIS SPECIALTY PHARMACY LLC	28049	04/07/2025
DOING BUSINESS AS PRAXIS RX PHARMACY		
STREET ADDRESS 5455 W. WATERS AVE SUITE 214	**TELEPHONE #** 888-903-7453	**EXT**
CITY TAMPA	**COUNTY** HILLSBOROUGH	**STATE/ZIP** FL/33634

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:00 AM - 6:00 PM
Monday N	Monday Hours
Tuesday N	Tuesday Hours
Wednesday N	Wednesday Hours
Thursday N	Thursday Hours
Friday N	Friday Hours
Saturday N	Saturday Hours CLOSED
Sunday N	Sunday Hours CLOSED

Registered Pharmacist / Intern / Tech

License # RPT 48561	Licensee Name Cherrell Funches
License Type Pharmacy Tech	
License # RPT 23101	Licensee Name Gloria Blakeman-Hoye
License Type Pharmacy Tech	
License # RPT 84094	Licensee Name Shelia Funches
License Type Pharmacy Tech	
License # RPT 10784	Licensee Name Regina Jones
License Type Pharmacy Tech	
License # PS 61887	Licensee Name Desiree Hamler
License Type Registered Pharmacists	

ACS Manager

ACSMGR Lisa Cannone	

Optional Information

Basic License Data - PSD

DEA Reg # Fp4937679	

License Relations

Pharmacy Affiliate

BURNS, JOHN WILLIAM	License #
COOPER, JEFFREY	License #
DELKUS, RANDALL B	License #
LICHTERMAN, JONATHAN D	License #
LONG, JOSEPH	License #
WASH, DARRYL	License #

RX DPT MGR/COR/POR

INV359 - Community Requirements

Insp # 185864 | PRAXIS SPECIALTY PHARMACY LLC | File # 20810

HAMLER, DESIREE ANNAMARIE	License # 61887

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.] *Inmar*	Yes
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	Yes
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.] *01/27/2025, 10/22/2024*	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.] *Maintained in ScriptPro*	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	N/A
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.] *McKesson*	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] *03/31/2025 Open of Business*	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	Yes
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A

Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

Routine inspection completed with Desiree Hamler. Operating requirements met.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

HODGES, PETER

Date:4/7/2025

Representative:

Desiree Hamler

Date:4/7/2025

Your license number is PH 28049.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
JANUARY 17, 2025	**PH 28049**	**149336**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy

EXPIRATION DATE: **FEBRUARY 28, 2027**

PRAXIS SPECIALTY PHARMACY LLC
PRAXIS RX PHARMACY
5455 W. WATERS AVE
SUITE 214
TAMPA, FL - 33634

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
JANUARY 17, 2025	**PH 28049**	**149336**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date: **FEBRUARY 28, 2027**

PRAXIS SPECIALTY PHARMACY LLC
PRAXIS RX PHARMACY

REGISTRANT SIGNATURE

Department of Health

PRAXIS SPECIALTY PHARMACY LLC

PRAXIS RX PHARMACY

License Number: PH28049

Data As Of 6/25/2025

Profession	Pharmacy
License	PH28049
License Status	Clear/
Qualifications	Community Pharmacy
License Expiration Date	2/28/2027
License Original Issue Date	04/16/2014
Address of Record	5455 W. WATERS AVE SUITE 214 TAMPA, FL 33634
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
BURNS, JOHN WILLIAM	PHARMACY AFFILIATE	PHARMACY AFFILIATE		04/08/2014
COOPER, JEFFREY	PHARMACY AFFILIATE	PHARMACY AFFILIATE		04/09/2014
DELKUS, RANDALL B	PHARMACY AFFILIATE	PHARMACY AFFILIATE		04/08/2014

Name	Relationship	Profession	License	Effective Date
HAMLER, DESIREE ANNAMARIE	RX DPT MGR/COR/POR	PHARMACIST	61887	06/01/2023
LICHTERMAN, JONATHAN D	PHARMACY AFFILIATE	PHARMACY AFFILIATE		04/08/2014
LONG, JOSEPH	PHARMACY AFFILIATE	PHARMACY AFFILIATE		01/20/2016
WASH, DARRYL	PHARMACY AFFILIATE	PHARMACY AFFILIATE		01/20/2016

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP4937679	03-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-08-2023

PRAXIS SPECIALTY PHARMACY LLC
PRAXIS RX PHARMACY
5455 W WATERS AVE STE 214
TAMPA, FL 336341208

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP4937679	03-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
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PRAXIS SPECIALTY PHARMACY LLC
PRAXIS RX PHARMACY
5455 W WATERS AVE STE 214
TAMPA, FL 336341208

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NABP

Select Business

Business e-Profile

e-Profile ID: 1523698

Praxis Specialty Pharmacy, LLC

Doing Business As
Praxis Rx Pharmacy

Formerly Known As

Open Date
Apr 16, 2014

Store Number

FEIN Number
352488187

NPI Number
1114343084

NCPDP Number
5720708

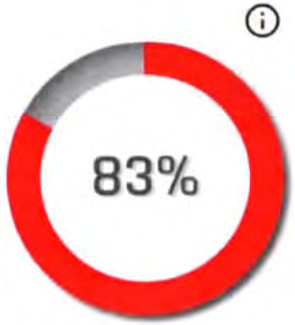
Website
www.praxisrx.com

Business Address
5455 West Waters Avenue, Suite 214 , Tampa, FL, US 33634

Business Email
licensing@praxisrx.com

Phone Number
(888) 903-7453

Fax Number
(888) 958-2831



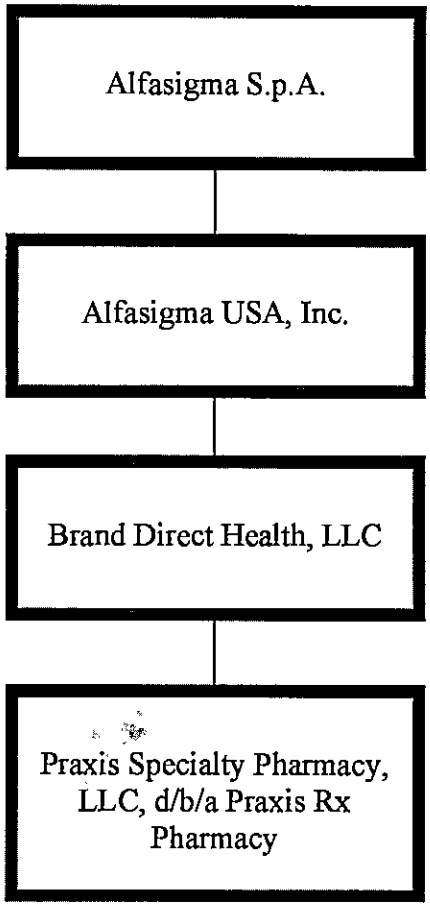
Attachment A

Pre-Close Organization Structure



Post-Close Organizational Structure

Note: All ownership percentages are 100% unless noted otherwise.



4QQQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Closed door mail order	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FV5072993 ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Vibrix Pharmacy

Physical Address: 384 S 400 W Suite 200

City: Lindon State: Utah Zip: 84042

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (801) 770-0042 Toll Free # (NAC 639.708, NRS 639.23286): (888) 709-8999

Fax: (888) 732-2005 Contact Email: licensing@vibrixpharmacy.com

Website: www.vibrixpharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Benjamin Blanchard

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): NV-21091
UT-6729797-1701

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Benjamin Blanchard	NV Pharmacist Registration #: 21091
Name: Gabrielle Pack	NV Pharmacist Registration #: 21121
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: ADVANCED CARE MANAGEMENT

Mailing Address: 160 W Canyon Crest Rd

City: Alpine State: Utah Zip: 84004

Telephone: (385) 213-4480 Email: utadmin@linqgs.com

Contact Person Name: Jeffery Bray

Please check type of partnership (NAC 639.214) ☐ General ☑ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☑ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Pharmacy Officer (title) for Vibrix Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Ben Blanchard

Print Name of Authorized Person

Original Signature of Authorized Person (copies or stamps not accepted)

7/15/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Ben Blanchard hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Pharmacy Officer (title) for Vibrix Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this July day of 15th, 2025

Jenna M. Rae
Notary Public

JENNA M RAE
Notary Public, State of Utah
Commission # 742598
My Commission Expires On
April 18, 2029

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ben Blanchard

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7/15/2025

Date

Board Use Only	Date Received: 7/17/25	Amount: $500 CK 1258924118

Vibrix Pharmacy

384 S 400 W, Suite 200, Lindon, UT 84042

www.vibrixpharmacy.com

Managers and Officers

Jeffery R. Bray – CEO/Manager

[redacted]

Benjamin Blanchard – Chief Pharmacy Officer/Pharmacist in Charge

[redacted]

Matthew Lovelady – Manager

[redacted]

Darron Hacker – Manger

[redacted]

May 08, 2025

CERTIFICATE OF EXISTENCE

Registration Number: 14536010-0160
Business Name: VIBRIX PHARMACY, LLC

May 08, 2025

CERTIFICATE OF EXISTENCE

Registration Number: 14536010-0160
Business Name: VIBRIX PHARMACY, LLC
Principal Office Address: 384 SOUTH 400 WEST, SUITE 100, LINDON, UT 84042
Registered Date: 01/23/2025
Entity Type: DOMESTIC LIMITED LIABILITY COMPANY
Current Status: ACTIVE - CURRENT

The Division of Corporations and Commercial Code of the State of Utah, custodian of the records of business registrations, certifies that the business entity on this certificate is authorized to transact business and was duly registered under the laws of the State of Utah. The Division also certifies that this entity has paid all fees and penalties owed to this state; its most recent annual report has been filed by the Division unless the status above is delinquent; and, that Articles of Dissolution have not been filed.

Adam Watson
Director
Division of Corporations and Commercial Code

Certificate Number: 202505081736688
Enter the certificate number at https://businessregistration.utah.gov/ to verify this certification.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Vibrix Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 384 S. 400 W. Ste. 200

City Lindon State Utah Zip 84042

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (801)770-0042 Website www.vibrixpharmacy.com

Licensing Company Email licensing@vibrixpharmacy.com

Section 2: Personal Information

First Benjamin Middle Lloyd Last Blanchard

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		8/2007 - 6/2010	
Address	**City**	**State**	**Zip**
10920 S. River Front Pkwy	South Jordan	UT	84095
Diploma/Degree obtained, if any	Doctor of Pharmacy		

School Name		From - To (MM/YY – MM/YY)	
Salt Lake Community College		8/04 - 6/07	
Address	**City**	**State**	**Zip**
4600 S. Redwood Rd	SLC	UT	84123
Diploma/Degree obtained, if any	Associate of Applied Science		

School Name		From - To (MM/YY – MM/YY)	
Taylorsville High School		8/94 - 6/97	
Address	**City**	**State**	**Zip**
5225 S. Redwood Rd	Taylorsville	UT	84123
Diploma/Degree obtained, if any	High School Diploma		

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
N/A			
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
N/A			
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/24 - Current	[redacted]			
12/23 - 1/24				
8/10 - 12/23				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Vibrix Pharmacy			01/25 - Current
Business Address	**City**	**State**	**Zip**
384 S. 400 W. Ste. 200	Lindon	UT	84042
Phone	**Title**	**Number of Employed Hours**	
(801) 770-0042	Chief Pharmacy Officer	1620	
Description of Duties			
Chief Pharmacy officer. Oversee all aspects of pharmacy including operations, compliance, and management.			

Business Name			From - To (MM/YY – MM/YY)
Byram Healthcare Centers Inc.			07/23 - 12/24
Business Address	**City**	**State**	**Zip**
3793 S. State Street	SLC	UT	84115
Phone	**Title**	**Number of Employed Hours**	
(877) 902-9726	Pharmacist in Charge	3120	
Description of Duties			
Pharmacist in Charge - Oversee all aspects of pharmacy operations and business development.			

Business Name			From - To (MM/YY – MM/YY)
MedQuest Pharmacy			3/20 - 7/23
Business Address	**City**	**State**	**Zip**
669 900 N	NSL	UT	84115
Phone	**Title**	**Number of Employed Hours**	
(888) 222-2956	Pharmacist in Charge	7160	
Description of Duties			
Pharmacist in Charge - Oversee all aspects of pharmacy operations			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Ben Blanchard, **certify that as the designated representative for**

Vibrix Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ben Blanchard

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/15/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ben Blanchard

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/15/25

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Utah

I, Ben Blanchard, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/15/25

Date

Subscribed and Sworn to before me this 15th day of July.

Notary Public Signature

JENNA M RAE
Notary Public, State of Utah
Commission # 742598
My Commission Expires On
April 18, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Vibnix Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) UT – 14203370-1704

Physical Address 3845 400 W Ste 200

City Lindon State Ut Zip 84042

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email licensing@vibnixpharmacy.com

Section 2: Personal Information

First Jeffery Middle Rex Last Bray

Aliases, nicknames, name changes, etc.) [redacted]

Telephone (801) 702-3414 Email Jeffbray@vibnixpharmacy.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name See Attached		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/21 - Present	[redacted]			
10/19 - 06/21				
10/19 - 04/21				
07/13 - 10/19				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Educational Background for Nevada State Board of Pharmacy

Jeffery Bray – Vibrix Pharmacy

1. **University of Oxford – Saïd Business School**
   Oxford Artificial Intelligence Programme Certificate
   Dates Attended: April 2025 – July 2025
   Address: Park End Street, Oxford OX1 1HP, United Kingdom
2. **Massachusetts Institute of Technology (MIT) – Sloan School of Management & CSAIL**
   Artificial Intelligence: Implications for Business Strategy Certificate
   Dates Attended: March 2025 – July 2025
   Address: 100 Main Street, Cambridge, MA 02142, USA
3. **Johns Hopkins University – Whiting School of Engineering**
   Applied Generative AI Certificate
   Dates Attended: March 2025 – June 2025
   Address: 3400 N Charles St, Baltimore, MD 21218, USA
4. **Ashland University**
   Strategic AI and Customer Experience in Healthcare Certificate
   Dates Attended: January 2025 – March 2025
   Address: 401 College Avenue, Ashland, OH 44805, USA
5. **Seton Hall University**
   Transformative Leadership in Disruptive Times Certificate
   Dates Attended: January 2025 – March 2025
   Address: 400 South Orange Avenue, South Orange, NJ 07079, USA
6. **University of Utah – David Eccles School of Business**
   Master of Business Administration (MBA), Executive MBA – International Business
   Dates Attended: August 2010 – May 2012
   Address: 1655 Campus Center Dr, Salt Lake City, UT 84112, USA
7. **University of Phoenix**
   Master of Arts in Education (MAED), Education
   Dates Attended: September 2002 – August 2003
   Address: 4035 S Riverpoint Pkwy, Phoenix, AZ 85040, USA
8. **University of Arizona**
   Bachelor of Arts (BA), History and French Literature
   Dates Attended: August 1999 – May 2001
   Address: 1200 E University Blvd, Tucson, AZ 85721, USA
9. **Brighton High School**
   High School Diploma
   Dates Attended: August 1991 – May 1994
   Address: 2220 E Bengal Blvd, Cottonwood Heights, UT 84121, USA

JRB

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Vibrix Pharmacy, INC			01/25 - Present
Business Address	**City**	**State**	**Zip**
384 S. 400 W. Suite 200	Lindon	UT	84042
Phone	**Title**		
801-702-3414	CEO		
Description of Duties			
Oversee all operational, compliance and strategic aspects of Vibrix Pharmacy			

Business Name			From - To (MM/YY – MM/YY)
See Attached			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Nevada State Board of Pharmacy Employment History

(Past 10 Years)

Jeffery Bray – Vibrix Pharmacy

1. Vibrix Pharmacy

Title: Co-Founder & Chief Executive Officer
Dates: January 2025 – Present
Address: 384 S 400 W Suite 200, Lindon, UT 84042
Phone: (801) 702-3414
Description:
Leads national mail-order pharmacy operations, compliance, technology integration, and strategic growth. Oversees licensure, fulfillment, prescriber engagement, AI tools, and pricing transparency. Manages executive team direction and innovation in patient support.

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2. MedQuest Pharmacy

Title: Chief Executive Officer
Dates: November 2011 – August 2022
Address: 669 W 900 N, North Salt Lake, UT 84054
Phone: [Not publicly available post-acquisition]
Description:
Directed large-scale compounding pharmacy operations including quality assurance, regulatory compliance, state/federal engagement, and provider services. Drove operational transformation and maintained industry leadership until acquisition in 2021.

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3. Medical Horizons

Title: Chief Executive Officer
Dates: November 2011 – August 2022 (concurrent with MedQuest)
Address: 669 W 900 N, North Salt Lake, UT 84054
Phone: [Not publicly available post-acquisition]
Description:
Led FDA-registered nutraceutical manufacturing facility. Oversaw GMP compliance, R&D, contract manufacturing, client relations, and quality systems. Scaled operations and supported personalized health initiatives until divestiture.

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4. Innovations Group, Inc. (IGI)

Title: Board Member & Chief Legislative Affairs Officer
Dates: October 2011 – August 2022
Address: [Umbrella holding company for MedQuest & affiliates]
Phone: [Not listed post-acquisition]
Description:
Governed enterprise-level strategy and legislative affairs across pharmacy services, software, diagnostics, and education verticals. Led regulatory alignment, policy advocacy, and risk mitigation during industry expansion.

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5. 10th Mountain Partners

Title: Chairman of the Board of Directors
Dates: April 2023 – Present
Address: 2083 Walker Lane, Salt Lake City, UT 84111
Phone: (801) 310-6557
Description:
Provides strategic leadership for a healthcare-focused private investment firm. Oversees capital deployment, portfolio growth, governance frameworks, and founder mentorship with focus on mission-driven value.

Board & Advisory Roles (Past 10 Years)

1. B-17 Partners

Title: Chairman of the Board of Directors
Dates: February 2018 – Present
Address: 2083 Walker Lane, Salt Lake City, UT 84111
Phone: (801) 310-6557
Description:
Leads governance and strategic oversight of a private investment and real estate holding firm. Guides asset growth, partnership development, and long-term value creation across commercial real estate and private equity ventures.

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2. Needs Beyond Medicine

Title: Chairman of the Board
Dates: September 2023 – Present

Address: PO Box 712043, Salt Lake City, UT 84171
Phone: (801) 450-4888
Description:
Chairs nonprofit supporting cancer patients with non-medical aid. Leads board governance, fundraising strategy, outreach, and equitable access initiatives.

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3. American Red Cross – Greater Salt Lake Area Chapter

Title: Board Member & Chair, Biomedical Services Committee
Dates: July 2024 – Present
Address: 6616 S 900 East, Salt Lake City, UT 84121
Phone: (801) 892-4000
Description:
Oversees regional blood services strategy, donor engagement, safety protocols, and regulatory alignment. Guides public health readiness and community education.

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4. The American Journal of Healthcare Strategy (AJHCS)

Title: Board Member – Chair of People and Culture
Dates: January 2024 – Present
Location: Washington, D.C. (remote)
Phone:
Description:
Provides leadership on organizational culture, board development, and executive governance for a national healthcare strategy journal.

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5. Gift of Adoption Fund – Utah Chapter

Title: Board Member – Investor Board
Dates: October 2023 – Present
Address: 1200 Shermer Rd, Suite 111, Northbrook, IL 60062
Phone: (877) 905-2367
Description:
Supports adoption funding nonprofit through donor strategy, fundraising, and board leadership to unite vulnerable children with families.

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6. Ashland University – Strategic AI & CX in Healthcare Program

Title: Advisory Board Member
Dates: March 2025 – Present
Address: 401 College Ave, Ashland, OH 44805
Phone: (419) 289-4142
Description:
Guides curriculum and strategy integrating AI into healthcare transformation and patient-centered design within academic program.

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7. Seton Hall University – Transformative Leadership in Disruptive Times Program

Title: Advisory Council Member
Dates: October 2024 – Present
Address: 400 S Orange Ave, South Orange, NJ 07079
Phone: (973) 761-9000
Description:
Advises on executive leadership and curriculum design for navigating disruption and leveraging innovation.

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9. Healthcare Shares

Title: Advisory Board Member
Dates: June 2025 – Present
Location: New York Metro Area
Phone:
Description:
Advises on investment strategy and operational alignment for healthcare innovation and equity through mission-driven finance.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffery Bray
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/15/2025
Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Utah

I, Jeffery B Bray, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/15/2025
Date

Subscribed and Sworn to before me this 15th day of July.

Notary Public Signature

JENNA M RAE
Notary Public, State of Utah
Commission # 742598
My Commission Expires On
April 18, 2029

(Seal)

UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

160 E 300 S
P.O. Box 16741
Salt Lake City, UT 84114-6741

Phone: (801) 530-6628
Toll Free: (866) 275-3675
Online: DOPL.utah.gov
Email: DOPLinvestigations@utah.gov

CLASS B
CLOSED DOOR

INSPECTION

☑ Opening ☐ Random

INFORMATION

Pharmacy Name: Vibrix Pharmacy, LLC Date: 4/2/25

License Number: 14203370-1704 Exp Date: 7/29/25

C.S. License Number: 14204470-8913 Exp Date: 7/29/25

DEA Registration: FV5072993 Exp Date: 5/31/27

Pharmacy FEIN # (Tax ID): 33-3029761

Pharmacy Email: bblanchard@vibrixpharmacy.com

Pharmacy Phone: 801-770-0042 Fax: 801-770-0016

Toll Free Number: 888-709-8999

Affiliated Websites: www.vibrixpharmacy.com

Pharmacy Hours: Monday-Friday: 8-5 Saturday: closed Sunday: closed

Pharmacy Address: 384 S 400 W Ste 200

City: Lindon State: UT Zip: 84042

Pharmacist In Charge (PIC): Benjamin Lloyd Blanchard

PIC License # 6729797-1701 Expiration Date: 9/30/25

Personnel

List ALL pharmacists, interns, pharmacy technicians and techs-in-training (attach a separate sheet, if necessary):

Name:	License # photo taken of list	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
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INSPECTION

	YES	NO	
1	✓		Class B pharmacy means a pharmacy located in Utah that is authorized to provide pharmaceutical care for patients in an institutional setting; and whose primary purpose is to provide a physical environment for patients to obtain health care services; and includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and pharmaceutical administration and sterile product preparation facilities. [UCA 58-17b-102 (11)(a)(i-ii)(b)(i-ii)]
2	✓		The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable. The list may be maintained in paper or electronic form. [UAC R156-17b-614a (5)(a)(i-iv)(b)]
3	✓		Notification has been provided to the Division in regards to the unique email address used in self audits or alerts for the pharmacy. The pharmacy will notify the Division of any change in the email address within seven days of the change. [UAC R156-17b-603(3)(t) (i-ii)]
4	✓		Notification has been provided to the Division in regards to the assignment of the PIC at the above stated pharmacy. The Division is notified of a change in PIC within 30 days of the change. [UAC R156-17b-603 (3) (s)]
5	✓		If the facility has a pharmacy technician training program, the program and curriculum of education and training, meets standards established by Division rule made in collaboration with the Board. [UAC R156-17b-303a (3)] N/A
6	✓		A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist, and in a ratio not to exceed one pharmacy technician trainee to one pharmacist or two pharmacy technician trainees to one pharmacist, if a licensed pharmacy technician or intern is working during the same shift [UAC R156-17b-601(4)(a)(i-ii)]
7	✓		Pharmacy technicians shall have general supervision by a pharmacist. [UCA 58-17b-102 (57)]
8	✓		The operating standards for a Pharmacist acting as a preceptor includes meeting the following criteria by providing direct, on-site supervision to no more than two pharmacy interns during a working shift. [UAC R156-17b-606(3)(a)]
9	✓		In accordance with Subsecton 58-17b-102(72)(b) all supportive personnel shall be under the supervision of a licensed pharmacist or DMP. The licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the serivces being performed except for the delivery of pre-filled prescriptions as provided in Subsection (1)(g) above. [UAC R156-17b-607 (3)]
10	✓		In accordance with Subsection 58-17b-102(72)(a), supportive personnel may assist in any tasks not related to drug preparation or processing including: stock ordering and restocking; cashiering; billing; filing; receiving a written prescription and delivering it to the pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP desigenee; housekeeping; and delivering a pre-filled prescription to a patient. [UAC R156-17b-607 (1)(a-g)]

11 ☑ ☐ The pharmacist-in-charge (PIC) is responsible for assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to pharmacy personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare. [UAC R156-17b-603 (3) (r)]

12 ☑ ☐ All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility does wear on their person a clearly visible and readable identification showing the individual's name and position. [UCA 58-17b-603 (1)]

13 ☑ ☐ When communicating by any means, written, verbal, or electronic, pharmacy personnel do identify themselves as to licensure classification. [UCA 58-17b-603 (2)]

14 ☑ ☐ The facility or parent company does maintain a record for not less than five years of the initials or identification codes that identify each dispensing pharmacist by name. The initials or identification codes shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used. [UAC R156-17b-614a (8)]

15 ☑ ☐ The facility does have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel: [UAC R156-17b-614a (4) (a-k)]

- ☑ UCA 58-1 (DOPL Licensing Act)
- ☑ UAC R156-1 (General Rules of DOPL)
- ☑ UCA 58-17b (Pharmacy Practice Act)
- ☑ UAC R156-17b (Pharmacy Practice Act Rules)
- ☑ UCA 58-37 (Controlled Substance Act)
- ☑ UAC R156-37 (Controlled Substance Act Rules)
- ☑ UCA 58-37f (Controlled Substance Database Act)
- ☑ UAC R156-37f (Controlled Substance Database Act Rule)
- ☑ Code of Federal Regulations Title 21 parts 1300 to end
- ☑ FDA Approved Drug Product (Orange Book)
- ☑ General Drug References

16 ☑ ☐ The facility is well lighted, ventilated, clean and sanitary. [UAC R156-17b-614a (1) (a)]

17 ☑ ☐ If transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, shall have a sink with hot and cold culinary water separate and apart from restroom facilities. All required equipment shall be clean and in good operating condition. [UAC R156-17b-614a (1) (b)(c)]

18 ☑ ☐ The facility is equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. [UAC R156-17b-614a (1)(d)(ii)(ii)]

19 ☑ ☐ The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility. [UAC R156-17b-614a (1) (e)]

20 ☑ ☐ All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label. [UAC R156-17b-605 (1)]

21 ☑ ☐ The facility is stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare. [UAC R156-17b-614a (1) (f)]

22 ☑ ☐ If dispensing controlled substances, the facility is equipped with a security system to permit detection of entry at all times when the facility is closed, and provide notice of unauthorized entry to an individual, and be equipped with a lock on any entrances to the facility where drugs are stored. [UAC R156-17b-614a (1)(g)(i-ii)(h)(i-ii)]

CLASS B CLOSED DOOR INSPECTION

23 ☑ ☐ If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy. [UAC R156-17b-614a (15)] ☐ N/A

24 ☑ ☐ Only a licensed Utah pharmacist or authorized pharmacy personnel does have access to the pharmacy when the pharmacy is closed. [UAC R156-17b-614a (7)]

25 ☑ ☐ A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist is physically present and immediately available in the facility. [UAC R156-17b-614a(6)]

26 ☑ ☐ The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (3)]

27 ☑ ☐ The temperature of the refrigerator and freezer is maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain the log entry for three years. [UAC R156-17b-614a (3)]

28 ☑ ☐ For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as: [UAC R156-17b-611 (2) (a-g)]

- ☑ Inappropriate drug utilization
- ☑ Drug-disease contraindications
- ☑ Incorrect drug dosage
- ☑ Drug-allergy interactions
- ☑ Therapeutic duplications
- ☑ Drug-drug interactions
- ☑ Incorrect duration of drug treatment
- ☑ Clinical abuse or misuse

29 ☐ ☑ Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the patient's drugs. [R156-17b-610 (7)]

30 ☑ ☐ Every pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed. If the patient's agent delivers the prescription in person to the pharmacist or pharmacy intern; or receives the drug in person at the time it is dispensed at the facility. [UCA 58-17b-613 (1)]

31 ☑ ☐ A pharmacist or pharmacy intern that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery shall provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses and provide each patient with a toll-free telephone number by which the patient can contact the pharmacist or pharmacy intern at the pharmacy for counseling. [UCA 58-17b-613(2)]

32 ☑ ☐ If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable: [UCA R156-17b-610(6)(a-c)

☑ the pharmacy shall provide the information specified in R156-17b-610(3) be delivered with the dispensed prescription in writing:
(a) the name and description of the prescription drug;
(b) the dosage form, dose, route of administration and duration of drug therapy;
(c) intended use of the drug, when known, and expected action;
(d) special directions and precautions for preparation, administration and use by the patient;
(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered,
including their avoidance, and the action required if they occur;
(f) techniques for self-monitoring drug therapy;
(g) proper storage;
(h) prescription refill information;
(i) action to be taken in the event of a missed dose;
(j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or
drug; and
(k) the date after which the prescription should not be taken or used, or the beyond use date.

☑ if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."

☑ written information provided in Subsection (b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information

33 ☑ ☐ Counseling shall be offered orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits oral communication [UAC R156-17b-610(1)]

34 ☑ ☐ A pharmacy facility shall orally offer to counsel but shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses counseling. [UAC R156-17b-610(2)]

35 ☑ ☐ The offer to counsel is documented and said documentation shall be available to the Division. These records must be maintained for a period of five years and be available for inspection within 7-10 business days. [UAC R156-17b-610 (4)]

36 ☑ ☐ A pharmacy may only deliver a prescription drug to a patient or a patient's agent in person at the pharmacy or via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is delivered to the patient or patient's agent or return to the pharmacy. [UCA 58-17b-602 (9)(a)(b)(i-ii)]

37 ☐ ☑ A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, or other responsible employee: [UAC R156-17b-608(1)(a-e)(2)(a-c)]

☑ Use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packing material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication.

☑ Use shipping containers that are sealed in a manner to detect evidence of opening or tampering.

☐ Develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drug.

☑ Provide for an electronic, telephonic, or written communication mechanism for a pharmacy to offer counseling to the patient as defined in section 58-17b-613; and provide documentation of such counseling.

☑ Provide information to the patient indicating what the patient should do if the integrity of the package or drug was compromised during shipment.

38 ☑ ☐ Each drug dispensed from the pharmacy does have a label securely affixed to the container indicating the required minimum information, including: [UCA 58-17b-602 (5) (a) (i-viii)]

- ☑ name, address, & phone number of pharmacy
- ☑ filling date or last dispensing date
- ☑ name of the prescriber
- ☑ trade, generic or chemical name
- *(Unless Otherwise Indicated by Prescriber)*
- ☑ serial number of prescription
- ☑ name of the patient or animal owner/species
- ☑ directions for use & cautionary statements
- ☑ amount dispensed & strength of dosage form
- ☑ beyond use date

39 ☑ ☐ Unless otherwise requested, child-resistant containers will be used for dispensing medications to patients. [UAC 58-1-502(6)& 16 CFR 1700.14]

40 ☑ ☐ Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.21]

41 ☑ ☐ The registered pharmacy does only processes electronically signed prescriptions for controlled substances under the following conditions: the pharmacy uses a pharmacy application that meets all the applicable requirements; the prescription is otherwise in conformity with the requirements of the Code of Federal Regulations; and Certification Authority (CA) has been obtained. The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form *(i.e. facsimile)* for transmission. [UAC R156-17b-613(1) & CFR, Title 21, Chapter 11, Section 1311]

42 ☑ ☐ Prescription files, including refill information, are maintained for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

43 ☑ ☐ Prescription records may be maintained electronically so long as the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains all of the information required by federal and state law; and an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders.
[UAC R156-37-602 (4) (a-b)]

44 ☑ ☐ All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years.
[UAC R156-37-602(3) (5)]

45 ☑ ☐ All records relating to Schedule III, IV, V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years.
[UAC R156-37-602(3) (6)]

46 ☑ ☐ Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems. [UAC R156-17b-605 (4)]

47 ☑ ☐ Requirements for taking the initial controlled substances inventory shall include the following: all pharmacies shall take an inventory on the opening day of business. Such inventory shall include all controlled substances including any out-of-date drugs and drugs in automated pharmacy systems. In the event a pharmacy commences business with no controlled substances on hand, the pharmacy shall record this fact as the initial inventory. An inventory reporting no Schedule I and II controlled substances shall be listed separately from an inventory reporting no Schedule III, IV, and V controlled substances. The initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection(4) of this section. [UAC R156-17b-605 (3)(a-c)]

☐ N/A

48 ☑ ☐ General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605(2)(a)(b)(c)(f)(g)(h)(k)(l)]

☑ the PIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;

☑ the inventory records shall be maintained for a period of five years and be readily available for inspection

☑ the inventory shall be filed separately from all records

☑ the inventory may be taken either as the opening of the business or the close of business on the inventory date;

☑ the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory.

☑ the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances;

☑ if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

49 ☑ ☐ All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances. [UAC R156-17b-605(6)]

50 ☑ ☐ The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(4)]

51 ☑ ☐ Any facility who experiences any theft, including diversion, or significant loss of controlled substances shall immediately file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau Division; and report the incident to the local law enforcement agency. [UAC R156-37-602 (2)]

52 ☑ ☐ Pharmacists or other responsible individuals do verify that the suppliers' invoices of controlled substances, listed on the invoices were actually received by clearly recording their initials and the actual date of receipt of the controlled substances. [UAC R156-17b-614a (11)]

53 ☑ ☐ The facility does maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (12)]

54 ☑ ☐ The facility does maintain a copy 3 of DEA order form (form 222) which has been properly dated, initialed, and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b-614a (9)(a-c)]

55	☑	☐	The Division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information: real-time submission of the information required to be submitted under this part of the controlled substance database; and 24-hour daily or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. [UCA 58-37f-203(1)(a)(i,ii)]
56	☑	☐	In accordance with 58-37f-203(6), the pharmacist-in-charge and the pharmacist identified in Subsections 58-37f-203(2) and (3) shall provide the following data fields to the Division: the state that issued identification, type of identification used, identification number used, and first and last name of the individual picking up dispensed drug. [UCA R156-37f-203 (4) (bb-ff)]
57	☐	☑	The pharmacy maintains emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMT's, ambulances)? If the answer is "yes", note name(s) of facilities or entities.
58	☐	☑	The pharmacy maintains automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home? If the answer is "yes", note type and location.
59	☐	☑	The pharmacy utilizes an Automated Pharmacy System? If the answer is "yes" to this question, a automation questionnaire must be completed. [UAC R156-17b-620]
60	☐	☑	Does the pharmacy purchase any compound products from other entities for dispensing to patients? [UAC 58-17b-102(18)(b)(i)]
61	☐	☑	The facility is engaged in compounding with hazardous drugs as defined by USP-NF Chapter 800. If you answer "yes" to this question, a compounding questionnaire must be completed.
62	☐	☑	The facility is engaged in simple, medium, or complex compounding activities as defined by USP 35 Chapter 795. If you answer "yes" to this question, a compounding questionnaire must be completed. [(UAC R156-17b-614a (2)]
63	☐	☑	The facility is engaged in low, medium, or high risk *sterile* compounding as defined by USP 35 Chapter 797. If you answer "yes" to this question, a compounding questionnaire must be completed. [UAC R156-17b-614a (2)]

COMMENTS

Assisted during the inspection by PIC Benjamin Blanchard and pharmacy technician Jenna Rae.

Pharmacy has a compliant list of licensed pharmacy employees. A photo was taken of the list.

Pharmacy has a compliant list of pharmacists and initials.

Pharmacy's ceiling has chicken wire.

37)* Pharmacy's SOPs do not address when medications do not arrive in a timely manner. Blanchard agreed to fix this.

Prescription labels are compliant.

Initial controlled substance inventory was compliant.

Pharmacy does not have any CIIs at this time.

Pharmacy will get an automated pharmacy system in the future.

Pharmacy is not engaged in any compounding.

Pharmacy is reporting to the CSDB on a daily basis.

Pharmacy is contracted with Third Party Administrators and serve their customers.

Counseling is provided with each prescription.

☑ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: Date: 4/2/25

Name of Responsible Party (Print): Benjamin Blanchard

Signature of Division Investigator: Date: 4/2/25

Name of Division Investigator (Print): Travis Drebing

Revised 8/2023

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

Vibrix Pharmacy, LLC

EFFECTIVE **01/29/2025**

EXPIRATION **09/30/2027**

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14203370-1704	Pharmacy - Class B
14203370-8913 License	Dispensing Controlled Substance

Closed Door

DBA:

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

VIBRIX PHARMACY, LLC
384 S 400 W STE 200
LINDON UT 84042

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

ACTIVE LICENSE

EFFECTIVE DATE: **01/29/2025**

EXPIRATION DATE: **09/30/2027**

ISSUED TO: **Vibrix Pharmacy, LLC**
384 S 400 W Ste 200
Lindon UT 84042

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14203370-1704 Pharmacy - Class B
14203370-8913 Dispensing Controlled Substance License
DBA:

Closed Door

Form #1

SPENCER J. COX
Governor
DEIDRE M. HENDERSON
Lieutenant Governor

State of Utah
Department of Commerce
Division of Professional Licensing

MARGARET W. BUSSE
Executive Director

MARK B. STEINAGEL
Division Director

VERIFICATION OF UTAH LICENSURE

Created On: 04/07/2025

This verification is considered a primary source from the State of Utah.

Name of Licensee (as it appears in our records): Vibrix Pharmacy, LLC

Classification of License Issued: Pharmacy - Class B

Specialties: Closed Door

License Number: 14203370-1704

Obtained By: Application

Current Status: Active

Original Date of Licensure: 01/29/2025

Expiration Date: 09/30/2027

Agency and Disciplinary Action: NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**

Docket and Citation Number(s):

E-Prescriber:

The information provided on this form is accurate and correct as of the verification creation date listed on the top of this form. Original issue dates listed, as 01/01/1910 and 01/01/1911 were unknown when the division implemented its first licensing database. This verification form does not show a complete history or interruptions in licensure. If you have any questions please contact the division.

www.dopl.utah.gov • Heber M. Wells Building • 160 East 300 South • PO Box 146741 • Salt Lake City • UT 84114-6741
phone: (801)530-6628 • toll-free in Utah:(866)275-3675 • fax:(801)530-6511 • investigations fax:(801)530-6301

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FV5072993	05-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-31-2025

VIBRIX PHARMACY LLC
384 S 400 W STE 200
LINDON, UT 840421959

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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FV5072993	05-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-31-2025

VIBRIX PHARMACY LLC
384 S 400 W STE 200
LINDON, UT 840421959

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Form DEA-223 (9/2016)

4RRR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FW5424990
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	■ Other: Veterinary Compounding	■ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			■ Other: Veterinary

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Wedgewood Pharmacy LLC

Physical Address: 1680 E. Northrop Blvd., Unit #5

City: Chandler State: AZ Zip: 85286

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-331-8272 Toll Free # (NAC 639.708, NRS 639.23286): 800-331-8272

Fax: 856-491-4365 Contact Email: az-compliance@wedgewoodpharmacy.com

Website: www.wedgewood.com

Nevada Business License # (if applicable) NV20222567471

Supervising/Managing Pharmacist Name (NRS 639.220): Andrew Warther

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Samantha Toliusis	NV Pharmacist Registration #: 22913
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Wedgewood Holdings Inc.

Corporation/Organization Name: Wedgewood Pharmacy LLC

Mailing Address: 405 Heron Drive, Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 800-331-8272 Email: licensing@wedgewoodpharmacy.com

Contact Person Name: Maria Kraus

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Financial Officer (title) for Wedgewood Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Maria Kraus

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/9/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Maria Kraus hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Financial Officer (title) for Wedgewood Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 9 day of July, 20 25

Samantha Botnick
Notary Public

SAMANTHA L BOTNICK
My Commission Expires 06-25-2030
NOTARY PUBLIC
Comm. # 50130085
STATE OF NEW JERSEY

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maria Kraus

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7/9/2025

Date

Board Use Only	Date Received: 7/10/25	Amount: $500 - CK 56263

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?

Please note that the answer to this question is 'no' in regard to this licensee located in Chandler, AZ; however, since the question appears to ask for information related to the owner, Wedgewood wishes to disclose the following:

03/19/2015 – MN/MI/AL Consent Orders – Swedesboro location only

Wedgewood Village Pharmacy, LLC ("*Wedgewood*") entered into a Consent Order with the Alabama Board of Pharmacy to resolve a "sister state" matter based on a 2015 Minnesota discipline and a subsequent "sister state" discipline from Michigan. Wedgewood entered into a stipulation and consent order with the Minnesota Board of Pharmacy for purposes of settlement only in 2015. Acting on a reasonable and good faith interpretation of Minnesota law, Wedgewood had dispensed compounds into Minnesota to a licensed veterinarian pursuant to a veterinarian's order for office use. The Minnesota Board of Pharmacy, however, asserted that Wedgewood needed a wholesaler license to dispense into Minnesota in this manner. For purposes of settlement only and admitting no wrongdoing, Wedgewood entered into a stipulation and consent order with Minnesota. Wedgewood subsequently entered into a consent order with Michigan to resolve a "sister state" matter based on the 2015 Minnesota discipline.

10/22/2015 – New Jersey Consent Agreement – Swedesboro location only

On October 22, 2015, Wedgewood Village Pharmacy, Inc., entered into a Consent Agreement with the New Jersey Board of Pharmacy resolving a dispute between the parties on the application of "beyond use dating" regulations for sterile compounds.

This is the same order that is referenced on the Swedesboro, NJ facility's home license however, per the terms of the Agreement, it is not to be construed as discipline and any reimbursement paid to the Board is not considered a fine or other sanction.

10/13/2017 – California Citation & Fine – Swedesboro location only

Issued as a result of an investigation by the CA BOP into an unlicensed individual who fraudulently set up an account with Wedgewood as a veterinarian using valid prescriber license information he acquired unlawfully. An administrative citation was issued and Wedgewood paid a nominal fine.

12/5/2018 – California Citation – Swedesboro location only

The California Board of Pharmacy issued a non-disciplinary, Administrative Citation with no penalty or fine based on a California Board inspector's interpretation of California regulations. In the Inspector's opinion, providing a 15ml ophthalmic container to a veterinarian for office use exceeded the "reasonable quantity" limitation for office use compounds. Wedgewood discontinued sales of all 15ml ophthalmic container for office use to California veterinarians. The Board issued a No penalty or Close Out letter on March 1, 2019. No penalty or fine was assessed.

6/17/2021 – California Citation & Fine – Swedesboro location only

Received notification of a non-disciplinary, Administrative Citation which was finalized on 07/29/2021. A fine was paid as part of the final citation. The basis for the citation was that Wedgewood did not have the necessary data to support the "beyond use dates" Wedgewood used.

10/18/2023 – DEA Letter of Admonition – Scottsdale location only

The Letter of Admonition contains some observations that Wedgewood considers minor and for which Wedgewood has put a corrective plan in place to address.

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval – Swedesboro location only

On February 21, 2024, the California Board of Pharmacy (the "Board") approved a Stipulated Settlement and Disciplinary Order for Public Reproval entered into with Wedgewood Village Pharmacy LLC relating to claims made by the Board regarding assignment of unsupported beyond use dates and other matters. The Order became effective on March 22, 2024 and Wedgewood agreed to pay the Board $11,054.75 as reimbursement of its costs in connection with this matter.

03/05/2025 Commonwealth of Pennsylvania – Swedesboro location only

On March 5, 2025, Wedgewood entered into a Consent Order with the Commonwealth of Pennsylvania to resolve a "sister state" action that arose out of self-reporting the California Board of Pharmacy Stipulated Settlement relating to assignment of unsupported beyond use dates and other matters.

This Consent Order did not include any findings or fact or penalties and merely represents the closure of the Board's review of the previously disclosed Stipulated Settlement with the California Board of Pharmacy.

Officer Information for Wedgewood Pharmacy LLC

FEIN 81-1186519

Wedgewood Pharmacy LLC will have the following three officers, none of whom are licensed pharmacists:

1. Stanley Howell

President and Chief Operating Officer
Business Address: 405 Heron Drive, Suite 200, Swedesboro, NJ 08085
[redacted]

2. Alejandro Bernal-Angel

CEO and Secretary
Business Address: 405 Heron Drive, Suite 200, Swedesboro, NJ 08085
[redacted]

3. Maria Kraus

CFO
Business Address: 405 Heron Drive, Suite 200, Swedesboro, NJ 08085
[redacted]

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "WEDGEWOOD PHARMACY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTEENTH DAY OF APRIL, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203446604

Date: 04-15-25

5944344 8300

SR# 20251581461

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Wedgewood Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1680 E. Northrop Blvd., Unit #5

City Chandler State AZ Zip 85286

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-331-8272 Website www.wedgewood.com

Licensing Company Email az-compliance@wedgewoodpharmacy.com

Section 2: Personal Information

First Samantha Middle Rose Last Toliusis

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University - Chicago College of Pharmacy		09/13-05/17	
Address	**City**	**State**	**Zip**
555 31st St	Downers Grove	IL	60515
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Central Arizona College			
Address	**City**	**State**	**Zip**
8470 N Overfield Rd	Coolidge	AZ	85128
Diploma/Degree obtained, if any			
Associate of Science			

School Name		From - To (MM/YY – MM/YY)	
Florence High School			
Address	**City**	**State**	**Zip**
1000 S Main St	Florence	AZ	85132
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/22 - present	[redacted]			
09/19 - 04/22				
05/19 - 10/19				
05/18 - 05/19				
06/17 - 05/18				
10/16 - 06/17				
05/16 - 10/16				
08/13 - 05/16				
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Wedgewood Pharmacy LLC			From - To (MM/YY – MM/YY): 10/17 - Present
Business Address: 7631 E Indian School Rd, Suite 105	City: Scottsdale	State: AZ	Zip: 85251
Phone: 800-331-8272	Title: Pharmacist Supervisor		Number of Employed Hours: 11,000+
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Samantha Toliusis, **certify that as the designated representative for**

Wedgewood Pharmacy LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Samantha Toliusis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/23/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samantha Toliusis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/23/25

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Samantha Toliusis, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/23/25

Date

Subscribed and Sworn to before me this 23rd day of May, 2025

Notary Public Signature

SARAH M HODGMAN
Notary Public - Arizona
Maricopa County
Commission # 672515
My Comm. Expires Jul 10, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Wedgewood Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1680 E. Northrop Blvd., Unit #5

City Chandler State AZ Zip 85286

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-331-8272 Website www.wedgewood.com

Licensing Company Email licensing@wedgewoodpharmacy.com

Section 2: Personal Information

First Alejandro Middle _____ Last Bernal-Angel

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Colegio Calasanz de Pereira			01/78 - 12/89)	
Address		**City**	**State**	**Zip**
Carrera 19 #46-50, EL JARDIN		Pereira	Risarand	00000
Diploma/Degree obtained, if any				
Bachiller				

School Name			From - To (MM/YY – MM/YY)	
Universidad de los Andes			2000	
Address		**City**	**State**	**Zip**
Bogota Colombia				
Diploma/Degree obtained, if any				
Master of Business Administration (MBA)				

School Name			From - To (MM/YY – MM/YY)	
Texas A&M University			1996	
Address		**City**	**State**	**Zip**
		College Station	TX	
Diploma/Degree obtained, if any				
Master of Science				

School Name			From - To (MM/YY – MM/YY)	
Universidad de Caldas			1994	
Address		**City**	**State**	**Zip**
Manizales, Colombia				
Diploma/Degree obtained, if any				
Doctor in Veterinary Medicine				

School Name			From - To (MM/YY – MM/YY)	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/24 - Present	[redacted]			
06/15-07/24				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Wedgewood Pharmacy LLC			07/2024? - Present	
Business Address		**City**	**State**	**Zip**
405 Heron Drive, Suite 200		Swedesboro	NJ	08085
Phone	**Title**			
800-331-8272	CEO & Secretary			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
PetDX			01/2023 - 04/2024	
Business Address		**City**	**State**	**Zip**
The Center for Novel Therapeutics, 9310 Athena Cir Suite 230		La Jolla	CA	92037
Phone	**Title**			
Closed	President & CEO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Mars Inc/Mars Petcare			03/2018 - 12/2022	
Business Address		**City**	**State**	**Zip**
Kleine Kloosterstraat 6, 1932 Zaventem, Belgium				
Phone	**Title**			
	President Mars Veterinary Health International and Global Diagnostics			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Zoetis Inc			2012 - 2018	
Business Address		**City**	**State**	**Zip**
10 Sylvan Way		Parsippany	NJ	07054
Phone	**Title**			
+1 973.822.7000	Executive Vice President and Group President Strategy, Commercial and Bus. Dev.			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alejandro Bernal-Angel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/11/25

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Gloucester

I, Alejandro Bernal, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/11/25

Date

Subscribed and Sworn to before me this 11 day of June, 2025

Samantha Botnick

Notary Public Signature

SAMANTHA L BOTNICK
My Commission Expires 06-25-2030
NOTARY PUBLIC
Comm. # 50130085
STATE OF NEW JERSEY

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Wedgewood Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1680 E. Northrop Blvd., Unit #5

City Chandler State AZ Zip 85286

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-331-8272 Website www.wedgewood.com

Licensing Company Email az-compliance@wedgewoodpharmacy.com

Section 2: Personal Information

First Stanley Middle Todd Last Howell

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Eastern University			From - To (MM/YY – MM/YY): 2004
Address: 1300 Eagle Rd	City: St Davids	State: PA	Zip: 19087
Diploma/Degree obtained, if any: MBA			
School Name: Millersville University			From - To (MM/YY – MM/YY): 2000
Address: 40 Dilworth Rd	City: Millersville	State: PA	Zip: 17551
Diploma/Degree obtained, if any: Bachelors in Psychology			
School Name: Manheim Township High School			From - To (MM/YY – MM/YY): 1984-1987
Address: 115 Blue Streak Blvd	City: Lancaster	State: PA	Zip: 17601
Diploma/Degree obtained, if any: High School Diploma			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): Present	[redacted]			
From - To (MM/YY – MM/YY): 2019-2025				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Wedgewood Pharmacy LLC				From - To (MM/YY – MM/YY): 01/2025 - Present
Business Address: 405 Heron Drive, Suite 200		City: Swedesboro	State: NJ	Zip: 08085
Phone: 800-331-8272	Title: President & COO			
Description of Duties: Responsible for operations.				

Business Name: Bristol Myers Squibb				From - To (MM/YY – MM/YY):
Business Address:		City: Morristown	State: NJ	Zip:
Phone:	Title: VP of Strategy			
Description of Duties:				

Business Name: Novartis				From - To (MM/YY – MM/YY):
Business Address:		City: Morris Plains	State: NJ	Zip:
Phone:	Title: VP of Operations			
Description of Duties:				

Business Name: Merck				From - To (MM/YY – MM/YY):
Business Address:		City: Lansdale	State: PA	Zip:
Phone:	Title: Executive Director of Operations			
Description of Duties:				

Business Name: Johnson & Johnson				From - To (MM/YY – MM/YY):
Business Address:		City: Lancaster	State: PA	Zip:
Phone:	Title: Lean Six Sigma Manager			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Stanley Howell

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/9/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Gloucester

I, Stanley Howell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/9/2025

Date

Subscribed and Sworn to before me this 9 day of July, 2025

Samantha Botnick

Notary Public Signature

Samantha L Botnick
My Commission Expires 06-25-2030
NOTARY PUBLIC
Comm. # 50130085
STATE OF NEW JERSEY

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Wedgewood Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1680 E. Northrop Blvd., Unit #5

City: Chandler State: AZ Zip: 85286

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-331-8272 Website: www.wedgewood.com

Licensing Company Email: az-compliance@wedgewoodpharmacy.com

Section 2: Personal Information

First: Huong Middle: T. Last: Kraus

Alias(es, nicknames, name changes, etc.): Maria

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pennsylvania State University		1993	
Address	City	State	Zip
	University Park	PA	
Diploma/Degree obtained, if any			
B.S. in Accounting			

School Name		From - To (MM/YY – MM/YY)	
Milton Hershey School		1989	
Address	City	State	Zip
	Hershey	PA	
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2006 - Present	[redacted]			
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Wedgewood Pharmacy LLC			07/2021 - Present
Business Address	**City**	**State**	**Zip**
405 Heron Drive, Suite 200	Swedesboro	NJ	08085
Phone	**Title**		
800-331-8272	CFO		

Description of Duties

Responsible for WWP's Finance function including working with the board of directors, private equity owners, the CEO, and other leaders to strategically drive and support growth organically and through key acquisitions.

Business Name			From - To (MM/YY – MM/YY)
ACCELERATED ENROLLMENT SOLUTIONS			2019 - 2021
Business Address	**City**	**State**	**Zip**
	Horsham	PA	
Phone	**Title**		
480-820-5656	CFO		

Description of Duties

Responsible for driving AES' financial vision, leading all financial operations, planning and analysis, accounting, commercial budgets and internal controls.

Business Name			From - To (MM/YY – MM/YY)
BIOCLINICA			2015 - 2019
Business Address	**City**	**State**	**Zip**
	Princeton	NJ	
Phone	**Title**		
609-275-5047	Executive Vice President, Corporate Development & Strategy		

Description of Duties

Responsible for Bioclinica's growth through mergers & acquisitions, key business partnerships and other strategic initiatives.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Huong Kraus

Print Name (First, Last)

H. Nu Kraus

Original Signature (electronic, copies or stamps not accepted)

7/9/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Gloucester

I, Huong Kraus, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

H. Nu Kraus

Original Signature

7/9/2025

Date

Subscribed and Sworn to before me this 9 day of July, 2025

Samantha Botnick

Notary Public Signature

SAMANTHA L BOTNICK
NOTARY PUBLIC
My Commission Expires 08-25-2030
Comm. # 50130085
STATE OF NEW JERSEY

(Seal)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# : Y010087

AZ Permit Exp.Date : 10/31/2026

Business Name : Wedgewood Pharmacy LLC

Address : 1680 E. Northrop Boulevard

Zip : 85286

City : Chandler

State : AZ

Phone : (800) 331-8272

Fax : (866) 646-2235

Email : az-compliance@wedgewoodpharmacy.com

Inspection Date : 05/02/2025

PIC : Andrew Warther

Pic License Exp Date: 10/31/2025

DEA # : Pending

Inspection Reviewed With : PIC

Reviewers License# : S020613

Inspection type : Opening

Inspection Conducted By : Steve Haiber

ACTIVITIES

1	Nonsterile Compounding	☑ YES	☐ NO
2	Nonsterile Hazardous Compounding	☐ YES	☑ NO
3	Sterile Compounding	☐ YES	☑ NO
4	Sterile Hazardous Compounding	☐ YES	☑ NO

Hospital Facility Data

Licensed Beds

DHS License #

PHARMACY DEPARTMENT

1	Size/Personnel	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675
	397 sq ft total permitted area / maximum personnel 4 limited to 2 at this time due to limited work counter area. | Per PIC the inspected area today is only the first phase of a remodel project which will continue with additional areas within the 90,000 sq ft facility becoming permitted.		
2	Shelves	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Design-efficient, safe pharmacy practice	☑ S ☐ C/P ☐ U ☐ N/A	R4-22-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)
4	Counter	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(B); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
	Limited work counter area restricts current total personnel within the pharmacy to no more than (2).		
5	Aisles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(C); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
6	Consultation area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(D)
7	Enclosed (barrier)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675
8	Entry doors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F), R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C), R4-23-674(A)(3); R4-23-675(A)
	(2) doors / keyed hardlocks on both / pharmacist only key		
9	Lighting	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

10	Temperature controlled/Ventilation HVAC all area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Working counter barrier No face to face Rx fill work performed	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(H)
12	Receiving/checking area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
13	Opening for Rx receipt when closed None	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-610(F)
14	Walls	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
15	Ceilings Hardboard - all areas	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
16	Windows Fixed	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
17	Floors Tile	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

18	Restroom	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	Sink (hot and cold running water) Initial pharmacy will utilize a portable sink / compliant for current pharmacy footprint needs	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
20	Nonsterile compounding area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-410(E)

SECURITY

1	Controlled substances Pharmacy does not hold a DEA registration at this time / application will be submitted to DEA *** REMINDER TO PIC TO NOTIFY THE COM PLIANCE OFFICER ONCE DEA NUMBER ASSIGNED ***	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Pharmacist access Pharmacy access only	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Additional pharmacy drug storage areas None	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Filled Rx medication storage	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)
5	Remote drug storage (hospitals) None	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-654(D); R4-23-672(C)

PHARMACY LIBRARY

1	Pharmacology or Toxicology reference On line suite	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Therapeutics reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Drug compatibility reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Drug product equivalency reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Sterile products reference	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)
6	Policy and procedure manual-pharmacy operations	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)
7	Policy and procedure manual-technicians	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D)
8	Policy and procedure manual-automation	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614; R4-23-615; R4-23-616; R4-23-654(D); R4-23-701.02; R4-23-701.04
9	Policy and procedure manual-compounding	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-410; R4-23-670
10	Arizona statutes/rules On line access	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

11	Current antidote/drug interaction information On line access	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
12	Poison Control # displayed Provided by CO to PIC for posting	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

PHARMACY EQUIPMENT/FORMS

1	Refrigerator	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Freezer Not required at this time	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Computer-security/data storage IOE system	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408
4	Computer-patient profiles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(3)
5	Computer-single drug usage report	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(4)
6	Computer-pharmacist log book/hard copy print out	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(C)(4)
7	Prescription label	☑ S ☐ C/P ☐ U ☐ N/A	ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C)

8	Federal transfer labels	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
9	Warning labels	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
10	Written patient information	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-402(C)(4); R4-23-402(I)
11	Consultation log	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-402(G)
12	Federal medication guides	☐ S ☐ C/P ☐ U ☑ N/A	21 CFR part 208
13	Hospital IV label	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-658
14	Generic Rx blanks Electronic direct entry by pharmacist	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-402(A); R4-23-407(D)
15	Immunization administration recordkeeping Not provided	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-411(F)
16	Schedule V register No OTC sales of exempt narcotics	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(2)

17	Methamphetamine precursor sales log No OTC sales of PSE drug	☐ S ☐ C/P ☐ U ☑ N/A	ARS 32-1977
18	Red C stamp 3 file	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	CSPMP reporting Non DEA registrant at this time ** REMINDER TO PIC TO ENSURE REPORTING TO AZ PMP ONCE DEA RECEIVED **	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-502
20	Graduates	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
21	Mortar & Pestle	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
22	Steel spatulas	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
23	Rubber (nonmetallic) spatula	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance Satorius electronic sale	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
25	Weights for Rx balance	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

26	Ointment tile	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
27	Automated storage and distribution system (patient access)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(3); R4-23-654(D)
29	Mechanical storage and counting device	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-615
30	Mechanical counting device	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-616
31	Emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02
32	Automated emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02(E)
33	Automated dispensing system (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.04

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size Pharmacy dose not perform sterile compounding activity	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)
2	Dedicated to compounding sterile products	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(1); R4-23-656(5)

3	Isolated from other pharmacy functions	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(2)
4	Restricts entry/access	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(3)
5	Free from unnecessary disturbances airflow	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(4)
6	Nonporous and cleanable floor	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
7	Nonporous and cleanable walls	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
9	Environment ISO 7	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(6)
10	Hood ISO 5	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-110; R4-23-670(E)(F)

NOTES

New permit / opening inspection - Wedgewood Pharmacy, LLC 1680 E. Northrop Blvd. Unit 5 , Chandler 85286

Overall inspection - satisfactory

Permit Y010087 opened and issued to PIC on 05/02/2025.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 03/07/2025
Receipt Number: 2025195920
Receipt Amount $: 480.00

Pharmacy - Independent

PERMIT NO
Y010087

EXPIRES
10/31/2026

Issued to : Wedgewood Pharmacy LLC
Wedgewood Pharmacy LLC
1680 E. NORTHROP BOULEVARD UNIT 5 CHANDLER, AZ 85286

Wedgewood Pharmacy LLC
1680 E. NORTHROP BOULEVARD UNIT 5
CHANDLER, AZ 85286

Xan Gaddis
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Wedgewood Pharmacy LLC
LICENSE NUMBER : Y010087
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

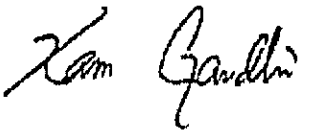
Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Wedgewood Pharmacy LLC
Address :	1680 E. Northrop Boulevard Unit 5 Chandler AZ 85286
Registration No :	Y010087
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	05/02/2025
Expiration Date :	10/31/2026
Status :	OPEN
Discipline :	No



Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 07/09/2025

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW5424990	05-31-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-12-2025

WEDGEWOOD PHARMACY LLC
1680 E NORTHROP BLVD
UNIT 5
CHANDLER, AZ 85286

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW5424990	05-31-2028	$888

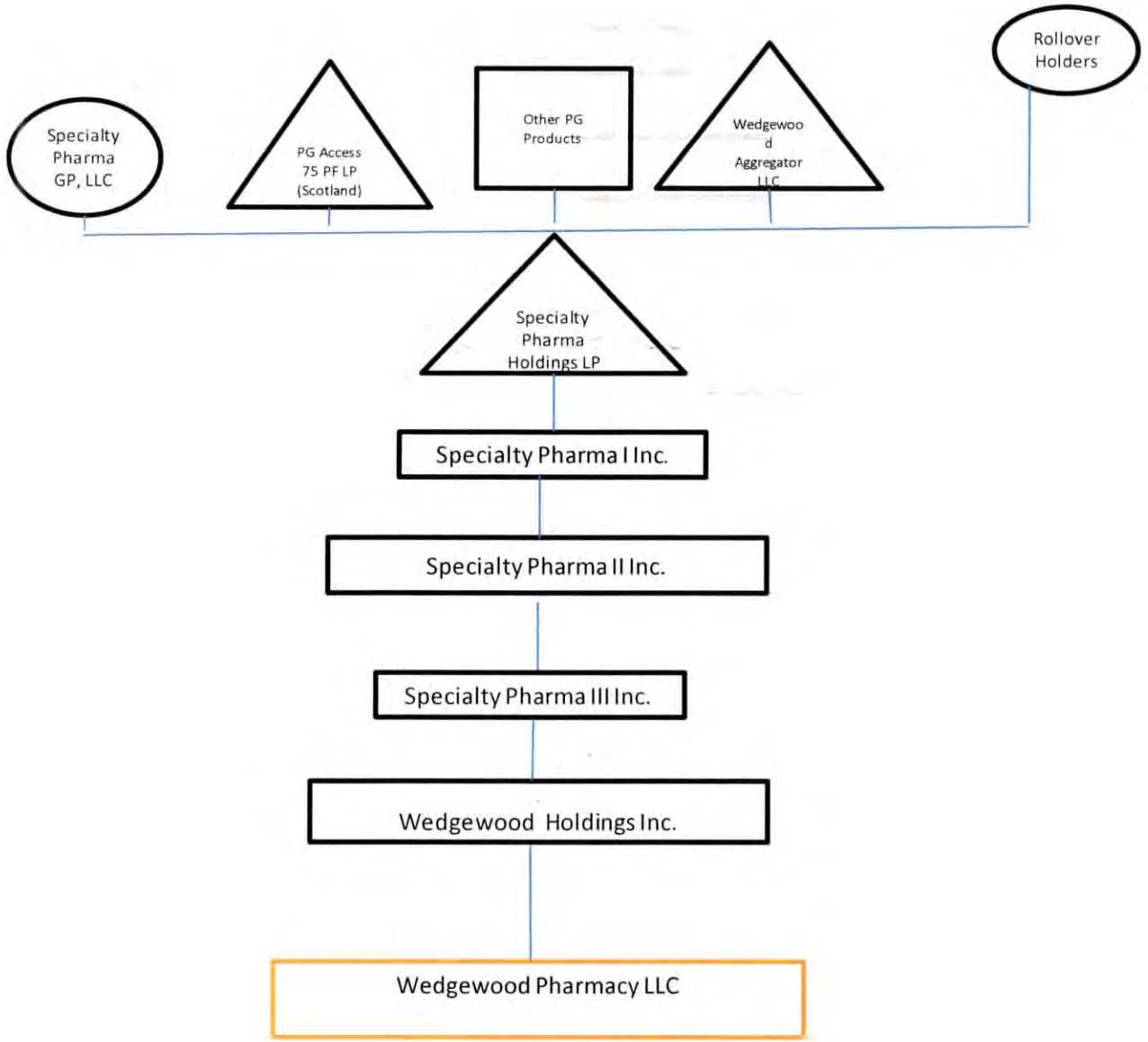
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-12-2025

WEDGEWOOD PHARMACY LLC
1680 E NORTHROP BLVD
UNIT 5
CHANDLER, AZ 85286

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)


Rollover Holders
Specialty Pharma GP, LLC
PG Access 75 PF LP (Scotland)
Other PG Products
Wedgewood Aggregator LLC
Specialty Pharma Holdings LP
Specialty Pharma I Inc.
Specialty Pharma II Inc.
Specialty Pharma III Inc.
Wedgewood Holdings Inc.
Wedgewood Pharmacy LLC

4SSS

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ■ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
■ Ownership Change*	ASC03943	■ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *		☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Medical and Dental Center of Nevada LLC

Physical Address: 4275 Burnham Ave, Ste 101

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): 9709 Lakeside Blvd, Ste. 350

City: Spring State: TX Zip: 77381

Telephone: (702) 470-2948 Fax: 725-257-7684

Contact Email: credentialing@bluecloudpsc.com Website bluecloudpsc.com

Nevada Business License # NV20181268665

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Edd Evans

Days of Operation

■ Monday	■ Tuesday	■ Wednesday	■ Thursday	■ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Blue Cloud Pediatric Surgery Centers, LLC (see attached for further ownership information)

Corporation/Organization Name: Medical and Dental Center of Nevada, LLC

Mailing Address: 9709 Lakeside Blve, Ste 350

City: Spring State: TX Zip: 77381

Telephone: (702) 470-2948 Email: credentialing@bluecloudpsc.com

Contact Person Name: Michelle Schweizer

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Medical & Dental Center of Nevada LLC :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle McCarty
Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

7-14-25
Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		

• **For General Partnerships, list the name of each partner. NAC 639.214(2)**
• **For Limited Partnerships, list the names of (NAC 639.214(3)):**
  ○ **All General Partners;**
  ○ **All Limited Partners who hold 10% or more of the interest.**
			✓	

• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Devin Larsen

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Devin L. Larsen

Original signature of Authorized Person (copies or stamps not accepted)

7/16/25

Date

Board Use Only	Date Received: 7/23/25	Amount: $500 cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **MEDICAL AND DENTAL CENTER OF NEVADA LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 04/16/2018, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/21/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507215920923
You may verify this certificate online at https://www.nvsilverflume.gov/home

Effective Date : 01/01/2025
Expiration Date : 12/31/2025

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
9405-ASC-6

Please display this license conspicuously

This license was printed from an online licensing system. VERIFY LICENSE IS VALID BY GOING TO: https://nvdpbh.aithent.com/login.aspx. Go to License Verification, Facility Locator & Inspection Reports "Click Here" and look up by license number (Credential Number) to verify that the license is active and valid.

Should you have any changes such as Name, Administrator, Location, Change of Ownership or Number of Beds go to: https://nvdpbh.aithent.com/login.aspx.

This Is To Certify That

MEDICAL AND DENTAL CENTER OF NEVADA, LLC

4275 BURNHAM AVE. #101
LAS VEGAS, NV 89119

Is hereby licensed as a(n)

SURGICAL CENTER FOR AMBULATORY PATIENTS

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following:

Facility Type : SURGICAL CENTER FOR AMBULATORY PATIENTS

Endorsement : CLASS - C, CLASS - A, CLASS - B

Bed Information : Operating Room - A - 4,Operating Room - B - 4,Operating Room - C - 3

If your license is not completely accurate, Please contact us at (775) 684-1030 so that we may resolve any problems.

LISA GENIO / Administrator

MEDICAL AND DENTAL CENTER OF NEVADA, LLC,DEVIN LARSEN,YEVGENIY KHAVKIN

Cody L Phinney / Administrator

Blue Cloud Ownership Chart

Entity	Address	TIN	Ownership
Blue Cloud Pediatric Surgery Centers, LLC	9709 Lakeside Blvd, Ste 350, The Woodlands, TX 77381	81-2751795	100% (direct)
Benson Parent, LLC	9709 Lakeside Blvd, Ste 350, The Woodlands, TX 77381	87-3733926	100% (indirect)
Benson Intermediate, LLC	9709 Lakeside Blvd, Ste 350, The Woodlands, TX 77381	87-3748300	100% (indirect)
Benson Topco, LLC	9709 Lakeside Blvd, Ste 350, The Woodlands, TX 77381	87-3743099	100% (indirect)
The Rise Fund II Benson BL, LLC	200 Clarendon Street, 29th Floor, Boston, MA 02116	87-3790706	100% (indirect)
Brave Purchaser Inc.	200 Clarendon Street, 29th Floor, Boston, MA 02116	39-2912941	100% (indirect)
Brave Intermediate Holdco, Inc.	200 Clarendon Street, 29th Floor, Boston, MA 02116	39-2935050	100% (indirect)
Brave Topco Holdings, LP	200 Clarendon Street, 29th Floor, Boston, MA 02116	39-2907379	100% (indirect)
Great Hill Equity Partners VIII, LP	200 Clarendon Street, 29th Floor, Boston, MA 02116	87-2534715	37.14% (indirect)
Great Hill Equity Partners VIII-Pref PV, LP	200 Clarendon Street, 29th Floor, Boston, MA 02116	87-2535349	13.36% (indirect)
Great Hill Equity Partners VIII-Pref, LP	200 Clarendon Street, 29th Floor, Boston, MA 02116	87-2535033	11.44% (indirect)
Great Hill Equity Partners VII, LP	200 Clarendon Street, 29th Floor, Boston, MA 02116	84-1939008	10.53% (indirect)
Other Ownership Interests (No individual or entity in these groups has more than 5% ownership of Brave Topco Holdings, LP)	N/A	N/A	13.03% (indirect)

Medical and Dental Center of Nevada, LLC: Director and Officer Slate

Company	Officer/Director	Title
Medical and Dental Center of Nevada, LLC	Devin Larsen	Manager
Medical and Dental Center of Nevada, LLC	Dennis Smythe	Manager

Medical and Dental Center of Nevada LLC

Officers/Directors List

Troy Thibodeaux, President

JC Rice, Chief Operating Officer

Dennis Smythe, Chief Financial Officer

Devin Larsen, Chief Executive Officer

Miriam Chan, Chief Medical Officer

LaRee Johnson, Chief Dental Officer

BlueCloud
Pediatric Surgery Centers

July 21, 2025

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway,
Suite 206,
Reno, NV 89521

Re: Change of Indirect Ownership – Medical and Dental Center of Nevada LLC DBA Las Vegas Children's Surgery Center

Lic#: ASC03943

To Whom It May Concern:

We are writing to provide your office notice of a change in the indirect ownership of Medical and Dental Center of Nevada LLC DBA Las Vegas Children's Surgery Center, which holds license number ASC03943 (the "Provider").

The transaction is expected to occur on or around August 7, 2025, on which date Brave Purchaser, Inc. (the "Buyer") will acquire an upstream, indirect ownership interest several levels above the Provider. Blue Cloud Pediatric Surgery Centers, LLC will continue to own and hold all membership interests in Provider and the direct ownership of the Provider will not change.

Accordingly, there are no changes to the Provider's business or operations as a result of this transaction. The Provider's federal employee identification number will remain same, and the Provider will continue to operate under the same name and at the same location. Further, we do not expect the transaction to result in any changes to the Provider's policies and procedures, personnel, or services.

A completed change of ownership application is attached. Should you have any questions regarding this letter, the application, or the planned transaction, please do not hesitate to contact me by phone at (613) 445-0593 or via email at mschwizer@bluecloudpsc.com.

Sincerely yours,

Michelle Schwizer

Credentialing Manager

4TTT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☑ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☑ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☑ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Platinum Medical Supplies LLC

MDEG Physical Address: 2520 Sunset Road Unit #3

City: Las Vegas State: NV Zip: 89120

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 7024765597 Website: platinummedltc.com

Email: sally@platinummedltc.com

Name of MDEG Administrator (NAC 639.694): Altan Trinidad

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
☑ Patients by prescriptions	☑ Medical Gases**
☐ Pharmacies[a]	☑ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Sally Chia
	Telephone: [redacted]

Check the Days the Business will be Opened and provide the Hours of Operation				
☐ Mon: 10am-3pm	☐ Tue: 10am-3pm	☐ Wed: 10am-3pm	☐ Thurs: 10am-3pm	☐ Fri: 10am-3pm
☐ Sat: closed	☐ Sun: closed	☐ Holidays: closed		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
PTAN 8227430001
Medicaid location ID: 250021822 OR 1659008910

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: No _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Sally Chia

Business Name: Platinum Medical Supplies LLC

Business Address: 2520 Sunset Road Unit #3

City: LAS VEGAS State: NV Zip: 89120

Telephone: 702-476-5597 Email: SALLY@PLATINUMMEDLTC.COM

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sally Chia

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

07/10/2025

Date

Board Use Only	Date Received: 7/22/25	Amount: $500 CK 1015

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Platinum Medical Supplies LLC dba Platinum Medical LTC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04448

Physical Address: 2520 Sunset Road Unit #3

City: Las Vegas State: NV Zip: 89120

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-476-5597 Website: platinummedltc.com

Licensing Company Email: sally@platinummedltc.com

Section 2: Personal Information

First: Sally Middle: Last: Chia

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: 89120

Telephone: [redacted] Email: sally@platinummedltc.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of the Sciences in Philadelphia		09/04 - 06/10	
Address	**City**	**State**	**Zip**
600 S 43rd St	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Central High School		09/00-05/04	
Address	**City**	**State**	**Zip**
1700 W Olney Ave	Philadelphia	PA	19141
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/24-present	[redacted]	[redacted]	[redacted]	89148
From - To (MM/YY – MM/YY)				Zip
07/15-05/24				89118
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
986 Pharmacy #8026			07/24-present	
Business Address		**City**	**State**	**Zip**
8536 Del Webb Blvd		Las Vegas	NV	89134
Phone	**Title**			
702-476-5888	Director/PIC			
Description of Duties				
Overall operation and management of a pharmacy. Overseeing staff, ensuring compliance with regulations, managing inventory, and maintaining patient safety				

Business Name			From - To (MM/YY – MM/YY)	
Refill Pharmacy			04/16-7/24	
Business Address		**City**	**State**	**Zip**
8536 Del Webb Blvd		Las Vegas	NV	89134
Phone	**Title**			
Description of Duties				
Overseeing staff, ensuring compliance with regulations, managing inventory, and maintaining patient safety				

Business Name			From - To (MM/YY – MM/YY)	
Platinum Medical Supplies LLC dba Platinum Medical LTC			10/22-present	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				
Overseeing staff, ensuring compliance with regulations, managing inventory, and maintaining patient safety				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, *member, officer, or director) been a party to a lawsuit (including any administrative* proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/17/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sally Chia
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/17/25
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Sally Chia, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/17/25
Date

Subscribed and Sworn to before me this 17th day of July.

Notary Public Signature

HECTOR CAMPOS-LEPE
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 04-16-28
Certificate No: 24-6762-01

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Platinum Medical Supplies LLC — MDEG License # (if applicable): _____

Physical Address: 2520 Sunset Road Unit #3

City: Las Vegas — State: NV — Zip: 89120

Mailing Address (if different from physical address): _____

City: _____ — State: _____ — Zip: _____

Telephone: 702-476-5597 — Website: platinummedltc.com

Licensing Company Email: sally@platinummedltc.com

Section 2: Personal Information

First: Altan — Middle: Sales — Last: Trinidad

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] — State: [redacted] — Zip: 89148

Telephone: [redacted] — Email: support@platinummedltc.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
MTI Tech Institute		09/01-05/05	
Address	**City**	**State**	**Zip**
1870 Whitney Mesa Drive	Henderson	NV	89014
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Silverado High School		08/99-05/00	
Address	**City**	**State**	**Zip**
1650 Silver Hawk Ave	Las Vegas	NV	89123
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/24-present	[redacted]	[redacted]	[redacted]	89148
07/15-05/24				89118
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Platinum Medical LTC			From - To (MM/YY – MM/YY): 10/22-present
Business Address: 6000 S. Eastern Ave Ste 1B	City: Las Vegas	State: NV	Zip: 89119
Phone: 702-476-5597	Title: DME Manager/Technician		Number of Employed Hours: 4200 hours
Description of Duties: assemble, maintain, fix, set up, and deliver durable medical equipment and supplies. Ensuring all rules and regulations are followed			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		*Governing, licensing, Arresting Presiding Body/Agency/Court*		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/10/25
Date

I, Altan Trinidad, **certify that as the MDEG Administrator for**

Platinum Medical Supplies LLC,

that I (initial that you have read and meet the following requirements):

1. AT Have a high school diploma or its equivalent;
2. AT Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. AT Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. AT Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Altan Trinidad

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/10/25

Date

Board Use Only	Date Received: 7/22/25

CUSTOMER NUMBER: 0100085991

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/10/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER

PHARMACISTS MUTUAL INSURANCE GROUP
808 HIGHWAY 18 W
PO BOX 370
ALGONA IA 50511-0370

CONTACT NAME:
PHONE (A/C, No, Ext): 800-247-5930 FAX (A/C, No):
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A: PHARMACISTS MUTUAL INSURANCE COMPANY	13714
INSURER B: CHIRON INSURANCE COMPANY	16356
INSURER C:	
INSURER D:	
INSURER E:	
INSURER F:	

INSURED

PLATINUM MEDICAL SUPPLIES LLC
PLATINUM MEDICAL SUPPLIES
6000 S EASTERN AVE STE 1B
LAS VEGAS NV 89119-3125

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY	N	N	VST 0008772 00	12/13/2024	12/13/2025	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 50,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ Included
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	OTHER						WATER LEGAL LIABILITY	$ Included
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N	N/A					PER STATUTE / OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTIONS OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Premises 1, Building 1
PLATINUM MEDICAL SUPPLIES
6000 S EASTERN AVE STE 1B, LAS VEGAS, NV 89119-3125

CERTIFICATE HOLDER

PALMETTO GBA (NP WEST)
AG-495
PO BOX 100142
COLUMBIA SC 29202-3142

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Michelle Chally

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SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Platinum Medical Supplies LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 05/04/2021, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/16/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507165909241
You may verify this certificate online at https://www.nvsilverflume.gov/home

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ANNUAL DISCIPLINE CASES Reporting Period: January 2025 – July 2025			
FINDING	**HARM**	**DISCIPLINE INDIVIDUAL**	**DISCIPLINE FACILITY**
SY was engaged to serve as medical director of a practice that allowed unlicensed persons to access, possess, furnish and administer dangerous drugs without a direct practitioner supervision, including drug products intended for distribution in foreign markets and not approved in the U.S.	No	Certificate of Registration No. CS27231, is placed on probation for a period of one year subject to the following conditions: 1) public reprimand; 2) $2,500 fine; and 3) assessed $1,000 for attorney's fees and costs.	N/A
MH was engaged to serve as medical director of a practice that allowed unlicensed persons to access, possess, furnish and administer dangerous drugs without a direct practitioner supervision, including drug products intended for distribution in foreign markets and not approved in the U.S.	No	Certificate of Registration No. CS22622 is suspended. The suspension is stayed, and Respondent is placed on probation for a period of one year subject to the following conditions: 1) public reprimand; 2) $2,500 fine; and 3) assessed $1,000 for attorney's fees and costs.	N/A
JG pled guilty pursuant to a plea agreement and was convicted on one felony count of conspiracy in United States of America v. Jeffrey Dave Gress, United States District Court for Central District of California, Case 8:18-cr-00014-JLS. Respondent subsequently surrendered his DEA Registration No. FG3245455 by executing a DEA Form 104	No	Certificate of Registration No. CS20182 is revoked; Respondent may not petition for reinstatement for a period of one year from the effective date of the Order. Respondent fined $5,000and assessed $1,000 for attorney's fees and costs.	N/A
WP dispensed a prescription with erroneous directions for use which resulted in negative outcome to patient and failed to properly document medication counseling.	Yes	N/A	Respondent fined $1,000 and assessed $500 for attorney's fees and costs.
WH performed data entry review and final product verification of a prescription and failed to detect erroneous directions for use which resulted in a negative outcome to the patient.	Yes	Respondent fined $1,000 and assessed $500 for attorney's fees and costs.	N/A

HB failed to properly document medication counseling for a prescription.	Yes	Respondent fined $1,000 and assessed $500 for attorney's fees and costs.	N/A
NSP compounded and dispensed drug products for 64 patients located in Nevada without holding a Nevada Pharmacy license, and the prescriptions dispensed may not have been compounded in compliance with Nevada Law.	No	N/A	Respondent fined $25,000 for the violations.
JK surrendered his Neveda Medical License No. 15386 to practice medicine for cause and no longer qualifies as a practitioner for registration to dispense controlled substances, and he committed acts that render his registration inconsistent with the public interest.	No	Certificate of Registration No. CS24228 is revoked; Respondent may not petition for reinstatement for a period of one year from the effective date of the Order. Respondent fined $2,000 and assessed $1,880.42 for attorney's fees and costs.	N/A
JB failed to disclose arrests and/or convictions on his original Pharmaceutical Technician in Training application. The Board held a hearing to address the charges against him on January 15, 2025, where he failed to appear, and a default order was taken.	No	Certificate of Registration No. PT28790 was revoked for a period of one year and assessed $511.46 in attorney's fees and costs.	N/A

AL transported a supply of controlled substances between his home/vehicle/office and various hospital operating rooms and/or surgery centers in a location other than a registered office in violation of Nevada Law. In addition, he knowingly or intentionally acquired controlled substances and/or dangerous drugs without a prescription and failed to query the controlled substance information in the PMP in violation of Nevada Law.	No	Certificate of Registration No. CS18089 is revoked. The revocation is stayed and placed on probation for a period of five years from the effective date of the Order. Respondent Lee shall not possess controlled substances except while on the premises of a hospital, a surgery center for ambulatory patients, or another medical facility where respondent is treating or caring for a surgical patient. Respondent Lee shall participate in four quarterly inspections from the effective date of the Order to January 14, 2026. Respondent fined $10,000 for the violations; and assessed $5,000 in attorney's fees and costs.	N/A
YS failed to secure dangerous drugs in a locked cabinet thereby allowing access to dangerous drugs by unlicensed personnel and administered drug products to a patient that were not acquired in compliance with Nevada Law.	No	YS accepts the Stipulation and Order as a public reprimand; fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
RR worked as a pharmaceutical technician in training without obtaining a certificate of registration from the Board for the work location.	No	Certificate of Registration No. PT28825 is revoked, and Respondent may not petition for reinstatement for a period of one year from the effective date of the Order; and assessed $1,222.85 in attorney's fees and costs.	N/A

JS failed to disclose disciplinary order on his 2022 biennial renewal application for his Certificate of Registration No. CS09874. Respondent JS issued sixty-eight controlled substance prescriptions on a suspended registration and permitted his medical assistants to forge and issue prescriptions for controlled substances.	No	Respondent's Certificate of Registration No. CS09874 is revoked, and Respondent may not petition for reinstatement for a period of two years from the effective date of the Order; Respondent fined $5,000 for the violations; and assessed $2,968.64 in attorney's fees and costs.	N/A
SCS engaged in the sale and or distribution of counterfeit HIV-1 drugs and transmitted falsified transaction records.	No	N/A	Respondent's License No. WH02131 is revoked, the revocation is stayed and Respondent placed on probation for a period of three years subject to the following conditions: a) Respondent shall pay a fine of $5,000 for the violations; b) assessed $3,584.10 in attorney's fees and costs; and c) Respondent shall be subject to an inspection by Board staff at respondent's expense.
WP is responsible for the acts of its employees who made an error in a prescription and failed to maintain a written record showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business on January 31, 2024.	No	N/A	Respondent fined $2,000 for the violations; and assessed $500 in attorney's fees and costs.
JE failed to maintain a written record showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business on January 31, 2024.	No	Respondent fined $500 for the violations; and assessed $500 in attorney's fees and costs.	N/A

CQ fined $500 for the violations; and assessed $500 in attorney's fees and costs.	No	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
OM billed insurers for products that were never delivered to patients, failed to maintain an adequate system to resolve complaints by these patients, and failed to notify the Board of the departure of its facility administrator within three business days.	No	N/A	Respondent is not eligible to apply for a license or engage in business as a medical products provider or medical products wholesaler for a period of two years after the effective date of this Stipulation; Respondent shall notify the Board in writing if it becomes aware that any of its current officers, directors, shareholders, partner, or members have applied in an individual or representative capacity for a license to conduct business as a medical products provide or medical products wholesaler; Respondent shall accept this Stipulation as a public reprimand; Respondent shall refund payments or deposits as described in sections 1a, 1b, 1c, 1d, and 1f of the Investigate Report by June 30, 2025; Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.
WP is responsible for the acts of an employee who accessed protected health information for the purpose of learning personal information about a patient.	No	N/A	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.

MR accessed protected health information for the purpose of learning personal information about a patient.	No	Certificate of Registration No. PT28786 is revoked retroactively to October 31, 2024, and may not petition the Board for reinstatement for a period of one year from the effective date of the revocation; and assessed $500 in attorney's fees and costs.	N/A
EC diverted controlled substances from her place of employment at CVS Pharmacy.	No	Certificate of Registration No. PT18610 is revoked and may not petition for reinstatement for a period of one year.	N/A
LI failed to properly service the respiratory equipment furnished to a patient at least every 24 months as required by the manufacturer's product manual.	N/A	N/A	Respondent fined $1,000 for the violations; and assessed $1,000 in attorney's fees and costs.
HM failed to pay the $10,000 fine and $544.55 in attorney's fees and costs in Case No. 20-070-PR-N ordered on April 17, 2024. The Board filed an Order to Show Cause due to non-compliance with the Order, and HM petitioned the Board to vacate the disciplinary actions in the case.	No	The Board denied the request to vacate the decision and upheld the $10,000 fine and $544.55 in attorney's fees and costs.	N/A
MPS is responsible for the acts of its employees who filled and dispensed unlawful prescriptions for controlled substances and compounded semiglutide, employed one pharmaceutical technician in training (PTT) on an expired registration and another PTT without obtaining a registration to work at Meta Pharmacy.	No	N/a	Respondent fined $10,000 for the violations; $2,000 in attorney's fees and costs; and quarterly inspections for a period of one year not to exceed $500 at owner's expense.

SB Respondent filled and dispensed unlawful prescriptions for controlled substances and compounded semiglutide, employed one pharmaceutical technician in training (PTT) on an expired registration and another PTT without obtaining a registration to work at MPS.	No	Certificate of Registration No. 17303 is revoked, the revocation is stayed, and respondent is placed on probation for a period of ten years subject to the following conditions: a) a public reprimand; b) pay a $10,000 fine for the violations; c) pay $2,000 in attorney's fees and costs; d) 12 additional continuing education on pharmacy law and ethics within six months of the Order date; e) shall not be a managing pharmacist at Meta Pharmacy or any pharmacy licensed by the Board during the probation period; f) shall divest himself of any ownership interest in Meta Pharmacy within 90 days of the Order and shall not hold any ownership in any pharmacy licensed by the Board during the probation period; and g) shall not work as a pharmacist for Meta Pharmacy for a period of two years from the effective date of the Order.	N/A
MB knowingly filled and dispensed unlawful prescriptions for controlled substances.	No	Certificate of Registration No. 14966-B is suspended, the suspension is stayed, and respondent is placed on probation for a period of one year subject to the following conditions: a) a public reprimand; b) pay a $1,000 fine for the violations; c) pay $1,000 in attorney's fees and costs	N/A

CP in Case No. 23-175-RPH-S refused to transfer a prescription as requested by a patient and engaged in unprofessional conduct, and he knowingly filled and dispensed unlawful prescriptions for controlled substances in Case No. 24-125-RPH-B-S.	No	Certificate of Registration No. 16325 is suspended, the suspension is stayed, and respondent is placed on probation for a period of two years subject to the following conditions: a) a public reprimand; b) pay a $2,000 fine for the violations; c) pay $2,000 in attorney's fees and costs; and d) shall complete ten additional continuing education (CE) hours on pharmacy law and ethics within six months of the effective date of the Order.	N/A
UAK has failed to pay the fine payment of $1,300 and $749 in attorney's fees and costs ordered December 1, 2021. The Board filed an Order to Show Cause due to non-compliance with the Order, and a default hearing was heard on April 16, 2025, due to his failure to appear.	No	The Board upheld the fine payment of $1,300 and $749 in attorney's fees and costs.	N/A
EM has failed to pay the fine payment of $5,000 and $812.50 in attorney's fees and costs ordered April 21, 2021. The Board filed an Order to Show Cause due to non-compliance with the Order, and a default hearing was heard on April 16, 2025, due to his failure to appear.	No	The Board upheld the fine payment of $5,000 and $812.50 in attorney's fees and costs.	N/A
The Board filed an Order of Summary Suspension based upon the preliminary findings that AG diverted controlled substances. AG failed to appear, and a default hearing was heard on April 16, 2025.	No	The Board upheld the summary suspension for AG's Certificate of Registration No. PT20499 pending the filing of charges.	N/A

As pharmacy/pharmacy owner, PSP is responsible for the acts of its employee in Case No. 23-175-PH-S who refused to transfer a prescription at the request of the patient. PSP is responsible for the acts of its employees in Case No. 23-239-PH-S who purchased drug substances from an unlicensed wholesaler in Nevada; dispensed several drug products to patients with directions to compound the drugs themselves; and furnished a patient's practitioner with prescription blanks bearing the name of the pharmacy. PSP is responsible for the acts of its employees in Case No. 23-429-PH-S who dispensed 512 invalid prescriptions issued for "Emergency Kits" or "COVID Kits" for which the drugs in each were not identified on the prescription and dispensed and substituted a different drug without permission in the "COVID Kits". PSP is responsible for the acts of its employees in Case No. 24-424-RPH-S who accepted, processed, and dispensed prescriptions that were not valid and those of which were controlled substance prescription were not transmitted electronically as required by Nevada Law.	No	N/A	Respondent PSP shall be revoked effective December 31, 2025. Before the revocation, PSP License No. PH02028 shall be placed on probation, effective immediately, and is subject to the following conditions of probation: 1) Respondent fined $10,000; 2) Respondent assessed $3,000 in attorney's fees and costs; 3) Respondent shall comply with all federal and state statutes and regulations concerning controlled substance and dangerous drugs and shall have no additional charges filed against it during the period of probation; and 4) Respondent shall submit to monthly inspections at its own expense during the probation period.
Respondent MB failed to complete his 2019 and 2021 continuing education hours as required by Nevada Law. Respondent's Certificate of Registration No. 18710 is placed on probation until July 18, 2025. He must produce proof of two and one-half continuing education credits and one law continuing education credit.	No	If he fails to provide proof, his Certificate of Registration No. 18710 will be suspended for a period of time not to exceed five months; any suspension will be lifted upon proof of his completed required continuing education credit. Respondent fined $1,000; and assessed $500 in attorney's fees and costs.	N/A

As managing pharmacist during the times of the events, Respondent JL is responsible for the acts of its employees who purchased drug substances from an unlicensed wholesaler in Nevada; dispensed several drug products to patients with directions to compound the drugs themselves; and furnished a patient's practitioner with prescription blanks bearing the name of the pharmacy.	No	Respondent JL, Certificate of Registration No. 17503, is revoked, effective immediately. The revocation is stayed and is placed on probation for a period of five years subject to the following conditions: 1) Respondent fined $10,000; 2) Respondent assessed $1,000 in attorney's fees and costs; 3) On or before December 31, 2025, Respondent shall complete twelve additional hours of continuing education on pharmacy law and ethics; During the period of probation, Respondent shall not work as a managing pharmacy for or hold an ownership in any pharmacy licensed by the Board other than EliteRx (License No. PH04615).; 4) Respondent shall comply with all federal and state statutes and regulations concerning controlled substances and dangerous drugs and have no additional charges filed against him during the probation; and 5) Respondent shall not engage in the practice of compounding "sterile compounded drug products" for a period of two years after the approval of the Stipulation.	N/A

As pharmacy owner and managing pharmacist during the times of the events, Respondent RS is responsible for the acts of its employees in Case No. 23-429-PH-S who dispensed 512 invalid prescriptions issued for "Emergency Kits" or "COVID Kits" for which the drugs in each were not identified on the prescription and dispensed and substituted a different drug without permission in the "COVID Kits". Respondent RS is responsible for the acts of its employees in Case No. 24-424-RPH-S who accepted, processed, and dispensed prescriptions that were not valid and those of which were controlled substance prescription were not transmitted electronically as required by Nevada Law.	No	Respondent RS, Certificate of Registration No. 13574, shall be revoked effective August 1, 2025. The revocation shall be stayed and is placed on probation for a period of five years subject to the following conditions: 1) Respondent shall pay a fined $10,000; 2) Respondent assessed $1,000 in attorney's fees and costs; 3) On or before December 31, 2025, Respondent shall complete twelve addition hours of continuing educations on pharmacy law and ethics; 4) On or after August 1, 2025, and through the end of probation, Respondent shall not work as a managing pharmacist for any pharmacy licensed by the Board; 5) On and after December 31, 2025, Respondent shall not hold an ownership in any pharmacy licensed by the Board; 6) On and after the entry of this Stipulation through the end of the period of probation, Respondent shall comply with all federal and state statutes and regulations concerning controlled substances and dangerous drugs and shall have no additional charges filed against him; and 7) On and after the entry of this Stipulation through the end of the period of probation, Respondent shall not engage in the practice of compounding drug products.	N/A

Respondent GD entered a Settlement Agreement with the Osteopathic Board's Case No. PN1407002 and voluntarily surrendered his license. The Nevada Board of Pharmacy took reciprocal action on Certificate of Registration No. CS03830 due to violations relating to controlled substances, engaging in unprofessional conduct, and acts committed that render his registration inconsistent with the public interest.	No	Respondent's Certificate of Registration No. CS03830 is revoked retroactively to October 31, 2024, and may not petition for reinstatement for a period of one year.	N/A
Respondent MC diverted controlled substances for 863 Alprazolam and 2,057mg of promethazine with codeine syrup.	No	Respondent's Certificate of Registration No. PT16852 is revoked and cannot petition for reinstatement for a period of one year. Respondent fined $1,000; and assessed $638.97 in attorney's fees and costs.	N/A
CVS is responsible for the acts of its employees who made an error in a prescription and failed to provide medication counseling to a patient.	No	N/A	Respondent fined $3,000 for the violations; and assessed $1,000 in attorney's fees and costs.
Respondent KK made an error in a prescription and failed to provide medication counseling to a patient.	No	Respondent fined $1,500 for the violations; and assessed $500 in attorney's fees and costs.	N/A
Respondent HR engaged in the business of selling, leasing, supply and/or distributing medical devices to hospitals and other licensed care facilities without a license to engage in business as a wholesaler.	No	N/A	Respondent fined $2,500 for the violations; and assessed $500 in attorney's fees and costs.
AA had was in violation of Board order for failing to pay $5,000 fine and $4,065.51 in attorney's fees and costs.	No	Respondent must pay $5,000 fine and $4,065.51 in attorney's fees and costs.	N/A
Respondent WP compounded essential copies of commercially available drugs without a "statement of significant difference" for each prescription documenting a medical need specific to the patient for the compounded product.	No	Respondent fined $2,500 for the violations; assessed $3,884.85 in attorney's fees and costs; and shall be subject to a Board inspection within the next six months at respondent's expense.	N/A

Respondent PS engaged in the business as a medical products provider and failed to service and communicate with a patient who needed emergency oxygen equipment and supplies.	Yes	N/A	Respondent accepts this Stipulation as a public reprimand; Previous License No. MP02951 is forfeited; Respondent fined $8,000 fine for the violations; and assessed $1,000 in attorney's fees and costs.
Respondent MVL allowed a non-practitioner to receive, possess, store and/or administer dangerous drugs outside of respondent's presence.	No	Respondent accepts this Stipulation as a public reprimand; Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
MS falsely stated on her renewal application that she had not been convicted of any felony or misdemeanor offenses since her last renewal. However, she was convicted of two felony offenses in July 2022. A default hearing was heard on July 16, 2025, due to her failure to appear.	No	Certificate of Registration No. PT17066, is retroactively revoked to October 31, 2024, and may not petition the Board for reinstatement of her registration for a period of one year from the date of the Order. Respondent fined $500 for the violations and assessed $757.41 in attorney's fees and costs, payable if Respondent ever petitions for reinstatement of her registration.	N/A
Respondent MO issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances while travelling out of country which is in violation of Nevada Law. In addition, respondent participated in deceitful transactions and billed Medicaid for services that respondent did not provide. Additionally, The Board took reciprocal action based on discipline that the Nevada State Board of Medical Examiners took for numerous findings of professional misconduct.	No	Certificate of Registration No. CS10934, is revoked, effective immediately, and may not petition the Board for reinstatement for a period of one year from the date of the Order. Respondent fined $10,000 for the violations; and assessed $3,000 in attorney's fees and costs.	N/A

Respondent KF stole $320 from her place of employment at Walgreen's Pharmacy #5862. A default hearing was heard on July 16, 2025, due to her failure to appear.	No	Certificate of Registration No. PT26333 is retroactively revoked to October 31, 2022, and may not petition for reinstatement for a period of one year from the date of the Order. Respondent fined $500 for the violations; and assessed $482.27 in attorney's fees and costs and must reimburse the Board if she ever petitions for reinstatement of her registration.	N/A
Respondent RI allowed his medical assistants to use his credentials to issue prescriptions for controlled substances and failed to query the PMP as required by Nevada Law. A default hearing was heard on July 16, 2025, due to his failure to appear.	No	Respondent is publicly reprimanded; Respondent fined $5,000 for the violations; and assessed $691.46 in attorney's fees and costs.	N/A

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FILED
JUN 30 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KARRI BURGNER, APRN,** **Certificate of Registration No. CS15148,** **Respondent.**	**CASE NO. 22-247-CS-A-N** **ORDER TO SHOW CAUSE**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), makes the following that will serve both a notice of intended action under NRS 233B.127(3) and as an order to show cause under NAC 639.965:

1. Karri Burgner, APRN, Certificate of Registration No. CS15148, is hereby directed to appear before the Board for a hearing to show cause scheduled on Wednesday, September 3, 2025 at the following location:

Hyatt Place
1790 E Plumb Ln.
Reno, NV 89502

2. On July 17, 2024, the Board entered a Stipulation and Order in Case No. 22-247-CS-A-N by which Respondent stipulated to discipline pursuant to NRS 453.241(1)(b) and NRS 639.255 (Order).

3. Respondent has failed to make payment of a fine of Two Thousand Dollars ($2,000.00) pursuant to the Order.

4. Respondent has failed to make payment of Five Hundred Dollars ($500.00) for attorney's fees and investigative costs pursuant to the Order.

5. Respondent is therefore directed to show cause why she should not be subject to further discipline pursuant to NRS Chapters 453 and 639, or otherwise demonstrate that her conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 30th day of June 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Karri Burgner
[redacted]
Sparks, NV [redacted]

Karri Burgner
[redacted]
Reno, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
MAR 19 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KARRI BURGNER, APRN,** **Certificate of Registration No. CS15148,** **RICARDO GONZALEZ, M.D.,** **Certificate of Registration No. CS11387,** **Respondents.**	**Case Nos. 22-247-CS-A-N** **22-247-CS-B-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has personal jurisdiction over Respondent Karri Burgner, APRN ("Burgner"), because at the time of the violations alleged herein, Burgner held certificate of registration no. CS15148, issued by the Board pursuant to NRS 453.226, authorizing Respondent to write prescriptions for controlled substances. Burgner has held certificate of registration no. CS15148 since May 1, 2007.

2. The Board has personal jurisdiction over Respondent Ricardo Gonzalez, M.D. ("Gonzalez"), because at the time of the violations alleged herein, Gonzalez held certificate of registration no. CS11387, issued by the Board pursuant to NRS 453.226, authorizing Respondent to write prescriptions for controlled substances. Gonzalez has held certificate of registration no. CS11387 since August 28, 2002.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the prescribing of controlled substances using a certificate of registration issued by the Board. NRS 453.226.

FACTUAL ALLEGATIONS

4. Burgner is an APRN who practices at Peavine Family Practice located at 2005 Sierra Highlands, Suite #101, Reno, Nevada 89523.

5. Gonzalez is an M.D. who practices at Peavine Family Practice located at 2005 Sierra Highlands, Suite #101, Reno, Nevada 89523.

6. On or about July 25, 2022, the Board received information stating that patient J.J. had been overprescribed Alprazolam.

7. On or about July 26, 2022, the Board's investigator queried the Prescription Monitoring Program ("PMP") for patient J.J. and determined that between that July 6, 2021 and July 13, 2022, Burgner and Gonzalez had prescribed patient J.J. sixty (60) tablets of alprazolam 0.5 MG, with instructions to take 1 tablet twice daily, on twenty-one (21) occasions.

8. On or about March 26, 2019, Burgner initially prescribed patient J.J. sixty (60) tablets of alprazolam 0.5 MG. Burgner did not conduct a patient utilization report query of the Prescription Monitoring Program ("PMP") for patient J.J. in conjunction with this initial prescription.

9. Burgner issued a total of 22 unique prescriptions for sixty (60) tablets of alprazolam 0.5 MG to patient J.J. before Burgner first queried the PMP to obtain a patient utilization report for patient J.J. on August 16, 2022.

10. Between December 10, 2015, and June 23, 2022, Burgner did not query the PMP's MyRx system.

11. On or about May 13, 2021, Gonzalez initially prescribed patient J.J. sixty (60) tablets of alprazolam 0.5 MG. Gonzalez did not conduct a patient utilization report query of the PMP for patient J.J. in conjunction with this initial prescription.

12. Gonzalez issued a total of 2 unique prescriptions for sixty (60) tablets of alprazolam 0.5 MG to patient J.J. before Burgner first queried the PMP to obtain a patient utilization report for patient J.J. on October 11, 2022.

13. Between January 29, 2018, and April 7, 2022, Gonzalez did not query the PMP's MyRx system.

14. Burgner and Gonzalez's conduct resulted in patient J.J. filling overlapping prescription(s) and/or refill(s) of alprazolam 0.5 MG tablets.

August 2021 – 180 Alprazolam 0.5 MG Tablets Dispensed

15. On or about August 3, 2021, CVS filled RX #1106765, written on by Gonzalez on July 28, 2021, and dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

16. On or about August 13, 2021, Walgreens filled RX #1190609, written by Burgner on August 13, 2021, and dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

17. On or about August 31, 2021, CVS refilled RX #1106765, written by Gonzalez on July 28, 2021, and dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

September 2021 – 120 Alprazolam 0.5 MG Tablets Dispensed

18. On or about September 11, 2021, patient J.J. filled RX #1198359, written by Burgner on September 7, 2021, and Walgreens #02474 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

19. On or about September 27, 2021, patient J.J refilled RX #1106765, written by Gonzalez on July 28, 2021, and CVS #4691 dispensed sixty (60) tablets of alprazolam 0.5 MG.

February 17-24, 2022 – 120 Alprazolam 0.5 MG Tablets Dispensed

20. On or about February 17, 2022, patient J.J. filled RX #1163507, written by Burgner on December 21, 2021, and CVS #4691 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

21. On or about February 24, 2022, patient J.J. filled RX #1246613, written by Burgner on October 6, 2021, and Walgreens #02474 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

March 16-26, 2022 – 120 Alprazolam 0.5 MG Tablets Dispensed

22. On or about March 16, 2022, patient J.J. refilled RX #1163507, written by Burgner on December 21, 2022, and CVS #4691 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

23. On or about March 24, 2022, patient J.J filled RX #1254025, written by Burgner on March 24, 2022, and Walgreens #02474 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

April 17-23, 2022 – 120 Alprazolam 0.5 MG Tablets Dispensed

24. On or about April 17, 2023, patient J.J. refilled RX #1163507, written by Burgner on December 21, 2022, and CVS #4691 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

25. On or about April 23, 2022, patient J.J. filled RX #1261552, written by Burgner on April 23, 2022, and Walgreens #02474 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

June 2022 – 180 Alprazolam 0.5 MG Tablets Dispensed

26. On or about June 13, 2022, patient J.J. refilled RX #1163507, written by Burgner on December 21, 2022, and CVS #4691 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

27. On or about June 20, 2022, patient J.J filled RX #1269150, written by Burgner on June 20, 2022, and Walgreens #02474 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

28. On or about June 29, 2022, patient J.J filled RX #1278977, written by Burgner on April 29, 2022, and Walgreens #02474 dispensed patient J.J. sixty (60) tablets of alprazolam 0.5 MG.

APPLICABLE LAW

29. Administrative proceedings brought by the Board against a Respondent pursuant to NRS Chapter 453, to deny, suspend or revoke a registration must be initiated, conducted, and concluded pursuant to the provisions of NRS 639.241 to NRS 639.257. Upon a finding of guilt against the Respondent, the Board shall suspend the right of the registrant to use his or her registration or a schedule thereof; or revoke the registration or a schedule thereof. NRS 453.241.

30. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

31. Unprofessional conduct includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

32. The Board may suspend or revoke a registration pursuant to NRS 453.231 to dispense controlled substances upon a finding that the registration has violated any provision of NRS 453.162 to 453.165, inclusive, or 639.23507. NRS 453.236(1)(d) and NRS 453.241.

33. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

34. A practitioner shall, before issuing an initial prescription for a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the computerized program established by the Board. NRS 639.23507.

35. Each practitioner who is authorized to write prescriptions for human consumption of controlled substances listed in schedule II, III, IV or V shall access the database of the PMP at least once every 6 months to review the information concerning the practitioner that is listed in the database, including, without limitation, information concerning prescriptions issued by the practitioner, and notify the Board if any such information is not correct, and to verify to the Board that he or she continues to have access to and has accessed the database as required by this subsection. NRS 453.164(7).

36. This Accusation constitutes a public record pursuant to NRS 622.330 and any discipline imposed by the Board shall be reported to the National Practitioner Data Bank as required by federal law. Title 42 USC § 1396r–2; 45 CFR Part 60.

37. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Acts Inconsistent with the Public Interest
Failure to Query Patients Prior to Issuing an Initial Prescription for a Controlled Substance
(Respondents Burgner and Gonzalez)

38. Respondents Burgner and Gonzalez failed to obtain a patient utilization report from the PMP prior to issuing the initial prescriptions of sixty (60) tablets of alprazolam 0.5 MG to patient J.J. This failure constituted a violation of NRS 639.23507 which requires a practitioner, before issuing an initial prescription for a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, to obtain a patient utilization report regarding the patient from the computerized program established by the Board. NRS 639.23507.

39. By failing to query patient J.J.'s patient utilization report upon issuing an initial prescription for sixty (60) tablets of alprazolam 0.5 MG and by failing to query patient J.J.'s patient utilization report every 90 days thereafter, Respondents Burgner and Gonzalez performed their duties in an incompetent, unskillful or negligent manner which constituted unprofessional conduct, as defined by NAC 639.945(1)(i) and NRS 639.210(4), and which renders their continued registration to prescribe controlled substances inconsistent with the public interest pursuant to NRS 453.236(1)(d) and/or (e). Therefore, Respondents Burgner and Gonzalez are subject to discipline pursuant to NRS 639.210(4); and/or NRS 639.255; and/or NRS 453.236(1)(d) or (e); and/or NRS 453.241.

COUNT TWO

Unprofessional Conduct – Acts Inconsistent with the Public Interest
Failure to Query PMP MyRx Every 6 Months
(Respondents Burgner and Gonzalez)

40. Respondents Burger violated NRS 453.164(7) by failing to make a query of her PMP MyRx account from December 10, 2015, and June 23, 2022, to ensure the legitimacy of the prescriptions dispensed under Burgner's DEA registration.

41. Respondent Gonzalez violated NRS 453.164(7) by failing to make a query of his PMP MyRx account between January 29, 2018, to April 7, 2022, to ensure the legitimacy of the prescriptions dispensed under Burgner's DEA registration.

42. By failing to make queries of their PMP MyRx accounts at least once every six months, Respondents Burgner and Gonzalez performed their duties in an incompetent, unskillful or negligent manner which constituted unprofessional conduct, as defined by NAC 639.945(1)(i) and NRS 639.210(4), and which renders their continued registration to prescribe controlled substances inconsistent with the public interest pursuant to NRS 453.236(1)(d) and/or (e). Therefore, Respondents Burgner and Gonzalez are subject to discipline pursuant to NRS 639.210(4); and/or NRS 639.255; and/or NRS 453.236(1)(d) or (e); and/or NRS 453.241.

43. WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 18th day of March 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KARRI BURGNER, APRN,** **Certificate of Registration No. CS15148,** **Respondent.**	**Case No. 22-247-CS-A-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 18th day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KARRI BURGNER, APRN,** **Certificate of Registration No. CS15148,** **Respondent.**	**Case No. 22-247-CS-A-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

KARRI BURGNER, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 19th day of March, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Karri Burgner
[redacted]
Sparks, NV [redacted]

Karri Burgner
[redacted]
Reno, NV [redacted]

Ricardo Gonzalez
[redacted]
Reno, NV [redacted]

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

FILED
APR - 8 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KARRI BURGNER, APRN,** **Certificate of Registration No. CS15148,** **Respondent.**	**Case No. 22-247-CS-A-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

From: karri burgner
To: Board Coordination; Gus Vanderdonck
Cc: Brett Kandt; Darlene Nases
Subject: Response to Case No. 22-247-CS-A-N
Date: Friday, April 5, 2024 6:24:33 PM

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

April 5, 2024

To Nevada State Board of Pharmacy,

Please consider this my response to the complaint I received on March 22, 2024.

In October of 2022 the Nevada State Board of Pharmacy filed this same complaint with the Nevada State Board of Nursing. This complaint involved the same patient, same time frame, and same allegations. The case number for this was 2022090123.

A full investigation was conducted and I reached an agreement with the Nevada State Board of Nursing. I acknowledged that I did not check the PMP prior to writing prescriptions for this patient, and that I had not kept up on checking MyRX. During their investigation they recognized that since receiving the complaint in October of 2022 I had significantly changed my PMP practices and was now in compliance with state laws. As a result I received a public reprimand and had to take 3 CME courses; including The Nevada Nurse Practice Act, Upholding the Standard: Professional Accountability in Nursing, and Nurse's Legal Advisor. I received the reprimand documentation on 5/5/23 via email, and everything was approved, completed, and documented as of 11/14/23. I have continued to check PMP reports, as well as MyRX, in compliance with state law ever since.

Please consider withdrawing this complaint as I have already been through an investigation, received a public reprimand, and taken the necessary CME classes related to the same allegations. Please do not hesitate to reach out to me for any further information. I have copies of the original complaint, the agreement, as well as the CME certificates if you would like them.

Thank you for your time and consideration,

Karri Burgner, APRN-BC

5B

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC,** **Pharmacy License No. PH01563, and** **McGUFF COMPANY, INC.,** **Wholesale License No. WH01300,** **Respondents.**	**CASE NOS. 23-070-PH-O** **23-070-WH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent McGuff Compounding Pharmacy Services, Inc, Pharmacy License No. PH01563 (McGuff Pharmacy), located in Santa Ana, California, was a pharmacy licensed by the Board, and McGuff Company, Inc, Wholesale License No. WH01300 (McGuff Company), located in Santa Ana, California, was a medical products wholesale distributor licensed by the Board.

FACTUAL ALLEGATIONS

2. McGuff Pharmacy and McGuff Company are both owned by Ronald M. McGuff.

3. On or about March 1, 2023, the California State Board of Pharmacy entered an Order in Case Nol. 7176 approving a stipulated settlement for voluntary surrender of Respondent McGuff Pharmacy's Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004, for numerous violations of federal and California state law related to compounding drug products, including, without limitation, various provisions of 21 U.S.C. § 353a, 42 U.S.C. §

262, Cal. Business and Professions Code § 4000 *et seq.*, and Cal. Code of Regulations, Title 16, Section 1700 *et seq.* (SEE EXHBIT A HERETO).

APPLICABLE LAW

4. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661 -.690, *inclusive*, and related federal law, 21 U.S.C. § 353a, establishing national standards for compounding medications. *See also* 42 U.S.C. § 262 (regulation of biological products).

5. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

7. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

8. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal and State Compounding Law/Unprofessional Conduct

8. Respondents, their owner, and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i) and violated various provisions of 21 U.S.C. § 353a,

42 U.S.C. § 262, Cal. Business and Professions Code § 4000 *et seq*., and Cal. Code of Regulations, Title 16, Section 1700 *et seq*. as detailed in the California State Board of Pharmacy's Order entered in Case Nol. 7176. Respondents are responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses of these Respondents.

Signed this 28th day of February 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

Exhibit A

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

January 30, 2023

CERTIFIED MAIL

McGuff Compounding Pharmacy Services Inc.
Attn: Ronald McGuff, President
2921 W. MacArthur Blvd, Suite 142
Santa Ana, CA 92704

RE: Administrative Case No. 7176
McGuff Compounding Pharmacy Services Inc., PHY 43950 & LSC 99004

Dear Mr. McGuff:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order regarding the above-referenced matter. Your attention is directed to pages 4 - 8 of the document.

Effective at 5:00 p.m. on March 1, 2023, Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc., is hereby surrendered and accepted by the Board and subject to the terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, Administrative Case Analyst, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

Enclosure(s)
cc: Desiree I. Kellogg, DAG
Joshua A. Room, SDAG
Tony J. Park, Pharm.D., J.D.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7176
McGuff Compounding Pharmacy Services Inc., PHY 43950 & LSC 99004

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
McGuff Compounding Pharmacy Services Inc. Attn: Ronald McGuff, President 2921 W. MacArthur Blvd, Suite 142 Santa Ana, CA 92704	7013 2630 0001 5115 0571
Tony J. Park, Pharm.D., J.D. California Pharmacy Lawyers 9090 Irvine Center Drive Irvine, CA 92618-6713	7013 2630 0001 5115 0595

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on January 30, 2023, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 30, 2023, at Sacramento, California.

Susan Cappello, Enforcement Manager

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER

Pharmacy Permit No. PHY 43950
Sterile Compounding License No. LSC 99004,

and

SI VAN PHAM

Pharmacist License No. RPH 49833

Respondents.

Agency Case No. 7176

OAH No. 2021120276

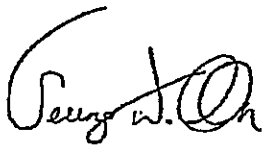
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 1, 2023.

It is so ORDERED on January 30, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
DESIREE I. KELLOGG
Deputy Attorney General
State Bar No. 126461
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9429
Facsimile: (619) 645-2061

JOSHUA A. ROOM
Supervising Deputy Attorney General
State Bar No. 214663
455 Golden Gate Avenue; Suite 11000
San Francisco, CA 94102
Telephone: (415) 510-3512
Facsimile: (415) 703-5480
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 OAH No. 2021120276 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy, Department of Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the Accusation with respect to Respondents McGuff Compounding Pharmacy Services Inc. and Si Van Pham.

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney General, and Joshua A. Room, Supervising Deputy Attorney General.

2. Respondents are represented in this proceeding by attorney Tony J. Park, Pharm.D., J..D., whose address is: California Pharmacy Lawyers, Law Offices of Tony J. Park, Inc., 9090 Irvine Center Drive, Irvine, CA 92618, telephone (949) 336-7854.

3. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc. Ronald M. McGuff has served or been listed in Board records as the sole shareholder and President, Vice-President, and Secretary of McGuff Compounding Pharmacy Services Inc. (Respondent McGuff Compounding aka MCPS). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to Respondent McGuff Compounding aka MCPS. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

5. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Respondent Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed. Respondent Pham has served and been listed in Board records as Pharmacist-in-Charge of Respondent McGuff Compounding aka MCPS since July 9, 2016.

JURISDICTION

6. Accusation No. 7176 was filed before the Board, against Respondents. Accusation No. 7176 and all other statutorily required documents were properly served on Respondents on October 28, 2021. Respondents timely filed their Notice(s) of Defense contesting the Accusation. First Amended Accusation No. 7176 was filed before the Board, and is currently pending against Respondents. The First Amended Accusation and all other statutorily required documents were properly served on Respondents on April 21, 2022. A copy of First Amended Accusation No. 7176 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 7176. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order on their respective permits and licenses.

8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel attendance of witnesses and production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

10. Respondents understand and agree that the charges and allegations in First Amended Accusation No. 7176, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Permit, Sterile Compounding License, and Pharmacist License. For the purposes of resolving this matter without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for charges in the First Amended Accusation, and Respondents hereby give up their right to contest those charges.

11. Respondents agree that their Pharmacy Permit, Sterile Compounding License, and Pharmacist License are each and severally subject to discipline and they agree to be bound by the Board's disciplinary terms as set forth in the Disciplinary Order below.

DESIRED LICENSE CATEGORY TRANSITION

12. Respondent MCPS has decided to seek a transition from being a licensed pharmacy engaged in compounding (a Section 503A facility under federal law) to being a registered and licensed outsourcing facility (a Section 503B facility under federal law). This will entail an application to the Food and Drug Administration (FDA) for registration under Section 503B as an outsourcing facility, and then an application to the Board to be licensed in California as an outsourcing facility. It could take some significant time for MCPS to prepare for and make these applications. In the interim, the MCPS facility will cease functioning as a pharmacy on the effective date of the Decision and Order by the Board of Pharmacy adopting this stipulation.

13. This settlement of the First Amended Accusation does not depend on whether MCPS, any successor or assign thereof, or any entity sharing ownership or management with MCPS, actually submits a subsequent application to the Board for licensure as an outsourcing facility. In the event such application is submitted, the Board will give it the same consideration it would any other application to be licensed as an outsourcing facility. This settlement does not preclude the Board from granting that license. Nor is the Board under any obligation from this settlement to grant that license. Any such application will receive ordinary and fair consideration for licensure. If such an outsourcing facility license is granted, there is one term below that will be applied by the Board to that license, and which Respondent MCPS acknowledges will apply to itself, any successor or assign, or any entity sharing ownership or management with Respondent MCPS.

IMMEDIATE CEASE AND DESIST

14. As of the last date of all signatures on this Stipulated Settlement and Disciplinary Order, both Respondents agree to voluntarily and completely cease and desist compounding, or sales or transfers of compounded preparations, using any active ingredients or drug products named or identified in First Amended Accusation No. 7176, or any other active ingredient or drug product that is not graded for pharmaceutical use.

15. Any compounding by Respondents, or sales or transfers of compounded preparations, using such active ingredients or drug products after that date shall constitute unprofessional conduct and further cause for discipline by both Respondents, and may be considered by the Board in deciding whether to grant or deny any subsequent application by Respondent MCPS, its successor or assign, or any entity sharing ownership or management with Respondent MCPS, including but not limited to a subsequent application for an outsourcing facility license.

CONTINGENCY

16. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

17. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

18. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

19. In consideration of the foregoing, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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DISCIPLINARY ORDER

AS TO RESPONDENT MCGUFF COMPOUNDING AKA MCPS

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 43950, and Sterile Compounding License No. LSC 99004, both issued to Respondent McGuff Compounding aka MCPS, are each and severally surrendered and accepted by the Board.

20. **Definition: Respondent**

For the purposes of paragraphs 20-33, "Respondent" shall refer to Respondent McGuff Compounding aka MCPS. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by Respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

21. The surrender of Respondent's Pharmacy Permit and Sterile Compounding License and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

22. Respondent shall lose all rights and privileges as a pharmacy and to perform sterile compounding in California as of the effective date of the Board's Decision and Order.

23. Respondent shall be jointly and severally liable to the Board, along with Respondent Pham, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order.

24. Within (5) business days of the date this Stipulated Settlement and Disciplinary Order is fully executed, Respondent shall submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the Board. Any transfers of drug inventory shall be conducted in compliance with state and federal law.

25. If permitted by state and federal law, Respondent may transfer current inventory to its commonly-owned facilities as necessary to prepare for testing and other requirements to establish subsequent eligibility for an outsourcing facility registration and/or license.

26. Respondent shall cause to be delivered to the Board its pocket license and, if any were issued, its wall certificates, on or before the effective date of the Decision and Order.

27. Respondent shall also, by the effective date of the Decision and Order, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of its written notice to the Board. For purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

28. Respondent shall also, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

29. Neither Respondent nor its successor or assign, nor any entity sharing ownership or management with Respondent, shall apply to the Board for any permit, license, or registration issued by the Board for a period of three (3) years, except that at any time it is eligible for same:

- Respondent may submit an application for an outsourcing facility license;
- Respondent may apply for a change of location for its wholesaler license (WLS 2947), so long as there is no change in ownership or management structure, or any other substantive change aside from the change in location; and
- Should the Board change the name or category of licensure applicable to the WLS license, Respondent may apply to adopt this change, so long as there is no change in ownership or management structure, or other substantive change.

30. If Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, ever applies for licensure, including as an outsourcing facility, or petitions for reinstatement, the Board shall treat it as a new application for licensure. The applicant/petitioner must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and charges and allegations in First Amended Accusation No. 7176 shall be deemed to be supported by a factual basis and not contested by Respondent when the Board determines whether to grant or deny the application or petition.

31. If an application for an outsourcing facility license is submitted by Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, the Board may in addition consider, in deciding whether to grant or deny that license: whether Respondent met its agreement for the pharmacy to cease and desist compounding, sales, or transfers of drug preparations using active ingredients or drug products named or identified in First Amended Accusation No. 7176, or that are not graded for pharmaceutical use; and whether the Board has received full payment of the costs of investigation and enforcement in this case.

32. If an outsourcing facility license is granted by the Board to Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, that applicant/licensee shall retain, at its own expense, for a period of one (1) year after licensure, an independent consultant for the outsourcing facility approved in advance by the Board or its designee.

33. That independent consultant shall be a pharmacist licensed in good standing by the Board, and shall be responsible for conducting in-person inspections to review the operations of the outsourcing facility on a monthly basis for compliance with applicable state and federal laws. The independent consultant shall prepare and submit written reports directly to Board staff; such reports shall not go first to or be made available to the licensee by the independent consultant.

AS TO RESPONDENT PHAM

IT IS HEREBY ORDERED that Pharmacist License No. RPH 49833, issued to Respondent Pham, is revoked. However, the revocation is stayed and Respondent Pham is placed on probation for thirty-five (35) months on the following terms and conditions:

34. **Definition: Respondent**

For the purposes of paragraphs 34-52, "Respondent" shall refer to Respondent Pham.

35. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime;
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

36. **Report to the Board**

Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

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37. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

38. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

39. **Cooperate with Board Staff**

Respondent shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

40. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current pharmacist license with the Board, including any period during which probation is tolled. Failure to maintain an active, current pharmacist license shall be considered a violation of probation.

If Respondent's pharmacist license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

41. **Submission of Letter to Board**

Respondent shall, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make

whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

42. **Reimbursement of Board Costs**

Respondent shall be jointly and severally liable to the Board, along with Respondent MCPS, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order. It shall be a condition precedent to successful completion of probation that these costs were timely paid. Failure to pay costs by the deadline shall also be considered a violation of probation.

43. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

44. **Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of one hundred (100) hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the Board or its designee.

If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a pharmacist in

California for the minimum of one hundred (100) hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The Board or its designee may post a notice of the extended probation period on its website.

45. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent shall enroll, at Respondent's expense, in a course in ethics approved in advance by the Board or its designee, that complies with California Code of Regulations, title 16, section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, Respondent shall submit a copy of the certificate of completion to the Board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the Board or its designee, shall be considered a violation of probation.

46. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the Board within ninety (90) days of the effective date of this decision and provide written proof thereof to the Board.

Failure to timely divest any legal or beneficial interest(s) or to immediately provide documentation thereof to the Board shall be considered a violation of probation.

47. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall notify the Board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address, or phone number.

Failure to timely notify the board of any change in name, residence or mailing address, email address, or phone number, shall be considered a violation of probation.

48. **Reporting of Employment and Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 7176 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the Board in writing the name, physical address, and mailing address of each employer(s), and the name(s) and telephone number(s) of all direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s), and Respondent's work schedule, if known. Respondent shall also include reason(s) for leaving the prior employment. Respondent shall sign and return to the Board a written consent authorizing the Board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the Board or its designee concerning Respondent's work status, performance, and monitoring.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause his (a) direct supervisor, (b) pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7176, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the Roard in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby.

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If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the Board of the decision in case number 7176, and the terms and conditions imposed thereby, in advance of Respondent commencing work at such licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board.

Failure to timely notify present or prospective employer(s), or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the Board, shall be considered a violation of probation. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist license is a requirement or criterion for employment, whether Respondent is an employee, independent contractor, or volunteer.

49. **Restrictions on Supervision and Oversight of Licensed Facilities –**

During the period of probation, Respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any single entity licensed by the Board, but only if Respondent or that entity retains, at his/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a monthly basis for compliance by Respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by Respondent with the obligations of his supervisory position, for the duration of Respondent's probation period.

Respondent may serve in such a position at only one entity licensed by the Board, only upon approval by the Board or its designee. Any such approval shall be site specific. The consultant shall be a pharmacist licensed by and not on probation with the Board, who has been approved by the Board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the Board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

50. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish his pharmacist license, including any indicia of licensure issued by the Board, along with a request to surrender the license. The Board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender will constitute a record of discipline and shall become a part of the Respondent's license history with the board.

Upon acceptance of the surrender, Respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the Board, within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

51. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

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52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY
SERVICES INC.
Respondent

52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/14/22

Ronald M. McGuff

Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY
SERVICES INC.
Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

SI VAN PHAM
Respondent

I have read and fully discussed with Respondent McGuff Compounding aka MCPS and Respondent Pham the terms and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

TONY J. PARK, PHARM.D., J..D.
CALIFORNIA PHARMACY LAWYERS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General

DESIREE L. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J.D. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12-14-22

SI VAN PHAM
Respondent

I have read and fully discussed with Respondent McGuff Compounding aka MCPS and Respondent Pham the terms and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/14/2022

TONY J. PARK, PHARM.D., J.D.
CALIFORNIA PHARMACY LAWYERS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: December 14, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General

/s/ Desiree I. Kellogg

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
DESIREE I. KELLOGG
Deputy Attorney General
State Bar No. 126461
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9429
Facsimile: (619) 645-2061
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc., Ronald M. McGuff, sole shareholder and President, Vice-President and Secretary and Si Pham, Pharmacist-in-Charge since July 9, 2016 (McGuff Compounding). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

3. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to McGuff Compounding Pharmacy Services Inc. (MCPS). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Si Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed.

JURISDICTION

5. This First Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 *et seq.*) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 *et seq.*).

7. Code section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.

8. Code section 4300.1 states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license

by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

9. Code section 4022 states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____" "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

10. Code section 4023.5 states:

For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

11. Code section 4113, subdivision (c) states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. Code section 4115, subdivision (a) states:

A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

13. Code section 4116, subdivision (a) states:

No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or re-packaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

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14. Code section 4127.1, subdivisions (e)(3) and (f) state:

(e)(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

15. Code section 4127.8, subdivision (a) states:

A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

16. Section 4169 subdivision (a)(2) of the Code state:

(a) A person or entity shall not do any of the following:

...

(2) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

17. Code section 4301 states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or any other state or federal regulatory agency.

...

18. Section 4306.5, subdivision (a) of the Code states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

...

19. Code section 4307, subdivision (a) states:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

20. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

21. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

22. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated.

23. Section 501(a)(2)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 351(a)(2)(A)) states:

A drug or device shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

REGULATORY PROVISIONS

24. California Code of Regulations, title 16, section 1714, subdivision (d) states:

Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

25. California Code of Regulations, title 16, section 1735.1, subdivision (ae) states:

"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

26. California Code of Regulations, title 16, section 1735.2, subdivisions (e), (g) and (h) state:

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

...

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength.

27. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F) states:

For each compounded drug preparation, pharmacy records shall include: A compounding log consisting of a single document containing all of the following: the manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

28. California Code of Regulations, title 16, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency,

quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

29. California Code of Regulations, title 16, section 1735.8, subdivision (a) states:

Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

30. California Code of Regulations, title 16, section 1751.3, subdivision (a) states:

Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled

areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable).

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

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31. California Code of Regulations, title 16, section 1751.4, subdivision (f) states:

Pharmacies preparing-g sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

COST RECOVERY

32. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DEFINITIONS

33. Hydrogen peroxide infusions may be used to treat inflammation, are not Food and Drug Administration (FDA) approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

34. Dimercapto-propane sulfonic acid (DMPS) infusions may be used to treat mercury and other metal poisoning, are not FDA approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

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35. Glutathione infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

36. Lipoic acid infusions may be used to treat nerve pain, are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

37. Methylcobalamin infusions may be used to treat neurological conditions and pain, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

38. Disodium nicotinamide adenine dinucleotide (NADH) infusions may be used to treat Alzheimer's disease and dementia, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

39. Taurine infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

40. MCPS is a sterile compounding pharmacy located in Santa Ana, California. It compounds non-sterile to sterile compounded sterile preparations and furnishes sterile injectable drugs (i.e., infusion therapies) to physicians and clinics for administration to patients. At all times relevant herein, Si Pham was the Pharmacist-in-Charge and Ronald McGuff was the sole shareholder and an officer of the corporation that owns MCPS. Board inspections revealed the following violations of Pharmacy Law.

41. Pharmacy technicians, facility foremen, plant managers, corporate representatives, chemists, engineers and/or other non-licensed staff possessed keys and alarm codes for areas where dangerous drugs were compounded and accessed those areas when pharmacists were not present.

42. In 2017 and 2018, MCPS received reports of adverse drug effects (i.e., headaches, high fevers, diarrhea, extreme fatigue, loss of consciousness, chills and nausea) suffered by patients after being administered infusions of lipoic acid compounded and dispensed by MCPS.

43. In January 2019, the Board issued Compounding Safety Alerts about the use of inappropriate ingredients to compound sterile injectable drugs and strongly encouraged sterile compounding pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action was required. The Board noted that dietary supplements, food grade chemicals, and cosmetic grade ingredients may have as much as ten times more impurities when compared to pharmaceutical grade ingredients, increasing the risk of patient harm. On February 1, 2019, the FDA warned compounders not to use a dietary grade bulk substance distributed by a manufacturer to compound sterile injectable drugs for patients due to higher levels of endotoxins in that dietary grade bulk substance.

44. MCPS compounded and dispensed sterile injectable drugs including hydrogen peroxide 3%, lipoic acid 40mg/ml, DMPS 50mg/ml, NADH 50 mg/ml and methylcobalamin 5mg/ml 30ml using ingredients (i.e., dietary grade, topical grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

45. On November 13, 2019, the Board issued an Order of Correction to MCPS for this unsafe practice and directed Si Pham to send a plan of correction.

46. On November 22, 2019, the FDA issued a Form FDA 483 to MCPS observing among other violations, that MCPS compounded and dispensed sterile injectable drugs with non-pharmaceutical grade ingredients containing high levels of contaminants (MCPS "currently uses …dietary grade bulk substances in sterile injectable drug products") and observed that the use of non-pharmaceutical grade bulk substances in MCPS's products resulted in a recall of Lipoic Acid 40 mg/ml, 30 ml vials due to a "filmy wispy precipitate" found in on-hand vials of released product and the discontinued production of NADH disodium 50 mg/ml due to out of specification endotoxin results.

47. During the "closeout" meeting on November 22, 2019, both the FDA and Board informed Ronald McGuff and Si Pham about the safety risks associated with MCPS's practice of

compounding sterile injectable drugs with inappropriate ingredients containing higher levels of contaminants and higher bioburden levels than pharmaceutical grade ingredients.

48. On December 5, 2019, MCPS wrote the Board that it was MCPS's "continuing desire and intention to comply with all requirements of California pharmacy laws and expectations of the Board of Pharmacy" and it had stopped the dispensing and compounding of sterile preparations compounded with dietary grade and non-compendial grade raw materials "regardless of whether the bulk drug substance appears on the FDA's Category 1 list until further guidance and/or clarification from both the FDA and CA BOP." On December 16, 2019, MCPS wrote the FDA that "[i]n the near term, MCPS has suspended compounding drug preparations containing the components listed in the observation and all USP dietary grade supplements. Drug preparation lots compounded with the listed components will not be dispensed...Corrective Actions for Observation 7: Suspend compounding and dispensing drug preparations utilizing non-pharmaceutical grade components until pharmaceutical grade replacements can be procured or until alternate assurance of material quality and fitness for intended used can be established."

49. However, MCPS continued to compound and dispense a large volume of sterile injectable drugs from inappropriate ingredients, including methylcobalamin and lipoic acid after making those representations to the Board and FDA and receiving the Compounding Safety Alerts.

50. MCPS compounded sterile injectable lipoic acid 40mg/ml 30 ml MDV (Lot No. 18M0991) and DMPS 50mg/ml 5ml SDV (Lot No. 18J1081) containing particulate or precipitate but failed to provide the Board with notice of the recalls of those drugs within twelve hours as required.

51. Patients reported to MCPS that they suffered adverse drug effects (i.e., excruciating pain) from one of its sterile injectable drug products, vitamin D3 10,00IU/ML 30ML MDV (Lot No. 20F1501:0920) but it failed to report those adverse effects to the Board within twelve hours as required.

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52. MCPS compounded sterile injectable chromium (Lot No. 19K411) without a master formula describing the equipment to be used, inactive ingredients to be used and the specific and essential compounding steps used to prepare that infusion.

53. MCPS did not possess all of the policies and procedures required to compound sterile injectable drugs, including procedures for quality assurance programs, cleaning and maintenance of ISO environments and for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process. It also did not possess a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

54. From January 17 through February 23, 2018, there was a 12.6% patch in the HEPA filter of MCPS's primary engineering control devices in Room 107 which was not completely repaired. Yet, MCPS continued to compound at least ten sterile injectable drugs with that primary engineering control device before it was re-certified and tested on February 23, 2018.

55. In November 2019, pharmacy technicians performed prefatory compounding functions, (washed and prepared empty vials) without a pharmacist being present on the premises.

56. In August and September 2020, MCPS failed to document the manufacturer of at least one component for the sterile injectable drug, methylcobalamin.

57. Despite the filing of the Accusation, the discussions with the FDA and Board about safety risks associated with using inappropriate ingredients, the receipt of the FDA Form 483, the receipt of the Board's Order of Correction and the Written Notice and Respondents' promises to cease compounding and dispensing sterile injectable drugs with dietary grade and non-compendial substances, from at least June 1, 2021 through December 1, 2021, MCPS continued to compound and dispense sterile injectable drugs, methylcobalamin 5mg/mL, glutathione 200mg/mL, taurine, lipoic acid and DMPS using inappropriate ingredients (i.e., dietary grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living

on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

58. In 2021, MCPS received reports of at least six adverse drug effects, including headaches, fever, chills and nausea from sterile injectable drugs compounded and dispensed, but failed to timely report at least four of those adverse drug effects to the Board. It also failed to report at least four of the adverse drug effects immediately to the MedWatch Program of the FDA.

59. On January 24, 2022, the Board issued an Order of Correction to Respondents for their continued use of ingredients in sterile injectable products that lacked quality and a Written Notice for the failure to report adverse drug effects to the Board within twelve hours and immediately to the MedWatch Program of the FDA.

FIRST CAUSE FOR DISCIPLINE

(Manufactured, Held, Sold, Offered for Sale and Delivered Adulterated Drugs)

60. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Health and Safety Code section 111295 and Business and Professions Code section 4169, subdivision (a)(2), in that they manufactured, held (including under insanitary conditions), sold, offered for sale and/or delivered drugs that were adulterated within the meaning of Health & Safety Code sections 111250 and/or 111255 and/or 501(a)(2)(A) of the Federal Food Drug and Cosmetic Act (21 U.SC. 351(a)(2)(A)), as set forth above in paragraphs 40 through 59.

SECOND CAUSE FOR DISCIPLINE

(Compounded Sterile Injectable Drugs Lacking in Quality)

61. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivisions (g) and (h), in that they compounded sterile injectable drug products lacking in quality as defined by California Code of Regulations, title 16, section 1735.1, subdivision (ae) and as set forth above in paragraphs 40 through 59.

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THIRD CAUSE FOR DISCIPLINE

(Dishonest Acts)

62. Respondents are subject to disciplinary action under Code section 4301, subdivision (f) in that those Respondents committed dishonest acts when they falsely claimed that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FOURTH CAUSE FOR DISCIPLINE

(Made Documents that Falsely Represent Facts)

63. Respondents subject to disciplinary action under Code section 4301, subdivision (g) in that those Respondents made documents that falsely represented the existence of a state of facts when they represented in writing that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FIFTH CAUSE FOR DISCIPLINE

(Lack of Security for Pharmacy Premises)

64. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4116, subdivision (a) and California Code of Regulations, title 16, section 1714, subdivision (d), in that pharmacy technicians and unlicensed personnel had access to pharmacy premises where dangerous drugs were compounded without a pharmacist being present and had keys to all of the pharmacy premises, as set forth above in paragraphs 40 through 59.

SIXTH CAUSE FOR DISCIPLINE

(Lack of Supervision of Pharmacy Technicians)

65. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4115, subdivision (a) as defined by Business and Professions Code section 4023.5, in that pharmacy technicians washed and prepared empty drug vials without a pharmacist on the premises, as set forth above in paragraphs 40 through 59.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Notify Board of Recall of Sterile Drug Products)

66. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code sections 4127.1, subdivision (e)(3) and 4127.8, subdivision (a) , in that they failed to provide to the Board, within 12 hours, recall notices issued by MCPS for sterile drug products it had compounded, as set forth above in paragraphs 40 through 59.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Report Adverse Drug Effects of Sterile Drug Product)

67. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4127.1, subdivision (f), in that they failed to report to the Board within 12 hours and immediately to the MedWatch program of the FDA, adverse drug effects reported to MCPS, about its sterile injectable drug products, as set forth above in paragraphs 40 through 59.

NINTH CAUSE FOR DISCIPLINE

(Failed to Possess All Policies and Procedures and a Written Quality Assurance Plan for Compounding Sterile Drug Preparations)

68. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, sections 1735.5, 1735.8, subdivision (a) and 1751.3, subdivision (a) because they failed to have all required written policies and procedures for compounding sterile drug preparations and a written quality assurance plan, as set forth in paragraphs 40 through 59 above.

TENTH CAUSE FOR DISCIPLINE

(Compounded with Incomplete Master Formulas)

69. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.2, subdivision (e), in that they compounded sterile injectable drug preparations without a complete written master formula, as set forth in paragraphs 40 through 59 above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Logs)

70. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F), in that they compounded sterile injectable drug preparations without preparing complete compounding logs, as set forth in paragraphs 40 through 59 above.

TWELFTH CAUSE FOR DISCIPLINE

(Compounded Sterile Drug Products in Uncertified Primary Engineering Control)

71. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1751.4, subdivision (f), in that they compounded sterile injectable drug preparations using an inappropriate primary engineering control device, as set forth in paragraphs 40 through 59 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Education, Training or Experience as a Pharmacist Against Respondent Si Pham)

72. Respondent Si Pham is subject to disciplinary action under Code section 4301, subdivision (o), for violating Business and Professions Code section 4306.5, subdivision (a) for his inappropriate exercise of his pharmacist education, training, or experience, as set forth in paragraphs 40 through 59.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

73. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities set forth in paragraphs 40 through 59 above.

DISCIPLINE CONSIDERATIONS

74. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 30, 2019, the Board issued Citation Number CI 2017 80272 to MCPS under Business and Professions Code section 4301, subdivision (n) because it

was disciplined by the Alabama Board of Pharmacy for selling, offering to sell, compounding and/or dispensed drugs into Alabama without a permit. That Citation is now final.

OTHER MATTERS

75. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc., it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated if they are revoked.

76. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Ronald M. McGuff has been a manager or owner and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding Licenses are reinstated, if they are revoked.

77. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Si Van Pham has been a manager and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked.

78. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 49833 issued to Si Van Pham, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if

the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 43950, issued to McGuff Compounding Pharmacy Services Inc.;

2. Revoking or suspending Sterile Compounding License Number LSC 99004, issued to McGuff Compounding Pharmacy Services Inc.;

3. Revoking or suspending Pharmacist License Number RPH 49833, issued to Si Van Pham;

4. Prohibiting McGuff Compounding Pharmacy Services Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

5. Prohibiting Ronald M. McGuff from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

6. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

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7. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 49833 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;

8. Ordering McGuff Compounding Pharmacy Services Inc. and Si Van Pham to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

9. Taking such other and further action as deemed necessary and proper.

DATED: 4/21/2022

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2022.04.21 07:56:10 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SD2021801578/83354838.docx

Members of the Board of Pharmacy:

We, the undersigned, write to you from the perspective of Board licensees who agreed to the imposition of discipline on our pharmacy and pharmacist licenses in the case titled *In the Matter of the Accusation Against McGuff Compounding Pharmacy Services, Inc., et al.*, Board Case No. 7176. We reached a settlement of the Accusation, of which this letter is part.

We wish to forthrightly and unequivocally state, here, that as persons with significant experience in pharmacy compounding, we agree with and support the following statements:

- All compounding pharmacies located in California or which provide services to California patients are governed both by relevant sections of federal statutes and regulations applicable to pharmacy compounding, including but not limited to section 501 [21 U.S.C. § 351] of the Federal Food, Drug, and Cosmetic Act (FDCA), which defines "adulterated" drugs to include those prepared, packed, or held under insanitary conditions, and FDCA section 503A [21 U.S.C. § 353a], which sets forth several federal requirements to engage in traditional pharmacy compounding, and by the California Pharmacy Law and its associated regulations;

- Further, best practices demand that section 503A traditional compounding pharmacies not use bulk drug substances that are not graded, nor those not designated by their manufacturers for pharmaceutical use, nor those lacking an appropriate USP/NF monograph;

- Best practices further demand that section 503A traditional compounding pharmacies only use bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph; (2) if such monograph does not exist, are drug substances that are components of FDA-approved drugs; and (3) if such monograph does not exist and the drug substance is not a component of an FDA-approved drug, then it must be on a list developed by the Secretary through regulations issued by the Secretary under subsection (c); and

- Best practices also demand that section 503A traditional compounding pharmacies: (1) only use bulk drug substances that are manufactured by an FDA-registered establishment; and (2) that are accompanied by valid certificates of analysis for each bulk drug substance.

We look forward to working with the FDA and the Board to be sure that Californians have access to prescribed medications that are held to the highest degree of quality assurance.

McGuff Compounding Pharmacy Services, Inc.

Ronald McGuff, CEO Date

Si Pham, Pharmacist-In-Charge Date

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC,** **Pharmacy License No. PH01563,** **Respondent.**	**Case Nos. 23-070-PH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of February 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC,** **Pharmacy License No. PH01563,** **Respondent.**	**Case No. 23-070-PH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

AUTHORIZED REPRESENTATIVE FOR McGUFF COMPOUNDING PHARMACY SERVICES, INC.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

McGuff Compounding Pharmacy Services, Inc.
2921 W MacArthur Blvd., Ste. 142
Santa Ana, CA 92704

McGUFF COMPANY, INC.
3524 W. Lake Center Drive #B
Santa Ana, CA 92704

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC.,** **Pharmacy License No. PH01563, and** **McGUFF COMPANY, INC.,** **Wholesale License No. WH01300,** **Respondents.**	**CASE NOS. 23-070-PH-O** **23-070-WH-O** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondents McGuff Compounding Pharmacy Services, Inc, expired Pharmacy License No. PH01563 (McGuff Pharmacy), and McGuff Company, Inc, Wholesale License No. WH01300, by and through counsel, Bridget Kelly, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about February 28, 2025, Respondents were served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. Respondent is entering into this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

3. Respondents are fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter

622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents have failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. The cause of action against McGuff Company, Inc, Wholesale License No. WH01300, as set forth in Count 1, Paragraph 8 of the Accusation, is hereby DISMISSED pursuant to NRS 622A.320(4).

7. Respondent McGuff Pharmacy does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. On or about March 1, 2023, the California State Board of Pharmacy entered an Order in Case Nol. 7176 approving a stipulated settlement for voluntary surrender of Respondent McGuff Pharmacy's Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004, for numerous violations of federal and California state law related to compounding drug products, including, without limitation, various provisions of 21 U.S.C. § 353a, 42 U.S.C. § 262, Cal. Business and Professions Code § 4000 *et seq*., and Cal. Code of Regulations, Title 16, Section 1700 *et seq*.

B. Respondent McGuff Pharmacy, its owner, and/or its personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i) and violated various provisions of 21 U.S.C. § 353a, 42 U.S.C. § 262, Cal. Business and Professions Code § 4000 *et seq*., and Cal. Code of Regulations, Title 16, Section 1700 *et seq*. as detailed in the California State Board of Pharmacy's Order entered in Case Nol. 7176. Respondent McGuff Pharmacy is responsible for

those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

8. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties:

A. The expired pharmacy license of McGuff Compounding Pharmacy Services, Inc, Pharmacy License No. PH01563, is revoked pursuant to NRS 639.255(1)(d);

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2025; and

C. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2025.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon that Respondent not inconsistent with the provisions of NRS Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 3, 2025.

Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents have fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 8 day of AUGUST 2025

McGUFF COMPOUNDING PHARMACY SERVICES, INC.
Pharmacy License No. PH01563

Signed this 8 day of AUGUST 2025

McGUFF COMPANY, INC.
Wholesale License No. WH01300

APPROVED AS TO FORM AND CONTENT
this 7th day of August 2025

BRIDGET KELLY, ESQ.
Counsel for Respondents

Signed this ___ day of _____ 2025

BRETT KANDT
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondents McGuff Compounding Pharmacy Services, Inc, Pharmacy License No. PH01563, and McGuff Company, Inc, Wholesale License No. WH01300, in Case Nos. 23-070-PH-O and 23-070-WH-O, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2025.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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FILED
FEB 2 8 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC,** **Pharmacy License No. PH01563, and** **McGUFF COMPANY, INC.,** **Wholesale License No. WH01300,** **Respondents.**	**CASE NOS. 23-070-PH-O** **23-070-WH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent McGuff Compounding Pharmacy Services, Inc, Pharmacy License No. PH01563 (McGuff Pharmacy), located in Santa Ana, California, was a pharmacy licensed by the Board, and McGuff Company, Inc, Wholesale License No. WH01300 (McGuff Company), located in Santa Ana, California, was a medical products wholesale distributor licensed by the Board.

FACTUAL ALLEGATIONS

2. McGuff Pharmacy and McGuff Company are both owned by Ronald M. McGuff.

3. On or about March 1, 2023, the California State Board of Pharmacy entered an Order in Case Nol. 7176 approving a stipulated settlement for voluntary surrender of Respondent McGuff Pharmacy's Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004, for numerous violations of federal and California state law related to compounding drug products, including, without limitation, various provisions of 21 U.S.C. § 353a, 42 U.S.C. §

262, Cal. Business and Professions Code § 4000 *et seq.*, and Cal. Code of Regulations, Title 16, Section 1700 *et seq.* (SEE EXHBIT A HERETO).

APPLICABLE LAW

4. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661 -.690, *inclusive*, and related federal law, 21 U.S.C. § 353a, establishing national standards for compounding medications. *See also* 42 U.S.C. § 262 (regulation of biological products).

5. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

7. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

8. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal and State Compounding Law/Unprofessional Conduct

8. Respondents, their owner, and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i) and violated various provisions of 21 U.S.C. § 353a,

42 U.S.C. § 262, Cal. Business and Professions Code § 4000 *et seq*., and Cal. Code of Regulations, Title 16, Section 1700 *et seq*. as detailed in the California State Board of Pharmacy's Order entered in Case Nol. 7176. Respondents are responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses of these Respondents.

Signed this 26th day of February 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

Exhibit A

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

January 30, 2023

CERTIFIED MAIL

McGuff Compounding Pharmacy Services Inc.
Attn: Ronald McGuff, President
2921 W. MacArthur Blvd, Suite 142
Santa Ana, CA 92704

RE: Administrative Case No. 7176
McGuff Compounding Pharmacy Services Inc., PHY 43950 & LSC 99004

Dear Mr. McGuff:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order regarding the above-referenced matter. Your attention is directed to pages 4 - 8 of the document.

Effective at 5:00 p.m. on March 1, 2023, Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc., is hereby surrendered and accepted by the Board and subject to the terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, Administrative Case Analyst, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

Enclosure(s)
cc: Desiree I. Kellogg, DAG
Joshua A. Room, SDAG
Tony J. Park, Pharm.D., J.D.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7176
McGuff Compounding Pharmacy Services Inc., PHY 43950 & LSC 99004

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
McGuff Compounding Pharmacy Services Inc. Attn: Ronald McGuff, President 2921 W. MacArthur Blvd, Suite 142 Santa Ana, CA 92704	7013 2630 0001 5115 0571
Tony J. Park, Pharm.D., J.D. California Pharmacy Lawyers 9090 Irvine Center Drive Irvine, CA 92618-6713	7013 2630 0001 5115 0595

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on January 30, 2023, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 30, 2023, at Sacramento, California.

Susan Cappello, Enforcement Manager

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER

Pharmacy Permit No. PHY 43950
Sterile Compounding License No. LSC 99004,

and

SI VAN PHAM

Pharmacist License No. RPH 49833

Respondents.

Agency Case No. 7176

OAH No. 2021120276

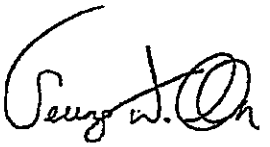
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 1, 2023.

It is so ORDERED on January 30, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
DESIREE I. KELLOGG
Deputy Attorney General
State Bar No. 126461
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9429
Facsimile: (619) 645-2061

JOSHUA A. ROOM
Supervising Deputy Attorney General
State Bar No. 214663
455 Golden Gate Avenue; Suite 11000
San Francisco, CA 94102
Telephone: (415) 510-3512
Facsimile: (415) 703-5480
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 OAH No. 2021120276 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy, Department of Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the Accusation with respect to Respondents McGuff Compounding Pharmacy Services Inc. and Si Van Pham.

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney General, and Joshua A. Room, Supervising Deputy Attorney General.

2. Respondents are represented in this proceeding by attorney Tony J. Park, Pharm.D., J.D., whose address is: California Pharmacy Lawyers, Law Offices of Tony J. Park, Inc., 9090 Irvine Center Drive, Irvine, CA 92618, telephone (949) 336-7854.

3. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc. Ronald M. McGuff has served or been listed in Board records as the sole shareholder and President, Vice-President, and Secretary of McGuff Compounding Pharmacy Services Inc. (Respondent McGuff Compounding aka MCPS). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to Respondent McGuff Compounding aka MCPS. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

5. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Respondent Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed. Respondent Pham has served and been listed in Board records as Pharmacist-in-Charge of Respondent McGuff Compounding aka MCPS since July 9, 2016.

JURISDICTION

6. Accusation No. 7176 was filed before the Board, against Respondents. Accusation No. 7176 and all other statutorily required documents were properly served on Respondents on October 28, 2021. Respondents timely filed their Notice(s) of Defense contesting the Accusation. First Amended Accusation No. 7176 was filed before the Board, and is currently pending against Respondents. The First Amended Accusation and all other statutorily required documents were properly served on Respondents on April 21, 2022. A copy of First Amended Accusation No. 7176 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 7176. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order on their respective permits and licenses.

8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel attendance of witnesses and production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

10. Respondents understand and agree that the charges and allegations in First Amended Accusation No. 7176, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Permit, Sterile Compounding License, and Pharmacist License. For the purposes of resolving this matter without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for charges in the First Amended Accusation, and Respondents hereby give up their right to contest those charges.

11. Respondents agree that their Pharmacy Permit, Sterile Compounding License, and Pharmacist License are each and severally subject to discipline and they agree to be bound by the Board's disciplinary terms as set forth in the Disciplinary Order below.

DESIRED LICENSE CATEGORY TRANSITION

12. Respondent MCPS has decided to seek a transition from being a licensed pharmacy engaged in compounding (a Section 503A facility under federal law) to being a registered and licensed outsourcing facility (a Section 503B facility under federal law). This will entail an application to the Food and Drug Administration (FDA) for registration under Section 503B as an outsourcing facility, and then an application to the Board to be licensed in California as an outsourcing facility. It could take some significant time for MCPS to prepare for and make these applications. In the interim, the MCPS facility will cease functioning as a pharmacy on the effective date of the Decision and Order by the Board of Pharmacy adopting this stipulation.

13. This settlement of the First Amended Accusation does not depend on whether MCPS, any successor or assign thereof, or any entity sharing ownership or management with MCPS, actually submits a subsequent application to the Board for licensure as an outsourcing facility. In the event such application is submitted, the Board will give it the same consideration it would any other application to be licensed as an outsourcing facility. This settlement does not preclude the Board from granting that license. Nor is the Board under any obligation from this settlement to grant that license. Any such application will receive ordinary and fair consideration for licensure. If such an outsourcing facility license is granted, there is one term below that will be applied by the Board to that license, and which Respondent MCPS acknowledges will apply to itself, any successor or assign, or any entity sharing ownership or management with Respondent MCPS.

IMMEDIATE CEASE AND DESIST

14. As of the last date of all signatures on this Stipulated Settlement and Disciplinary Order, both Respondents agree to voluntarily and completely cease and desist compounding, or sales or transfers of compounded preparations, using any active ingredients or drug products named or identified in First Amended Accusation No. 7176, or any other active ingredient or drug product that is not graded for pharmaceutical use.

15. Any compounding by Respondents, or sales or transfers of compounded preparations, using such active ingredients or drug products after that date shall constitute unprofessional conduct and further cause for discipline by both Respondents, and may be considered by the Board in deciding whether to grant or deny any subsequent application by Respondent MCPS, its successor or assign, or any entity sharing ownership or management with Respondent MCPS, including but not limited to a subsequent application for an outsourcing facility license.

CONTINGENCY

16. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

17. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

18. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

19. In consideration of the foregoing, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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DISCIPLINARY ORDER

AS TO RESPONDENT MCGUFF COMPOUNDING AKA MCPS

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 43950, and Sterile Compounding License No. LSC 99004, both issued to Respondent McGuff Compounding aka MCPS, are each and severally surrendered and accepted by the Board.

20. **Definition: Respondent**

For the purposes of paragraphs 20-33, "Respondent" shall refer to Respondent McGuff Compounding aka MCPS. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by Respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

21. The surrender of Respondent's Pharmacy Permit and Sterile Compounding License and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

22. Respondent shall lose all rights and privileges as a pharmacy and to perform sterile compounding in California as of the effective date of the Board's Decision and Order.

23. Respondent shall be jointly and severally liable to the Board, along with Respondent Pham, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order.

24. Within (5) business days of the date this Stipulated Settlement and Disciplinary Order is fully executed, Respondent shall submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the Board. Any transfers of drug inventory shall be conducted in compliance with state and federal law.

25. If permitted by state and federal law, Respondent may transfer current inventory to its commonly-owned facilities as necessary to prepare for testing and other requirements to establish subsequent eligibility for an outsourcing facility registration and/or license.

26. Respondent shall cause to be delivered to the Board its pocket license and, if any were issued, its wall certificates, on or before the effective date of the Decision and Order.

27. Respondent shall also, by the effective date of the Decision and Order, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of its written notice to the Board. For purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

28. Respondent shall also, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

29. Neither Respondent nor its successor or assign, nor any entity sharing ownership or management with Respondent, shall apply to the Board for any permit, license, or registration issued by the Board for a period of three (3) years, except that at any time it is eligible for same:

- Respondent may submit an application for an outsourcing facility license;
- Respondent may apply for a change of location for its wholesaler license (WLS 2947), so long as there is no change in ownership or management structure, or any other substantive change aside from the change in location; and
- Should the Board change the name or category of licensure applicable to the WLS license, Respondent may apply to adopt this change, so long as there is no change in ownership or management structure, or other substantive change.

30. If Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, ever applies for licensure, including as an outsourcing facility, or petitions for reinstatement, the Board shall treat it as a new application for licensure. The applicant/petitioner must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and charges and allegations in First Amended Accusation No. 7176 shall be deemed to be supported by a factual basis and not contested by Respondent when the Board determines whether to grant or deny the application or petition.

31. If an application for an outsourcing facility license is submitted by Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, the Board may in addition consider, in deciding whether to grant or deny that license: whether Respondent met its agreement for the pharmacy to cease and desist compounding, sales, or transfers of drug preparations using active ingredients or drug products named or identified in First Amended Accusation No. 7176, or that are not graded for pharmaceutical use; and whether the Board has received full payment of the costs of investigation and enforcement in this case.

32. If an outsourcing facility license is granted by the Board to Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, that applicant/licensee shall retain, at its own expense, for a period of one (1) year after licensure, an independent consultant for the outsourcing facility approved in advance by the Board or its designee.

33. That independent consultant shall be a pharmacist licensed in good standing by the Board, and shall be responsible for conducting in-person inspections to review the operations of the outsourcing facility on a monthly basis for compliance with applicable state and federal laws. The independent consultant shall prepare and submit written reports directly to Board staff; such reports shall not go first to or be made available to the licensee by the independent consultant.

AS TO RESPONDENT PHAM

IT IS HEREBY ORDERED that Pharmacist License No. RPH 49833, issued to Respondent Pham, is revoked. However, the revocation is stayed and Respondent Pham is placed on probation for thirty-five (35) months on the following terms and conditions:

34. **Definition: Respondent**

For the purposes of paragraphs 34-52, "Respondent" shall refer to Respondent Pham.

35. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime;
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

36. **Report to the Board**

Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

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37. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

38. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

39. **Cooperate with Board Staff**

Respondent shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

40. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current pharmacist license with the Board, including any period during which probation is tolled. Failure to maintain an active, current pharmacist license shall be considered a violation of probation.

If Respondent's pharmacist license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

41. **Submission of Letter to Board**

Respondent shall, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make

whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

42. **Reimbursement of Board Costs**

Respondent shall be jointly and severally liable to the Board, along with Respondent MCPS, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order. It shall be a condition precedent to successful completion of probation that these costs were timely paid. Failure to pay costs by the deadline shall also be considered a violation of probation.

43. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

44. **Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of one hundred (100) hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the Board or its designee.

If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a pharmacist in

California for the minimum of one hundred (100) hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The Board or its designee may post a notice of the extended probation period on its website.

45. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent shall enroll, at Respondent's expense, in a course in ethics approved in advance by the Board or its designee, that complies with California Code of Regulations, title 16, section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, Respondent shall submit a copy of the certificate of completion to the Board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the Board or its designee, shall be considered a violation of probation.

46. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the Board within ninety (90) days of the effective date of this decision and provide written proof thereof to the Board.

Failure to timely divest any legal or beneficial interest(s) or to immediately provide documentation thereof to the Board shall be considered a violation of probation.

47. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall notify the Board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address, or phone number.

Failure to timely notify the board of any change in name, residence or mailing address, email address, or phone number, shall be considered a violation of probation.

48. **Reporting of Employment and Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 7176 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the Board in writing the name, physical address, and mailing address of each employer(s), and the name(s) and telephone number(s) of all direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s), and Respondent's work schedule, if known. Respondent shall also include reason(s) for leaving the prior employment. Respondent shall sign and return to the Board a written consent authorizing the Board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the Board or its designee concerning Respondent's work status, performance, and monitoring.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause his (a) direct supervisor, (b) pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7176, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the Roard in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby.

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If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the Board of the decision in case number 7176, and the terms and conditions imposed thereby, in advance of Respondent commencing work at such licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board.

Failure to timely notify present or prospective employer(s), or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the Board, shall be considered a violation of probation. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist license is a requirement or criterion for employment, whether Respondent is an employee, independent contractor, or volunteer.

49. **Restrictions on Supervision and Oversight of Licensed Facilities –**

During the period of probation, Respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any single entity licensed by the Board, but only if Respondent or that entity retains, at his/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a monthly basis for compliance by Respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by Respondent with the obligations of his supervisory position, for the duration of Respondent's probation period.

Respondent may serve in such a position at only one entity licensed by the Board, only upon approval by the Board or its designee. Any such approval shall be site specific. The consultant shall be a pharmacist licensed by and not on probation with the Board, who has been approved by the Board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the Board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

50. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish his pharmacist license, including any indicia of licensure issued by the Board, along with a request to surrender the license. The Board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender will constitute a record of discipline and shall become a part of the Respondent's license history with the board.

Upon acceptance of the surrender, Respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the Board, within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

51. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

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52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY
SERVICES INC.
Respondent

52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/14/22

Ronald M. McGuff

Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY SERVICES INC.
Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

SI VAN PHAM
Respondent

I have read and fully discussed with Respondent McGuff Compounding aka MCPS and Respondent Pham the terms and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

TONY J. PARK, PHARM.D., J..D.
CALIFORNIA PHARMACY LAWYERS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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DATED: 12/14/2022

TONY J. PARK, PHARM.D., J..D.
CALIFORNIA PHARMACY LAWYERS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: December 14, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General

/s/ Desiree I. Kellogg

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
DESIREE I. KELLOGG
Deputy Attorney General
State Bar No. 126461
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9429
Facsimile: (619) 645-2061
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc., Ronald M. McGuff, sole shareholder and President, Vice-President and Secretary and Si Pham, Pharmacist-in-Charge since July 9, 2016 (McGuff Compounding). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

3. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to McGuff Compounding Pharmacy Services Inc. (MCPS). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Si Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed.

JURISDICTION

5. This First Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 *et seq.*) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 *et seq.*).

7. Code section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.

8. Code section 4300.1 states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license

by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

9. Code section 4022 states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____" "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

10. Code section 4023.5 states:

For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

11. Code section 4113, subdivision (c) states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. Code section 4115, subdivision (a) states:

A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

13. Code section 4116, subdivision (a) states:

No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or re-packaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

///

14. Code section 4127.1, subdivisions (e)(3) and (f) state:

(e)(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

15. Code section 4127.8, subdivision (a) states:

A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

16. Section 4169 subdivision (a)(2) of the Code state:

(a) A person or entity shall not do any of the following:

...

(2) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

17. Code section 4301 states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or any other state or federal regulatory agency.

...

18. Section 4306.5, subdivision (a) of the Code states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

...

19. Code section 4307, subdivision (a) states:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

20. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

21. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

22. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated.

23. Section 501(a)(2)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 351(a)(2)(A)) states:

A drug or device shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

REGULATORY PROVISIONS

24. California Code of Regulations, title 16, section 1714, subdivision (d) states:

Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

25. California Code of Regulations, title 16, section 1735.1, subdivision (ae) states:

"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

26. California Code of Regulations, title 16, section 1735.2, subdivisions (e), (g) and (h) state:

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

...

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength.

27. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F) states:

For each compounded drug preparation, pharmacy records shall include: A compounding log consisting of a single document containing all of the following: the manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

28. California Code of Regulations, title 16, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency,

quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

29. California Code of Regulations, title 16, section 1735.8, subdivision (a) states:

Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

30. California Code of Regulations, title 16, section 1751.3, subdivision (a) states:

Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled

areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable).

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

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31. California Code of Regulations, title 16, section 1751.4, subdivision (f) states:

Pharmacies preparing-g sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

COST RECOVERY

32. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DEFINITIONS

33. Hydrogen peroxide infusions may be used to treat inflammation, are not Food and Drug Administration (FDA) approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

34. Dimercapto-propane sulfonic acid (DMPS) infusions may be used to treat mercury and other metal poisoning, are not FDA approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

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35. Glutathione infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

36. Lipoic acid infusions may be used to treat nerve pain, are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

37. Methylcobalamin infusions may be used to treat neurological conditions and pain, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

38. Disodium nicotinamide adenine dinucleotide (NADH) infusions may be used to treat Alzheimer's disease and dementia, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

39. Taurine infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

40. MCPS is a sterile compounding pharmacy located in Santa Ana, California. It compounds non-sterile to sterile compounded sterile preparations and furnishes sterile injectable drugs (i.e., infusion therapies) to physicians and clinics for administration to patients. At all times relevant herein, Si Pham was the Pharmacist-in-Charge and Ronald McGuff was the sole shareholder and an officer of the corporation that owns MCPS. Board inspections revealed the following violations of Pharmacy Law.

41. Pharmacy technicians, facility foremen, plant managers, corporate representatives, chemists, engineers and/or other non-licensed staff possessed keys and alarm codes for areas where dangerous drugs were compounded and accessed those areas when pharmacists were not present.

42. In 2017 and 2018, MCPS received reports of adverse drug effects (i.e., headaches, high fevers, diarrhea, extreme fatigue, loss of consciousness, chills and nausea) suffered by patients after being administered infusions of lipoic acid compounded and dispensed by MCPS.

43. In January 2019, the Board issued Compounding Safety Alerts about the use of inappropriate ingredients to compound sterile injectable drugs and strongly encouraged sterile compounding pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action was required. The Board noted that dietary supplements, food grade chemicals, and cosmetic grade ingredients may have as much as ten times more impurities when compared to pharmaceutical grade ingredients, increasing the risk of patient harm. On February 1, 2019, the FDA warned compounders not to use a dietary grade bulk substance distributed by a manufacturer to compound sterile injectable drugs for patients due to higher levels of endotoxins in that dietary grade bulk substance.

44. MCPS compounded and dispensed sterile injectable drugs including hydrogen peroxide 3%, lipoic acid 40mg/ml, DMPS 50mg/ml, NADH 50 mg/ml and methylcobalamin 5mg/ml 30ml using ingredients (i.e., dietary grade, topical grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

45. On November 13, 2019, the Board issued an Order of Correction to MCPS for this unsafe practice and directed Si Pham to send a plan of correction.

46. On November 22, 2019, the FDA issued a Form FDA 483 to MCPS observing among other violations, that MCPS compounded and dispensed sterile injectable drugs with non-pharmaceutical grade ingredients containing high levels of contaminants (MCPS "currently uses …dietary grade bulk substances in sterile injectable drug products") and observed that the use of non-pharmaceutical grade bulk substances in MCPS's products resulted in a recall of Lipoic Acid 40 mg/ml, 30 ml vials due to a "filmy wispy precipitate" found in on-hand vials of released product and the discontinued production of NADH disodium 50 mg/ml due to out of specification endotoxin results.

47. During the "closeout" meeting on November 22, 2019, both the FDA and Board informed Ronald McGuff and Si Pham about the safety risks associated with MCPS's practice of

compounding sterile injectable drugs with inappropriate ingredients containing higher levels of contaminants and higher bioburden levels than pharmaceutical grade ingredients.

48. On December 5, 2019, MCPS wrote the Board that it was MCPS's "continuing desire and intention to comply with all requirements of California pharmacy laws and expectations of the Board of Pharmacy" and it had stopped the dispensing and compounding of sterile preparations compounded with dietary grade and non-compendial grade raw materials "regardless of whether the bulk drug substance appears on the FDA's Category 1 list until further guidance and/or clarification from both the FDA and CA BOP." On December 16, 2019, MCPS wrote the FDA that "[i]n the near term, MCPS has suspended compounding drug preparations containing the components listed in the observation and all USP dietary grade supplements. Drug preparation lots compounded with the listed components will not be dispensed...Corrective Actions for Observation 7: Suspend compounding and dispensing drug preparations utilizing non-pharmaceutical grade components until pharmaceutical grade replacements can be procured or until alternate assurance of material quality and fitness for intended used can be established."

49. However, MCPS continued to compound and dispense a large volume of sterile injectable drugs from inappropriate ingredients, including methylcobalamin and lipoic acid after making those representations to the Board and FDA and receiving the Compounding Safety Alerts.

50. MCPS compounded sterile injectable lipoic acid 40mg/ml 30 ml MDV (Lot No. 18M0991) and DMPS 50mg/ml 5ml SDV (Lot No. 18J1081) containing particulate or precipitate but failed to provide the Board with notice of the recalls of those drugs within twelve hours as required.

51. Patients reported to MCPS that they suffered adverse drug effects (i.e., excruciating pain) from one of its sterile injectable drug products, vitamin D3 10,00IU/ML 30ML MDV (Lot No. 20F1501:0920) but it failed to report those adverse effects to the Board within twelve hours as required.

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52. MCPS compounded sterile injectable chromium (Lot No. 19K411) without a master formula describing the equipment to be used, inactive ingredients to be used and the specific and essential compounding steps used to prepare that infusion.

53. MCPS did not possess all of the policies and procedures required to compound sterile injectable drugs, including procedures for quality assurance programs, cleaning and maintenance of ISO environments and for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process. It also did not possess a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

54. From January 17 through February 23, 2018, there was a 12.6% patch in the HEPA filter of MCPS's primary engineering control devices in Room 107 which was not completely repaired. Yet, MCPS continued to compound at least ten sterile injectable drugs with that primary engineering control device before it was re-certified and tested on February 23, 2018.

55. In November 2019, pharmacy technicians performed prefatory compounding functions, (washed and prepared empty vials) without a pharmacist being present on the premises.

56. In August and September 2020, MCPS failed to document the manufacturer of at least one component for the sterile injectable drug, methylcobalamin.

57. Despite the filing of the Accusation, the discussions with the FDA and Board about safety risks associated with using inappropriate ingredients, the receipt of the FDA Form 483, the receipt of the Board's Order of Correction and the Written Notice and Respondents' promises to cease compounding and dispensing sterile injectable drugs with dietary grade and non-compendial substances, from at least June 1, 2021 through December 1, 2021, MCPS continued to compound and dispense sterile injectable drugs, methylcobalamin 5mg/mL, glutathione 200mg/mL, taurine, lipoic acid and DMPS using inappropriate ingredients (i.e., dietary grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living

on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

58. In 2021, MCPS received reports of at least six adverse drug effects, including headaches, fever, chills and nausea from sterile injectable drugs compounded and dispensed, but failed to timely report at least four of those adverse drug effects to the Board. It also failed to report at least four of the adverse drug effects immediately to the MedWatch Program of the FDA.

59. On January 24, 2022, the Board issued an Order of Correction to Respondents for their continued use of ingredients in sterile injectable products that lacked quality and a Written Notice for the failure to report adverse drug effects to the Board within twelve hours and immediately to the MedWatch Program of the FDA.

FIRST CAUSE FOR DISCIPLINE

(Manufactured, Held, Sold, Offered for Sale and Delivered Adulterated Drugs)

60. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Health and Safety Code section 111295 and Business and Professions Code section 4169, subdivision (a)(2), in that they manufactured, held (including under insanitary conditions), sold, offered for sale and/or delivered drugs that were adulterated within the meaning of Health & Safety Code sections 111250 and/or 111255 and/or 501(a)(2)(A) of the Federal Food Drug and Cosmetic Act (21 U.SC. 351(a)(2)(A)), as set forth above in paragraphs 40 through 59.

SECOND CAUSE FOR DISCIPLINE

(Compounded Sterile Injectable Drugs Lacking in Quality)

61. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivisions (g) and (h), in that they compounded sterile injectable drug products lacking in quality as defined by California Code of Regulations, title 16, section 1735.1, subdivision (ae) and as set forth above in paragraphs 40 through 59.

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THIRD CAUSE FOR DISCIPLINE

(Dishonest Acts)

62. Respondents are subject to disciplinary action under Code section 4301, subdivision (f) in that those Respondents committed dishonest acts when they falsely claimed that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FOURTH CAUSE FOR DISCIPLINE

(Made Documents that Falsely Represent Facts)

63. Respondents subject to disciplinary action under Code section 4301, subdivision (g) in that those Respondents made documents that falsely represented the existence of a state of facts when they represented in writing that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FIFTH CAUSE FOR DISCIPLINE

(Lack of Security for Pharmacy Premises)

64. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4116, subdivision (a) and California Code of Regulations, title 16, section 1714, subdivision (d), in that pharmacy technicians and unlicensed personnel had access to pharmacy premises where dangerous drugs were compounded without a pharmacist being present and had keys to all of the pharmacy premises, as set forth above in paragraphs 40 through 59.

SIXTH CAUSE FOR DISCIPLINE

(Lack of Supervision of Pharmacy Technicians)

65. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4115, subdivision (a) as defined by Business and Professions Code section 4023.5, in that pharmacy technicians washed and prepared empty drug vials without a pharmacist on the premises, as set forth above in paragraphs 40 through 59.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Notify Board of Recall of Sterile Drug Products)

66. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code sections 4127.1, subdivision (e)(3) and 4127.8, subdivision (a) , in that they failed to provide to the Board, within 12 hours, recall notices issued by MCPS for sterile drug products it had compounded, as set forth above in paragraphs 40 through 59.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Report Adverse Drug Effects of Sterile Drug Product)

67. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4127.1, subdivision (f), in that they failed to report to the Board within 12 hours and immediately to the MedWatch program of the FDA, adverse drug effects reported to MCPS, about its sterile injectable drug products, as set forth above in paragraphs 40 through 59.

NINTH CAUSE FOR DISCIPLINE

(Failed to Possess All Policies and Procedures and a Written Quality Assurance Plan for Compounding Sterile Drug Preparations)

68. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, sections 1735.5, 1735.8, subdivision (a) and 1751.3, subdivision (a) because they failed to have all required written policies and procedures for compounding sterile drug preparations and a written quality assurance plan, as set forth in paragraphs 40 through 59 above.

TENTH CAUSE FOR DISCIPLINE

(Compounded with Incomplete Master Formulas)

69. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.2, subdivision (e), in that they compounded sterile injectable drug preparations without a complete written master formula, as set forth in paragraphs 40 through 59 above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Logs)

70. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F), in that they compounded sterile injectable drug preparations without preparing complete compounding logs, as set forth in paragraphs 40 through 59 above.

TWELFTH CAUSE FOR DISCIPLINE

(Compounded Sterile Drug Products in Uncertified Primary Engineering Control)

71. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1751.4, subdivision (f), in that they compounded sterile injectable drug preparations using an inappropriate primary engineering control device, as set forth in paragraphs 40 through 59 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Education, Training or Experience as a Pharmacist Against Respondent Si Pham)

72. Respondent Si Pham is subject to disciplinary action under Code section 4301, subdivision (o), for violating Business and Professions Code section 4306.5, subdivision (a) for his inappropriate exercise of his pharmacist education, training, or experience, as set forth in paragraphs 40 through 59.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

73. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities set forth in paragraphs 40 through 59 above.

DISCIPLINE CONSIDERATIONS

74. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 30, 2019, the Board issued Citation Number CI 2017 80272 to MCPS under Business and Professions Code section 4301, subdivision (n) because it

was disciplined by the Alabama Board of Pharmacy for selling, offering to sell, compounding and/or dispensed drugs into Alabama without a permit. That Citation is now final.

OTHER MATTERS

75. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc., it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated if they are revoked.

76. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Ronald M. McGuff has been a manager or owner and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding Licenses are reinstated, if they are revoked.

77. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Si Van Pham has been a manager and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked.

78. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 49833 issued to Si Van Pham, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if

the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 43950, issued to McGuff Compounding Pharmacy Services Inc.;

2. Revoking or suspending Sterile Compounding License Number LSC 99004, issued to McGuff Compounding Pharmacy Services Inc.;

3. Revoking or suspending Pharmacist License Number RPH 49833, issued to Si Van Pham;

4. Prohibiting McGuff Compounding Pharmacy Services Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

5. Prohibiting Ronald M. McGuff from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

6. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

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7. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 49833 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;

8. Ordering McGuff Compounding Pharmacy Services Inc. and Si Van Pham to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

9. Taking such other and further action as deemed necessary and proper.

DATED: 4/21/2022

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2022.04.21 07:56:10 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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Members of the Board of Pharmacy:

We, the undersigned, write to you from the perspective of Board licensees who agreed to the imposition of discipline on our pharmacy and pharmacist licenses in the case titled *In the Matter of the Accusation Against McGuff Compounding Pharmacy Services, Inc., et al.*, Board Case No. 7176. We reached a settlement of the Accusation, of which this letter is part.

We wish to forthrightly and unequivocally state, here, that as persons with significant experience in pharmacy compounding, we agree with and support the following statements:

- All compounding pharmacies located in California or which provide services to California patients are governed both by relevant sections of federal statutes and regulations applicable to pharmacy compounding, including but not limited to section 501 [21 U.S.C. § 351] of the Federal Food, Drug, and Cosmetic Act (FDCA), which defines "adulterated" drugs to include those prepared, packed, or held under insanitary conditions, and FDCA section 503A [21 U.S.C. § 353a], which sets forth several federal requirements to engage in traditional pharmacy compounding, and by the California Pharmacy Law and its associated regulations;

- Further, best practices demand that section 503A traditional compounding pharmacies not use bulk drug substances that are not graded, nor those not designated by their manufacturers for pharmaceutical use, nor those lacking an appropriate USP/NF monograph;

- Best practices further demand that section 503A traditional compounding pharmacies only use bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph; (2) if such monograph does not exist, are drug substances that are components of FDA-approved drugs; and (3) if such monograph does not exist and the drug substance is not a component of an FDA-approved drug, then it must be on a list developed by the Secretary through regulations issued by the Secretary under subsection (c); and

- Best practices also demand that section 503A traditional compounding pharmacies: (1) only use bulk drug substances that are manufactured by an FDA-registered establishment; and (2) that are accompanied by valid certificates of analysis for each bulk drug substance.

We look forward to working with the FDA and the Board to be sure that Californians have access to prescribed medications that are held to the highest degree of quality assurance.

McGuff Compounding Pharmacy Services, Inc.

Ronald McGuff, CEO Date

Si Pham, Pharmacist-In-Charge Date

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPANY, INC,** **Wholesale License No. WH01300,** **Respondent.**	**Case Nos. 23-070-WH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 20th day of FEBRUARY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPANY, INC.,** **Wholesale License No. WH01300,** **Respondent.**	**Case No. 23-070-WH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR McGUFF COMPANY, INC.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

McGuff Compounding Pharmacy Services, Inc.
2921 W MacArthur Blvd., Ste. 142
Santa Ana, CA 92704

McGUFF COMPANY, INC.
3524 W. Lake Center Drive #B
Santa Ana, CA 92704

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

McGuff Company, Inc.
3524 W. Lake Center Drive #B
Santa Ana, CA 92704

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC.,** **Pharmacy License No. PH01563, and** **McGUFF COMPANY, INC.,** **Wholesale License No. WH01300,** **Respondents.**	**CASE NOS. 23-070-PH-O** **23-070-WH-O** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondents McGuff Compounding Pharmacy Services, Inc, expired Pharmacy License No. PH01563 (McGuff Pharmacy), and McGuff Company, Inc, Wholesale License No. WH01300, by and through counsel, Bridget Kelly, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about February 28, 2025, Respondents were served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. Respondent is entering into this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

3. Respondents are fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter

622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents have failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. The cause of action against McGuff Company, Inc, Wholesale License No. WH01300, as set forth in Count 1, Paragraph 8 of the Accusation, is hereby DISMISSED pursuant to NRS 622A.320(4).

7. Respondent McGuff Pharmacy does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. On or about March 1, 2023, the California State Board of Pharmacy entered an Order in Case Nol. 7176 approving a stipulated settlement for voluntary surrender of Respondent McGuff Pharmacy's Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004, for numerous violations of federal and California state law related to compounding drug products, including, without limitation, various provisions of 21 U.S.C. § 353a, 42 U.S.C. § 262, Cal. Business and Professions Code § 4000 *et seq*., and Cal. Code of Regulations, Title 16, Section 1700 *et seq*.

B. Respondent McGuff Pharmacy, its owner, and/or its personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i) and violated various provisions of 21 U.S.C. § 353a, 42 U.S.C. § 262, Cal. Business and Professions Code § 4000 *et seq*., and Cal. Code of Regulations, Title 16, Section 1700 *et seq*. as detailed in the California State Board of Pharmacy's Order entered in Case Nol. 7176. Respondent McGuff Pharmacy is responsible for

those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

8. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties:

A. The expired pharmacy license of McGuff Compounding Pharmacy Services, Inc, Pharmacy License No. PH01563, is revoked pursuant to NRS 639.255(1)(d);

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2025; and

C. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2025.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon that Respondent not inconsistent with the provisions of NRS Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 3, 2025.

Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents have fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 8 day of AUGUST 2025

Ronnie M. McGuff

McGUFF COMPOUNDING PHARMACY SERVICES, INC.
Pharmacy License No. PH01563

Signed this 8 day of AUGUST 2025

Ronnie M. McGuff

McGUFF COMPANY, INC.
Wholesale License No. WH01300

APPROVED AS TO FORM AND CONTENT
this 7th day of August 2025

Bridget Kelly

BRIDGET KELLY, ESQ.
Counsel for Respondents

Signed this ___ day of _____ 2025

_____

BRETT KANDT
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondents McGuff Compounding Pharmacy Services, Inc, Pharmacy License No. PH01563, and McGuff Company, Inc, Wholesale License No. WH01300, in Case Nos. 23-070-PH-O and 23-070-WH-O, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2025.

_____

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5D

FILED
JUL 2 4 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #06625,** **Pharmacy License No. PH02556, and** **VICTOREEA S. HARRIS, RPH,** **Certificate of Registration No. 20276,** **Respondents.**	**CASE NOS. 23-314-PH-N** **23-314-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Victoreea S. Harris, RPh (Harris), Certificate of Registration No. 20276, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #06625, Pharmacy License No. PH02556, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Harris was employed as managing pharmacist by CVS Pharmacy #06625 at the time of the events alleged herein.

3. On July 31, 2023, prescriber S.P. issued an electronic prescription for patient J.W. for Yuvafem 10Mcg Vaginal Insert, with directions to take "1 tablet nightly for two weeks, then decrease to twice a week, vaginal 90 days."

4. The prescription was submitted to CVS Pharmacy #06625, where in the course of performing data entry on August 1, 2023, pharmacy staff erroneously entering directions to take

"1 tablet by mouth nightly for two weeks, then decrease to twice a week, vaginal 90 days" and the CVS computer system designated this prescription no. 872597.

5. Harris performed final product verification for prescription no. 872597 on August 1, 2023, and failed to detect the erroneous direction to take by mouth on the label, and prescription no. 872597 was dispensed to J.W.'s husband that day.

6. On or about August 4, 2023, J.W. ingested the first dose of the medication orally and suffered severe stomach cramps.

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Harris)

7. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. Harris engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when she dispensed prescription no. 872597 and failed to detect the erroneous direction to take by mouth on the label, and is therefore subject to discipline pursuant to NRS 639.210(4).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS Pharmacy #06625)

9. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

10. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #06625 is responsible for those violations, including all errors and omissions of Respondent Harris and other pharmacy personnel in filling and dispensing

prescription no. 872597 with the erroneous direction to take by mouth on the label, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 24th day of July 2025

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #06625,** **Pharmacy License No. PH02556,** **Respondent.**	**Case No. 23-314-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #06625,** **Pharmacy License No. PH02556,** **Respondent.**	**Case No. 23-314-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY #06625

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

CVS Pharmacy #6625
1081 Steamboat Pkwy
Reno NV 89521

CVS Pharmacy #6625 c/o
Brian J. Convery, Esq.
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5E

FILED
JUL 24 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #06625,** **Pharmacy License No. PH02556, and** **VICTOREEA S. HARRIS, RPH,** **Certificate of Registration No. 20276,** **Respondents.**	**CASE NOS. 23-314-PH-N** **23-314-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Victoreea S. Harris, RPh (Harris), Certificate of Registration No. 20276, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #06625, Pharmacy License No. PH02556, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Harris was employed as managing pharmacist by CVS Pharmacy #06625 at the time of the events alleged herein.

3. On July 31, 2023, prescriber S.P. issued an electronic prescription for patient J.W. for Yuvafem 10Mcg Vaginal Insert, with directions to take "1 tablet nightly for two weeks, then decrease to twice a week, vaginal 90 days."

4. The prescription was submitted to CVS Pharmacy #06625, where in the course of performing data entry on August 1, 2023, pharmacy staff erroneously entering directions to take

"1 tablet by mouth nightly for two weeks, then decrease to twice a week, vaginal 90 days" and the CVS computer system designated this prescription no. 872597.

5. Harris performed final product verification for prescription no. 872597 on August 1, 2023, and failed to detect the erroneous direction to take by mouth on the label, and prescription no. 872597 was dispensed to J.W.'s husband that day.

6. On or about August 4, 2023, J.W. ingested the first dose of the medication orally and suffered severe stomach cramps.

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Harris)

7. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. Harris engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when she dispensed prescription no. 872597 and failed to detect the erroneous direction to take by mouth on the label, and is therefore subject to discipline pursuant to NRS 639.210(4).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS Pharmacy #06625)

9. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

10. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #06625 is responsible for those violations, including all errors and omissions of Respondent Harris and other pharmacy personnel in filling and dispensing

prescription no. 872597 with the erroneous direction to take by mouth on the label, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 24th day of July 2025

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VICTOREEA S. HARRIS, RPH,** **Certificate of Registration No. 20276,** **Respondent.**	**Case No. 23-314-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VICTOREEA S. HARRIS, RPH,** **Certificate of Registration No. 20276,** **Respondent.**	**Case No. 23-314-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

VICTOREEA S. HARRIS, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Victoreea Harris, RPh
[redacted]
Sparks, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5F

FILED
JUL 24 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL RODOLFO CHACON, MD,** **Certificate of Registration No. CS05273,** **Respondent.**	**CASE NO. 23-348-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because, at the time of the events alleged herein, Respondent Samuel Rodolfo Chacon, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS05273, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about September 5, 2023, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 23-12762-1, summarily suspending Respondent's NSBME License No. 9105 to practice medicine for cause pursuant to NRS 630.326(1), on the basis that Respondent's acts placed the health, safety or welfare of the public at risk of imminent harm.

3. The NSBME subsequently filed 6 separate complaints against Respondent in Case Nos. 23-12762-1, 23-12762-2, 23-12762-3, 23-12762-4, 23-12762-5 and 23-12762-6.

4. On or about September 12, 2023, Board staff served Respondent with notice that the suspension of his NSBME License No. 9105 to practice medicine operated as an immediate suspension of his Certificate of Registration No. CS05273 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

5. On or about June 6, 2025, the NSBME and Respondent entered a settlement agreement and order in Case Nos. 23-12762-1, 23-12762-2, 23-12762-3, 23-12762-4, 23-12762-5 and 23-12762-6 (NBSME's Order), revoking Respondent's NSBME License No. 9105 to practice medicine for cause.

APPLICABLE LAW

6. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

7. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

8. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

9. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board

pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

10. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

11. By the revocation of his NSBME License No. 9105 to practice medicine for cause as detailed in the NSBME's Order, Respondent has performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

COUNT TWO

Revocation of NSBME License for Cause

12. By the revocation of his NSBME License No. 9105 to practice medicine for cause as detailed in the NSBME's Order, Respondent no longer qualifies as a practitioner for registration to dispense controlled substances under federal or state law and his Certificate of Registration No. CS05273 is subject to revocation pursuant to NRS 453.236(1) and NRS 453.241(1).

COUNT THREE

Commission of Acts that Render Registration Inconsistent with the Public Interest

13. By the revocation of his NSBME License No. 9105 to practice medicine for cause as detailed in the NSBME's Order, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL RODOLFO CHACON, MD,** **Certificate of Registration No. CS05273,** **Respondent.**	**CASE NO. 23-348-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL RODOLFO CHACON, MD,** **Certificate of Registration No. CS05273,** **Respondent.**	**CASE NO. 23-348-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

SAMUEL RODOLFO CHACON, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Samuel Chacon, MD c/o
Women's Health Center of Reno
540 W Plumb Lane #200
Reno, NV 89509

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Samuel Chacon, MD
c/o Eric Stryker, Esq.
770 E Warm Springs Rd., Suite 360
Las Vegas, NV 89119

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of the Charges and Complaint Against: **SAMUEL RODOLFO CHACON, M.D., Respondent.**	**Case No.: 23-12762-1**

FILED
SEP - 5 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER OF SUSPENSION AND NOTICE OF HEARING

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board) hereby **IMMEDIATELY SUSPENDS** the license of Samuel Rodolfo Chacon, M.D. (Respondent) from the practice of medicine, pursuant to the Board's authority to regulate the practice of medicine in the State of Nevada pursuant to Nevada Revised Statutes (NRS) Chapter 630.

The IC issues this Order of Suspension (Order) based on its determination that Respondent's acts place the health, safety, or welfare of the public at risk of imminent harm pursuant to NRS 630.326(1).

Prior to the preparation of this Order, Board Staff presented to the IC the following:

1. Respondent is a medical doctor licensed to practice medicine in the State of Nevada (License No. 9105). Respondent was originally licensed by the Board on July 27, 1999, with a specialty listed as Obstetrics/Gynecology since 2003.

2. On November 22, 2022, Respondent lost his hospital privileges at Renown Regional Medical Center (Renown) following a voluntary surrender of his clinical privileges while under, or to avoid, an investigation relating to his professional competence or conduct.

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[1] The Investigative Committee of the Nevada State Board of Medical Examiners is composed of Board members Aury Nagy, M.D., Chairman, Nicola (Nick) M. Spirtos, M.D., F.A.C.O.G., and Ms. Maggie Arias-Petrel.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

3. Following Respondent's November 22, 2022, surrender of hospital privileges at Renown, Respondent held no hospital privileges, and therefore could not deliver any of his prenatal patients.

4. Patient A[2] was a prenatal patient of Respondent when he surrendered his hospital privileges at Renown.

5. On September 8, 2022, Patient A was diagnosed with a twin pregnancy. Patient A's pregnancy was classified as high-risk due to her twin pregnancy and gestational diabetes.

6. From October 26, 2022, until March 30, 2023, Patient A was seen by a high-risk pregnancy specialist on no less than five (5) occasions for high-risk pregnancy and prenatal care including performance of ultrasounds. Due to the fetal growth restriction of Twin A, Patient A was recommended by the high-risk pregnancy specialist to be induced between thirty-six (36) weeks and thirty-six weeks and three days (36.3) weeks gestation.

7. Despite Patient A's classification as a high-risk pregnancy, Respondent failed to refer her to an appropriate care provider who could deliver Patient A, nor did he make arrangements with another physician group who could assume the prenatal care of Patient A for delivery services.

8. On March 31, 2023, Respondent, unable to induce labor or deliver Patient A, instructed her to present to the emergency department at Renown when she went into labor. This resulted in exposure of Patient A and her twin children to unnecessary danger and great risk of harm, as Patient A would not be induced as recommended by the high-risk pregnancy specialist.

9. Board investigations reveal that Respondent is continuing to offer prenatal care to other established patients and advertise for and accept new prenatal patients, despite his lack of hospital privileges and his inability to deliver his patients, and without any relationship with another provider or practice group to whom he could transfer his patients for delivery services.

10. Based on the foregoing, the IC finds that the health, safety, and welfare of the Respondent's patients and the public are at imminent risk of harm if Respondent is permitted to continue practicing medicine, and that an immediate suspension of Respondent's license to

[2] Patient A's true identity is not disclosed herein to protect her privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Order.

practice medicine in the State of Nevada is necessary for the protection of the Public. *See* NRS 630.326(1).

ORDER

IT IS HEREBY ORDERED that the License of Samuel Rodolfo Chacon, M.D. (9105) is **SUMMARILY SUSPENDED** until further order of the IC or Board, and Respondent is **prohibited** from engaging in any acts that constitute the practice of medicine pursuant to NRS 630.020; and

IT IS FURTHER ORDERED that a hearing on this matter is set for the **12th day of October, 2023, at 2:00 p.m.,** at the Board's office located at 9600 Gateway Drive, Reno, Nevada 89521, to determine whether this suspension may continue, unless the parties mutually agree in writing to a different date and/or time. *See* NRS 630.326(2).

DATED this 5th day of September, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

AURY NAGY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **SAMUEL RODOLFO CHACON, M.D.,** **Respondent.**	**Case No. 23-12762-1**

FILED
SEP - 5 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through its counsel, Ian J. Cumings, Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Samuel Rodolfo Chacon, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a physician holding an active license to practice medicine in the State of Nevada (License No. 9105). Respondent was originally licensed by the Board on July 27, 1999, with a specialty in Obstetrics/Gynecology.

2. Patient A[2] was a twenty-six (26) year-old female at the time of the events at issue.

3. On January 26, 2022, Patient A established care with Respondent for routine gynecological care.

4. On September 8, 2022, Patient A was seen by Respondent who diagnosed her with a twin pregnancy via ultrasound testing.

/ / /

[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Aury Nagy, M.D., Chairman, Nicola (Nick) Spirtos, M.D., F.A.C.O.G., and Ms. Maggie Arias-Petrel.

[2] Patient A's true identity is not disclosed herein to protect her privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

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9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

5. On October 26, 2022, Patient A was seen by a perinatologist at a high-risk pregnancy center due to her twin pregnancy and diagnosed with gestational diabetes. Patient A's pregnancy continued to be monitored with serial ultrasounds.

6. On November 22, 2022, Respondent lost his hospital privileges at Renown Regional Medical Center (Renown Hospital) following a voluntary surrender of his clinical privileges while under, or to avoid, an investigation relating to his professional competence or his conduct.

7. On February 8, 2023, Patient A underwent ultrasound testing at the high-risk pregnancy center which indicated Twin A was growth restricted. Following Twin A's diagnosis of growth restriction, Patient A was recommended to deliver sometime between thirty-six (36) and thirty-seven (37) weeks of gestation by her perinatologist and to continue to receive ultrasound testing every two (2) weeks to monitor her pregnancy.

8. On March 30, 2023, at thirty-six (36) weeks pregnant, Patient A underwent further ultrasound testing that was performed by the perinatologist which demonstrated little growth from the previous ultrasound on March 13, 2023. The perinatologist recommended delivery between thirty-six weeks (36) and thirty-six weeks and three days (36.3) weeks.

9. On March 30, 2023, Patient A was seen by Respondent who performed a membrane sweep on Patient A to help induce labor. As Respondent did not have hospital privileges and was unable to fully induce labor in Patient A nor deliver Patient A's children, he instructed her to present to the emergency department at Renown Hospital should she go into labor.

10. Respondent failed to refer Patient A to an appropriate care provider or physician group who could properly induce Patient A for delivery of her pregnancy, despite his knowledge of the perinatologist's delivery recommendation.

11. On April 1, 2023, Patient A had yet to go into labor, and presented to Renown Hospital for delivery of her children within the recommended time given to her by the perinatologist. Patient A ultimately delivered her children by cesarean section on April 2, 2023, at Renown Hospital by a physician with privileges at the hospital.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

COUNT I

NRS 630.301(4) - Malpractice

12. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

13. NRS 630.301(4) provides that malpractice of a Physician is grounds for initiating disciplinary action against a licensee.

14. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

15. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when he rendered medical services to Patient A by failing to make arrangements for Patient A's delivery of her high-risk her twin pregnancy following the loss of his hospital privileges on November 22, 2022. Moreover, Respondent committed malpractice by continuing to see Patient A for obstetrical care without having a relationship with any physician or physician group to appropriately deliver Patient A's pregnancy.

16. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.306(1)(b)(2) - Violation of Standards of Practice Established by Regulation – Failure to Consult

17. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

18. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

19. NAC 630.210 requires a physician to "seek consultation with another provider of health care in doubtful or difficult cases whenever it appears that consultation may enhance the quality of medical services."

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9600 Gateway Drive
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(775) 688-2559

20. Respondent failed to timely seek consultation with an appropriate care provider in regard to Patient A's medical condition from November 22, 2022, through April 2, 2023 to address the doubtfulness of the diagnosis of Patient A's medical condition and such a timely consultation would have confirmed or denied such a diagnosis and may have enhanced the quality of medical care provided to Patient A with regard to the delivery of Patient A's twin pregnancy.

21. By reason of the foregoing, Respondent is subject to discipline by the Nevada State Board of Medical Examiners as provided in NRS 630.352.

COUNT III

NRS 630.306(1)(g) - Continual Failure to Exercise Skill or Diligence

22. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

23. Continual failure by the Respondent to exercise the skill or diligence or use the methods ordinarily exercised under the same circumstances by physicians in good standing practicing in the same specialty or field is grounds for disciplinary action against a licensee pursuant to NRS 630.306(1)(g)

24. Respondent continually failed to exercise skill or diligence as demonstrated by his continuing prenatal care of Patient A without making arrangements or an appropriate referral for the delivery of Patient A's high-risk pregnancy.

25. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352

COUNT IV

NRS 630.306(1)(p) - Unsafe or Unprofessional Conduct

26. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

27. Engaging in any act that is unsafe or unprofessional conduct in accordance with regulations adopted by the Board is grounds for disciplinary action against a licensee pursuant to NRS 630.306(1)(p).

28. As demonstrated by, but not limited to, the above-outlined facts, Respondent's conduct was unsafe and unprofessional when he continued to provide obstetrical care to Patient A without making the proper arrangements with an obstetrical care provider who possessed privileges to practice to deliver Patient A's pregnancy, exposing Patient A and her children to an unacceptable and high-risk of complications during delivery. Respondent's conduct was unsafe and unprofessional.

29. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

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9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 5th day of September, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

IAN J. CUMINGS
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: icumings@medboard.nv.gov
Attorney for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Aury Nagy, M.D., having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 5th day of September, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
AURY NAGY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **SAMUEL RODOLFO CHACON, M.D., Respondent.**	**Case No. 23-12762-2**

FILED
SEP 08 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through its counsel, Deonne E. Contine, General Counsel and Ian J. Cumings, Deputy General Counsel and attorneys for the IC, having a reasonable basis to believe that Samuel Rodolfo Chacon, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a physician holding an active license to practice medicine in the State of Nevada (License No. 9105). Respondent was originally licensed by the Board on July 27, 1999, with a specialty in Obstetrics/Gynecology.

2. Patient A[2] was a sixty-nine (69) year-old female at the time of the events at issue.

3. Records indicate that Respondent first saw Patient A on December 28, 2018, after referral by her primary care physician for evaluation of a six-week medical history of vaginal discharge, at times bloody, that was not responding to antifungal or antibacterial treatment.

4. Respondent's note states that Patient A's chief complaint was vaginal discharge, irregular spotting, and urinary urgency. Respondent states that Patient A had significant urinary

[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Aury Nagy, M.D., Chairman, Nicola (Nick) Spirtos, M.D., F.A.C.O.G., and Ms. Maggie Arias-Petrel.

[2] Patient A's true identity is not disclosed herein to protect her privacy but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

urgency, that she did not feel as if she fully emptied her bladder, and that she gets up to urinate up to three (3) times per night.

5. Respondent discussed with Patient A undergoing a Urodynamic study to assess Patient A's urinary incontinence. Respondent's notes document that Patient A agreed to the testing, which was performed on December 28, 2018, during a scheduled appointment.

6. Records for the Urodynamic study description indicated mild incontinence. However, no testing data or analysis was included in Patient A's medical records.

7. The Assessment/Diagnosis from the December 28, 2018, appointment note Patient A "will proceed with the evaluation of the vulvovaginal atrophy if her symptoms worsen."

8. Respondent's medical records from January 16, 2019, indicated results from a vaginal ultrasound were unremarkable; nevertheless, Patient A was counseled regarding the findings of the ultrasound and the notes stated that she would proceed with further work-up given the concern. Patient A proceeded with a CT scan of the abdomen and pelvis with and without contrast.

9. January 16, 2019, records also indicate that Patient A "has had one episode of unprotected sexual activity but had a normal cycle after the last encounter." However, a normal cycle is hard to imagine in any 69-year-old woman, but especially in a woman who had a hysterectomy. The fact that she had a hysterectomy was documented in Patient A's records on the same page that indicated she had a normal cycle.

10. On January 24, 2019, Patient A had a follow-up appointment where she was counseled regarding the CT scan results which were unremarkable and did not warrant further review. At this appointment another Urodynamics study was described in Patient A's medical records, which noted again, that Patient A had mild incontinence. However once more, no data or analysis regarding the urodynamic testing was included in Patient A's medical records.

11. The January 24, 2019, records further noted that Patient A wished to proceed with an expectant management approach to her incontinence.

12. Seemingly in contradiction to the desire of Patient A to proceed with an expectant management approach to her incontinence, documentation in the records for January 24, 2019,

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

also stated that Patient A was "no longer interested in proceeding with conservative management and now wishes she wishes [sic] to proceed with definitive surgery to correct not only her known pelvic floor relaxation but her [stress urinary incontinence]."

13. Respondent's records for Patient A showed an encounter on January 31, 2019, during which it was noted that Patient A, "was given preoperative instructions and wishes to proceed with the pelvic floor corrective surgery on the specified date."

14. The preoperative diagnosis or reason for surgery documentation stated "Symptomatic pelvic floor relaxation, pelvic pain, mixed urinary incontinence with strong type 2 stress urinary incontinent component as noted on urodynamic studies."

15. However, no documentation noting any objective finding of symptomatic pelvic organ prolapse was ever recorded in Respondent's records for Patient A, and pelvic floor related issues were not documented at any time prior to the issue appearing in the January 31, 2019, encounter, which was after all consents were obtained and surgery was scheduled.

16. Additionally, Patient A's medical records do not contain results of any urodynamic study that support a diagnosis of "mixed urinary incontinence with strong type 2 stress urinary incontinent component."

17. The only finding of prolapse in any of Patient A's medical records related to this issue, was of posterior prolapse documented by a colorectal surgeon, who noted "a small rectocele" on February 7, 2019, four (4) days before Patient A's surgery was scheduled to take place.

18. On February 11, 2019, Patient A presented to Saint Mary's Regional Medical Center where records showed Respondent performed the following surgical procedures: anterior and posterior vaginal repair, enterocele repair, perineoplasty, sacrospinous vault suspension, trans obturator tape mid urethral sling procedures and cystoscopy. These procedures were not performed on the basis of any documented complaints by Patient A nor any medical diagnoses.

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

COUNT I

NRS 630.301(4) - Malpractice

19. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

20. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

21. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

22. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when he performed the unindicated surgical procedures on Patient A as described herein.

23. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.3062(1)(a) - Failure to Maintain Complete Medical Records

24. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

25. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient" constitute grounds for initiating discipline against a licensee.

26. Respondent failed to maintain complete medical records relating to the diagnosis, treatment and care of Patient A, by, among other things, failing to document any complaints made by Patient A of symptomatic pelvic organ prolapse before he performed surgery on Patient A. Additionally, Respondent's records stated, "[Patient A] has had one episode of unprotected sexual activity but had a normal cycle after the last encounter." Patient A was sixty-nine (69) years old, post-menopausal, and had a positive surgical history of a hysterectomy thereby eliminating the menses or cycle of Patient A. Finally, there were additional

inconsistencies and omissions in Respondent's records for Patient A, whose medical records were not timely, legible, accurate, and complete.

27. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT III

NRS 630.301(8) - Failure to Provide Procedures, Studies, Services, Referrals

28. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

29. NRS 630.301(8) provides that the failure to offer appropriate procedures or studies, to provided necessary services or to refer a patient to an appropriate provider, when the failure occurs with intent of positively influencing the financial well-being of the practitioner are grounds for discipline.

30. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated NRS 630.301(8) regarding Patient A's medical conditions when Respondent performed unindicated surgery on Patient A, including anterior and posterior vaginal repair, enterocele repair, perineoplasty, sacrospinous vault suspension, trans obturator tape mid urethral sling procedures and cystoscopy. Respondent performed all the aforementioned procedures without a medical purpose or diagnosis and with the intent of positively influencing the financial well-being of Respondent's practice.

31. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT IV

NRS 630.301(7) – Violation of Patient Trust and Exploitation of Physician and Patient Relationship for Financial or Personal Gain

32. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

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Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

33. NRS 630.301(7) provides that "engaging in conduct that violates the trust of a patient and exploits the relationship between the physician and the patient for financial or other personal gain" is grounds for initiating discipline against a licensee.

34. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated the trust of and exploited the relationship between Respondent and Patient A when he performed surgical procedures on Patient A that were not indicated because they were not based on any documented patient complaints or medical diagnoses.

35. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 8 day of September, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: Deonne E. Contine

DEONNE E. CONTINE
General Counsel
IAN J. CUMINGS
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dcontine@medboard.nv.gov
icumings@medboard.nv.gov
Attorneys for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Aury Nagy, M.D., having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 8th day of September, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
AURY NAGY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **SAMUEL RODOLFO CHACON, M.D., Respondent.**	**Case No. 23-12762-3**

FILED
SEP 08 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By: _____

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through its counsel, Deonne E. Contine, General Counsel and Ian J. Cumings, Deputy General Counsel and attorneys for the IC, having a reasonable basis to believe that Samuel Rodolfo Chacon, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a physician holding an active license to practice medicine in the State of Nevada (License No. 9105). Respondent was originally licensed by the Board on July 27, 1999, with a specialty in Obstetrics/Gynecology.

2. Patient A[2] was a sixty-five (65) year-old female at the time of the events at issue.

3. Records indicate that Respondent first saw Patient A on February 24, 2021, when she presented with a right labial mass. The mass was determined to be a Bartholin cyst that had decreased in size over time and Patient A was given instructions on sitz baths. The records for Patient A from the Assessment and Diagnosis section for this

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[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Aury Nagy, M.D., Chairman, Nicola (Nick) Spirtos, M.D., F.A.C.O.G., and Ms. Maggie Arias-Petrel.

[2] Patient A's true identity is not disclosed herein to protect her privacy but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

visit indicated a plan to follow-up with a biopsy of a right-sided mole, which was presumably discovered during a gynecological examination that day.

4. There was no documentation of urinary incontinence in any section of the February 24, 2021, medical records from Respondent for Patient A.

5. Respondent's medical records did not document any communication between Patient A and Respondent or his staff regarding incontinence, bladder issues, or conducting urodynamics testing[3] prior to Patient A presenting to Respondent's office for her biopsy appointment on March 5, 2021.

6. On March 5, 2021, within Respondent's notes in the Chief Complaint section of Patient A's medical records, there was inclusion of Urodynamics testing. This testing was not discussed with Patient A prior to this visit.

7. Patient A complained that when she presented for her appointment on March 5, 2021, for the biopsy of the Bartholin cyst, the room was set up for a Urodynamics study. After Patient A argued with Respondent and his office staff regarding the actual purpose of her visit, Patient A ultimately convinced Respondent to perform the biopsy.

8. Thereafter, over Patient A's objection that she had no bladder problems, Respondent insisted that Patient A complete the bladder test anyway and proceeded to conduct the Urodynamics study immediately following collection of the biopsy specimen. Patient A's medical records did not include documentation of a written or oral consent to the Urodynamics study performed on March 5, 2021.

9. Respondent scheduled the Urodynamics study *prior* to Patient A's March 5, 2021, appointment. However, the first mention in Respondent's medical records of urinary incontinence and pelvic pressure for Patient A was from the March 5, 2021, visit.

10. Respondent's records are inaccurate because Patient A did not discuss urinary incontinence with Respondent at any time and, in fact, Patient A had never complained to Respondent of any problems with her bladder.

[3] A Urodynamic study is a test used to help diagnose problems with urination or urinary incontinence. It involves insertion of a catheter into the bladder and may involve an additional catheter placed in a patient's vagina or rectum.

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Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

11. Patient A's medical records lacked any documentation of either subjective or objective urinary incontinence evaluations nor documented any discussions between Respondent and Patient A about any degree of bother that urinary incontinence presented for her.

12. With respect to the Urodynamics study results, the 3-Channel CMG (cystometrogram) portion **DOES NOT match** the documented description from Patient A's March 5, 2021, records and the CMG tracing **DOES NOT match** the markings on the tracing.

13. Following her March 5, 2021, appointment, Respondent's staff called Patient A to schedule her return for her biopsy results; however, Patient A never returned to see Respondent for gynecological care.

COUNT I

NRS 630.301(4) - Malpractice

14. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

15. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

16. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

17. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when he performed an unindicated procedure (the Urodynamics study) on Patient A because he had no documentation of either subjective or objective urinary incontinence and no documented discussion regarding the degree of bother that urinary incontinence presented for Patient A. Patient A had never complained to or asked Respondent to address urinary incontinence because she did not have any bladder problems.

18. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

COUNT II

NRS 630.3062(1)(a) - Failure to Maintain Appropriate Medical Records

19. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

20. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient" constitute grounds for initiating discipline against a licensee.

21. Respondent failed to maintain complete medical records relating to the diagnosis, treatment and care of Patient A, by, among other things, failing to document either subjective or objective urinary incontinence or any discussion regarding the degree of bother that urinary incontinence presented for Patient A in support of him performing the Urodynamics study.

22. Respondent's records are inaccurate because Patient A never discussed urinary incontinence with Respondent and, in fact, Patient A had never complained to Respondent of any problems with her bladder.

23. Finally, there are numerous additional inconsistencies, inaccuracies, and omissions in Respondent's records for Patient A, whose medical records were not timely, legible, accurate, or complete.

24. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT III

NRS 630.301(8) - Failure to Provide Procedures, Studies, Services, Referrals

25. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

NRS 630.301(8) provides that the failure to offer appropriate procedures or studies, to provided necessary services or to refer a patient to an appropriate provider, when the failure occurs with intent of positively influencing the financial well-being of the practitioner are grounds for discipline.

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27. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated NRS 630.301(8) regarding Patient A's medical conditions when Respondent performed an unindicated procedure on Patient A, specifically the Urodynamics study. Respondent's performance of the aforementioned procedure occurred without a medical purpose and with the intent of positively influencing the financial well-being of the Respondent's practice.

28. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT IV

NRS 630.301(7) – Violation of Patient Trust and Exploitation of Physician and Patient Relationship for Financial or Personal Gain

29. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

30. NRS 630.301(7) provides that "engaging in conduct that violates the trust of a patient and exploits the relationship between the physician and the patient for financial or other personal gain" is grounds for initiating discipline against a licensee.

31. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated the trust of and exploited the relationship between the Respondent and Patient A by performing the Urodynamics study on Patient A over her objection and despite having no objective or subjective documentation of urinary incontinence and no documented discussion with or complaint from Patient A regarding urinary incontinence or bladder problems.

32. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT V

NRS 630.301(6) – Disruptive Behavior

33. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

34. NRS 630.301(6) provides that disruptive behavior with patients that interferes with patient care or has an adverse impact on the quality of care rendered to a patient is grounds for initiating disciplinary action against a physician.

35. Respondent's behavior by performing a Urodynamic study procedure of which Patient A did not consent and which was conducted for no medical purpose, was demeaning, humiliating, and traumatizing to Patient A and thus adversely affected the quality of care rendered to her.

36. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 8 day of September, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: Deonne E. Contine

DEONNE E. CONTINE
General Counsel
IAN J. CUMINGS
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dcontine@medboard.nv.gov
icumings@medboard.nv.gov
Attorneys for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Aury Nagy, M.D., having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 8th day of September, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

AURY NAGY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **SAMUEL RODOLFO CHACON, M.D.,** **Respondent.**	**Case No. 23-12762-4**

FILED
OCT - 4 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through its counsel, Ian J. Cumings, Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Samuel Rodolfo Chacon, M.D., (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a physician holding an active license to practice medicine in the State of Nevada (License No. 9105). Respondent was originally licensed by the Board on July 27, 1999, with a specialty in Obstetrics/Gynecology.

2. Patient A[2] was a forty-four (44) year-old female at the time of the events at issue.

3. On February 5, 2019, Patient A presented to the emergency room following complaints of mild cramping and dysuria (pain or difficulty urinating), where she was diagnosed with uterine fibroids.

4. On February 6, 2019, Patient A was seen by a urologist who documented Patient A had intermittent hematuria (blood in the urine) for one (1) week prior to her visit with right flank

[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Aury Nagy, M.D., Chairman, Nick M. Spirtos, M.D., F.A.C.O.G., and Ms. Maggie Arias-Petrel.

[2] Patient A's true identity is not disclosed herein to protect her privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

pain, urinary urgency, abdominal pain, and dysuria without a history of trauma prior to the onset of her symptoms.

5. On February 11, 2019, Patient A was referred by her primary care physician to Respondent for her recurrent urinary tract infection (UTI) symptoms and uterine fibroids to be evaluated for a potential hysterectomy. Upon Patient A's initial clinical presentation, Respondent documented Patient A had abnormal (heavy) uterine bleeding and dysmenorrhea (pelvic pain) associated with her known uterine fibroids and agreed with Patient A to perform an endometrial biopsy.

6. Patient A returned to Respondent on February 15, 2019, with complaints of pelvic pain associated with menstruation. Respondent diagnosed Patient A with stress urinary incontinence and pelvic organ prolapse. Respondent's records from the February 15, 2019, visit are contradictory. Respondent documented Patient A had received Kegel exercise instructions, and then asserts Patient A had failed conservative management with pelvic floor exercises and wished to proceed with definitive surgical management of her pelvic pain and urodynamic stress urinary incontinence. This visit was Patient A's first time having received any information from Respondent about Kegel exercises.

7. During the February 15, 2019, visit Respondent performed a urodynamics study without clinical indication, as Patient A did not complain of stress urinary incontinence and was referred for a consultation for a hysterectomy for her known uterine fibroids and heavy bleeding during her menstrual cycles. Respondent diagnosed Patient A with stage two (2) uterovaginal prolapse without a proper supporting examination or indication documented in the medical record.

8. On March 19, 2019, Respondent performed a laparoscopically assisted vaginal hysterectomy, bilateral salpingectomy, anterior and posterior repair, enterocele repair, perineoplasty, transobturator mid-urethral sling, and sacrospinous ligament vaginal vault suspension, despite no clinical indication or complaints of pelvic organ prolapse.

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

COUNT I

NRS 630.301(4) - Malpractice

9. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

10. NRS 630.301(4) provides that malpractice of a Physician is grounds for initiating disciplinary action against a licensee.

11. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

12. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patient A when he performed an unnecessary urodynamics study and surgery to treat pelvic organ prolapse, which was not indicated.

13. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.3062(1)(a) - Failure to Maintain Proper Medical Records

14. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

15. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient" constitute grounds for initiating discipline against a licensee.

16. Respondent failed to maintain proper medical records relating to the diagnosis, treatment and care of Patient A, by, among other things, documenting pelvic organ prolapse and urinary incontinence without patient complaints prior to performance of surgery or a urodynamics study on Patient A.

17. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

COUNT III

NRS 630.301(8) - Failure to Provide Procedures, Studies, Services, Referrals

18. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

19. NRS 630.301(8) provides that the failure to offer appropriate procedures or studies, to provided necessary services or to refer a patient to an appropriate provider, when the failure occurs with intent of positively influencing the financial well-being of the practitioner are grounds for discipline.

20. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated NRS 603.301(8) with regard to Patient A's medical conditions when Respondent failed to offer appropriate procedures or studies and failed to provide necessary services or refer Patient A to an appropriate provider. Respondent's failure to perform all of the aforementioned occurred with the intent of positively influencing the financial well-being of the Respondent and/or Respondent's practice.

21. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT IV

NRS 630.301(7) – Violation of Patient Trust and Exploitation of Physician and Patient Relationship for Financial or Personal Gain

22. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

23. NRS 630.301(7) provides that "engaging in conduct that violates the trust of a patient and exploits the relationship between the physician and the patient for financial or other personal gain" is grounds for initiating discipline against a licensee.

24. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated the trust of and exploited the relationship between Respondent and Patient A when he performed surgical procedures on Patient A to correct stage two (2) uterovaginal prolapse that was

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not indicated because his decisions were not based on any documented patient complaints or medical diagnoses.

25. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 4th day of October, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

IAN J. CUMINGS
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: icumings@medboard.nv.gov
Attorney for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Aury Nagy, M.D., having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 4th day of October, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

AURY NAGY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **SAMUEL RODOLFO CHACON, M.D., Respondent.**	**Case No. 23-12762-5**

FILED
OCT - 6 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through Ian J. Cumings, Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Samuel Rodolfo Chacon, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a medical doctor holding an active license to practice medicine in the State of Nevada (License No. 9105). Respondent was originally licensed by the Board on July 27, 1999, with a specialty in Obstetrics/Gynecology.

2. Patient A[2] was a forty-three (43) year-old female at the time of the events at issue.

3. On November 21, 2019, Patient A presented to Respondent for her annual gynecologic exam, and to establish gynecological care with complaints of consistent pelvic pain and irregular bleeding. Patient A denied any urinary incontinence, constipation, or diarrhea.

4. During the November 21, 2019, visit establishing care, Respondent performed an annual exam, ordered ultrasound testing and proceeded to perform an endometrial biopsy on

[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Aury Nagy, M.D., Chairman, Nicola (Nick) Spirtos, M.D., F.A.C.O.G., and Ms. Maggie Arias-Petrel.

[2] Patient A's true identity is not disclosed herein to protect her privacy but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

Patient A. Respondent scheduled a follow-up appointment, documenting Patient A had failed medical management and was considering surgical intervention.

5. Laboratory testing demonstrated Patient A's endometrial biopsy was normal, and negative for hyperplasia or atypia.

6. On November 27, 2019, Patient A returned for her scheduled follow-up appointment with Respondent. Respondent documented Patient A now complained of stress urinary incontinence and that Patient A would, "like to move forward with hysterectomy and pelvic floor repair surgery," and was instructed on performing Kegel exercises.

7. On January 7, 2020, Patient A presented for an outpatient visit at Renown Medical Center ("Renown") with Respondent. During this visit she was scheduled for surgery on January 21, 2020, for symptomatic pelvic floor relaxation. Respondent recommended: hysterectomy, bilateral salpingectomy, native tissue repair in the form of anterior and posterior vaginal repair, enterocele repair, perineoplasty, sacrospinous vault suspension and a transobturator tape midurethral sling procedure. Respondent documented the reason for surgery as symptomatic pelvic floor relaxation with associated pelvic pain, dyspareunia, and mixed urinary incontinence symptoms with a strong type 2 urinary incontinent component as noted on urodynamic studies.

8. Respondent documented that Patient A's urodynamic studies demonstrated type 2 stress urinary incontinence, despite no such urodynamic study ever being performed on Patient A.

9. On January 8, 2020, Patient A underwent a sonograph which demonstrated no masses or cysts, with a small fundal fibroid.

10. Prior to the January 21, 2020, procedure, Patient A canceled her scheduled surgery with Respondent at Renown.

11. Patient A sought a second opinion on February 7, 2020, from a different OB/GYN physician who documented that Patient A exhibited no evidence of vaginal or bladder prolapse and was unsure of Respondent's indications for the recommended hysterectomy or bladder suspension. Subsequent ultrasound testing demonstrated unremarkable findings.

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

COUNT I

NRS 630.301(4) - Malpractice

12. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

13. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

14. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

15. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patient A when he diagnosed Patient A with stress urinary incontinence and scheduled Patient A for a hysterectomy, bilateral salpingectomy, native tissue repair in the form of anterior and posterior vaginal repair, enterocele repair, perineoplasty, sacrospinous vault suspension and a transobturator tape midurethral sling procedure, despite no clinical indication or diagnostic testing supporting his diagnosis or treatment plan.

16. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.3062(1)(a) - Failure to Maintain Proper Medical Records

17. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

18. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient," constitutes grounds for initiating discipline against a licensee.

19. Respondent failed to maintain proper medical records relating to the diagnosis, treatment and care of Patient A, by failing to correctly document his actions when he treated Patient A, whose medical records were not timely, legible, accurate, and complete, by, among

other things, falsely documenting Patient A had stress urinary incontinence on a study, despite no such study having been ever performed.

20. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT III

NRS 630.306(1)(b)(2) - Violation of Standards of Practice Established by Regulation – Falsification of Medical Records

21. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

22. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

23. NAC 630.230(1)(a) provides that a physician shall not, "falsify records of health care."

24. Respondent falsified Patient A's medical records by, among other things, documenting in Patient A's medical records that Patient A had type 2 stress urinary incontinence as demonstrated on a urodynamics study as an indication for the recommended surgery, despite no such study having ever been performed.

25. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT IV

NRS 630.301(8) - Failure to Provide Procedures, Studies, Services, Referrals

26. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

27. NRS 630.301(8) provides that the failure to offer appropriate procedures or studies, to provided necessary services or to refer a patient to an appropriate provider, when the failure occurs with the intent of positively influencing the financial well-being of the practitioner are grounds for discipline.

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

28. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated NRS 630.301(8), regarding Patient A's medical conditions when Respondent scheduled unindicated procedures on Patient A, specifically complex procedures to repair vaginal prolapse. Respondent's diagnosis and scheduling of the procedure occurred without a recognized medical purpose and with the intent of positively influencing the financial well-being of Respondent and his practice.

29. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT IV

NRS 630.301(7) – Violation of Patient Trust and Exploitation of Physician and Patient Relationship for Financial or Personal Gain

30. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

31. NRS 630.301(7) provides that "engaging in conduct that violates the trust of a patient and exploits the relationship between the physician and the patient for financial or other personal gain," is grounds for initiating discipline against a licensee.

32. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated the trust of, and exploited the relationship between, the Respondent and Patient A by improperly diagnosing Patient A with type 2 stress urinary incontinence without subjective documentation or testing supporting Respondent's diagnosis of urinary incontinence and/or bladder problems.

33. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 6th day of October, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

IAN J. CUMINGS
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: icumings@medboard.nv.gov
Attorney for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Aury Nagy, M.D., having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 6 day of October, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

AURY NAGY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **SAMUEL RODOLFO CHACON, M.D., Respondent.**	**Case No. 23-12762-6**

FILED
NOV 03 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through its counsel, Deonne E. Contine, General Counsel and Ian J. Cumings, Deputy General Counsel as attorneys for the IC, having a reasonable basis to believe that Samuel Rodolfo Chacon, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a physician holding an active license to practice medicine in the State of Nevada (License No. 9105). Respondent was originally licensed by the Board on July 27, 1999, with a specialty in Obstetrics/Gynecology.

2. Patient A[2] was a forty-three (43) year-old female at the time of the relevant events at issue in this Complaint.

3. On November 18, 2021, Patient A saw her family physician, Dr. Kimberly Clinite for abnormal uterine bleeding which had been ongoing for two (2) weeks. Patient A was concerned that her bleeding might be caused by her intrauterine device (IUD) and wished to have

[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Aury Nagy, M.D., Chairman, Nicola (Nick) Spirtos, M.D., F.A.C.O.G., and Ms. Maggie Arias-Petrel.

[2] Patient A's true identity is not disclosed herein to protect her privacy but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

the IUD removed. There was no pelvic organ prolapse noted on a detailed pelvic examination in the records for this appointment.

4. Dr. Clinite removed the IUD, however, the left arm broke off during extraction and Dr. Clinite was unable to retrieve it. Thereafter, she referred Patient A to Respondent for evaluation for removal of the retained IUD arm.

5. Patient A saw Respondent on December 15, 2021. In Patient A's intake paperwork, she indicated that her reason for the visit was "retained IUD parts." Similarly, Patient A identified her chief complaint as "retained IUD arm."

6. In Respondent's medical record for the December 15, 2021, appointment he notes Patient A's chief complaints to be retained IUD, irregular bleeding, pelvic pressure and incontinence.

7. On her New Patient Medical History form, which she completed at her December 15, 2021, appointment, Patient A answered no to a series of questions regarding abdominal or pelvic pain, concerns regarding sex, night urination, or any bulging sensation from her vagina.

8. Patient A answered yes to a single question on the New Patient Medical History form regarding loss of urine. However, Respondent's December 15, 2021, medical record does not document any specific history of urinary incontinence nor is there any notation in the medical records supporting that Patient A complained about stress urinary incontinence and that it negatively impacted her quality of life.

9. Despite no documented pelvic examination, no documented history of stress urinary incontinence, nor any documented complaint from Patient A that she suffered from urinary incontinence, during the December 15, 2021, visit, Respondent performed a urodynamics study.[3] There is no documentation of consent to perform the urodynamics study in Patient A's medical records. Patient A was never given any results of the urodynamics study and thereafter developed a urinary tract infection.

[3] A Urodynamic study is a test used to help diagnose problems with urination or urinary incontinence. It involves insertion of a catheter into the bladder and may involve an additional catheter placed in a patient's vagina or rectum.

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10. The urodynamics study summary report that is included in Patient A's medical records contains irrational and inaccurate data, and it is not reliable for diagnostic purposes, clinical reasoning, or clinical decision making.

11. Respondent documented that Patient A complained of pelvic pain radiating to her back. His notes state that she would begin taking Vicodin for the pain. Even though Patient A lives in Susanville, California, Respondent noted that he would see her, or she would be seen in the emergency room after-hours if her pain worsened.

12. Elsewhere in Respondent's notes in the medical records of Patient A, it states "She will start her Vicodin which was prescribed today and may take before surgery if sig [sic] pelvic pain or pressure."

13. Respondent's Prescriber Activity Report from the Nevada Prescription Monitoring Program shows no prescriber activity by Respondent for Patient A on December 15, 2021, or at any other time.

14. At the December 15, 2021, 2021 visit Respondent documented that Patient A, "wishes to proceed with endometrial ablation in order to address cycles as she states that she has exhausted conservative options of management." In fact, records from that day document that Patient A had normal cycles. Additionally, Respondent noted that Patient A "wishes to proceed with bladder repair as she tried Kegel exercises in the past and that Patient A "wishes to proceed with surgical options at this time." There was no diagnosis documented at that time.

15. At the December 15, 2021, visit, although no specific diagnosis was documented in the medical records of Patient A other than the retained IUD arm, for which she was to have a hysteroscopy, Patient A was consented for the following additional surgical procedures:
1) salpingectomy 2) endometrial ablation; 3) sacrospinous vault suspension; 4) enterocele repair; 5) cystoscopy; 6) perineoplasty; 7) mid-urethral sling; and 8) any additional necessary procedures.

16. Respondent documented a pelvic examination of Patient A only in the preoperative history which was written and dictated in the early evening of December 15, 2021, after the appointment with Patient A had taken place and after the surgical procedure had been planned and Patient A had consented.

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17. All surgical procedures were scheduled for January 6, 2022, at Renown Regional Medical Center.

18. Prior to the January 6, 2022, appointment, Patient A canceled her scheduled surgeries with Respondent.

19. On January 4, 2022, Patient A saw a different OB/GYN physician ("second OB/GYN") regarding removal of the retained IUD and possible tubal ligation. General history notes from her January 4, 2022, appointment state that Patient A had no other complaints and she reported regular monthly cycles and no pelvic pain or pressure.

20. On January 20, 2022, Patient A saw the second OB/GYN where it was documented that she reported normal menses and no pelvic pain or pressure. Patient A indicated her desire to proceed with a bilateral laparoscopic salpingectomy and the hysteroscopy to remove the retained IUD arm and had consented to those surgical procedures during the January 20, 2022, appointment.

COUNT I

NRS 630.301(4) - Malpractice

21. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

22. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

23. NAC 630.040 defines malpractice as, "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

24. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patient A when he scheduled Patient A for an endometrial ablation; sacrospinous vault suspension; enterocele repair; cystoscopy; perineoplasty; mid-urethral sling; and any additional procedures despite there being no clinical indication or diagnostic testing supporting this treatment plan.

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25. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.301(4) - Malpractice

21. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

22. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

23. NAC 630.040 defines malpractice as, "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

24. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when subjecting Patient A to the urinary dynamics testing when the data was not used for clinical decision making.

25. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT III

NRS 630.3062(1)(a) - Failure to Maintain Proper Medical Records

26. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

27. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient," constitutes grounds for initiating discipline against a licensee.

28. Respondent failed to maintain proper medical records relating to the diagnosis, treatment, and care of Patient A, by failing to correctly document his actions when he treated Patient A, whose medical records were not timely, legible, accurate, and complete, by, among

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other things, falsely documenting Patient A had stress urinary incontinence on a study, despite no such study having indicated such findings.

29. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT IV

NRS 630.306(1)(b)(2) - Violation of Standards of Practice Established by Regulation – Falsification of Medical Records

30. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

31. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

32. NAC 630.230(1)(a) provides that a physician shall not, "falsify records of health care."

33. Respondent falsified Patient A's medical records by, among other things, documenting in Patient A's medical records that Patient A had type 2 stress urinary incontinence as demonstrated on a urodynamics study as an indication for the recommended surgery, despite no such study having indicated such findings.

34. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT V

NRS 630.301(8) - Failure to Provide Procedures, Studies, Services, Referrals

35. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

36. NRS 630.301(8) provides that the failure to offer appropriate procedures or studies, to provided necessary services or to refer a patient to an appropriate provider, when the failure occurs with the intent of positively influencing the financial well-being of the practitioner are grounds for discipline.

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37. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated NRS 630.301(8), regarding Patient A's medical conditions when Respondent scheduled unindicated procedures on Patient A, specifically complex procedures to repair vaginal prolapse. Respondent's diagnosis and scheduling of the procedure occurred without a recognized medical purpose and with the intent of positively influencing the financial well-being of Respondent and his practice.

38. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT VI

NRS 630.301(7) – Violation of Patient Trust and Exploitation of Physician and Patient Relationship for Financial or Personal Gain

39. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

40. NRS 630.301(7) provides that "engaging in conduct that violates the trust of a patient and exploits the relationship between the physician and the patient for financial or other personal gain," is grounds for initiating discipline against a licensee.

41. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated the trust of, and exploited the relationship between, Respondent and Patient A by improperly diagnosing Patient A with type 2 stress urinary incontinence without subjective documentation or testing supporting Respondent's diagnosis of urinary incontinence and/or bladder problems.

42. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

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2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 3 day of November, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: Deonne E. Contine

DEONNE E. CONTINE, General Counsel
IAN J. CUMINGS, Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dcontine@medboard.nv.gov
icumings@medboard.nv.gov
Attorneys for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Aury Nagy, M.D., having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 3rd day of November, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
AURY NAGY, M.D.
Chairman of the Investigative Committee

JOE LOMBARDO
Governor



HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

September 12, 2023

VIA CERTIFIED U.S. MAIL & E-MAIL:
Dr. Samuel Rodolfo Chacon, M.D.
540 W. Plumb Lane, #200
Reno, Nevada 89509
tensaceman@gmail.com

Re: ***Case No. 23-348-CS-N – Notice of Suspension of Certificate to Dispense Controlled Substances, Certificate of Registration No. CS05273***

Dr. Samuel Chacon:

The Nevada State Board of Pharmacy ("Board") has been notified by the Nevada State Board of Medical Examiners that your Nevada Medical License No. 9105 was suspended on September 2, 2023, in Case No. 23-12762-1.

Please be advised that pursuant to NRS 639.2107 the suspension Nevada Medical License operates as an immediate suspension of your Certificate of Registration to Dispense Controlled Substances, Certificate of Registration No. CS05273 with the Board. You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST possessing, administering and/or prescribing controlled substances for Nevada patients. Furthermore, your access to the Nevada Prescription Monitoring Program ("PMP") database is terminated effective immediately since you are no longer a practitioner authorized to access the PMP pursuant to NAC 453.078.

The pre-hearing suspension of your Certificate of Registration No. CS05273 pursuant to NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991). You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Please be aware that the forgoing does not preclude a formal investigation or filing of an accusation pursuant to NRS 639.241. If you have any questions, please do not hesitate to contact me at 775-850-1440 ext. 123 or pkeegan@pharmacy.nv.gov.

Best regards,

Peter Keegan
General Counsel

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaints Against:	**Case Nos. 23-12762-1, 23-12762-2, 23-12762-3, 23-12762-4, 23-12762-5, 23-12762-6**
SAMUEL RODOLFO CHACON, M.D.,	
Respondent.	

FILED
JUN 06 2025
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Ian J. Cumings, Senior Deputy General Counsel for the Board and attorney for the IC, and Samuel Rodolfo Chacon, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Eric K. Stryker, Esq., of the law firm of Freeman, Mathis & Gary LLP, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in suspended status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on July 27, 1999 (License No. 9105).

2. On March 27, 2024, in Case No. 23-12762-1, the IC filed a formal First Amended Complaint (Complaint 1) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges two (2) violations of NRS 630.301(4), Malpractice (Counts I-II); one (1) violation of NRS 630.306(1)(b)(2), Violation of Standards of Practice Established by Regulation – Failure to Consult (Count III); one (1) violation of NRS 630.306(1)(g), Continual

[1] All agreements and admissions made by Respondent are solely for final disposition of these matters and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

Failure to Exercise Skill or Diligence (Count IV); one (1) violation of NRS 630.306(1)(p), Unsafe or Unprofessional Conduct (Count V); one (1) violation of NRS 630.306(1)(b)(1), Deceptive Conduct (Count VI); one (1) violation of NRS 630.301(7), Violation of Patient Trust for Financial Gain (Count VII); and one (1) violation of NRS 630.306(1)(b)(2), Violation of Standards of Practice – Falsification of Medical Records (Count VIII).

3. On September 8, 2023, in Case No. 23-12762-2, the IC filed a formal Complaint (Complaint II) charging Respondent with violating the Medical Practice Act. Specifically, Complaint II alleges one (1) violation of NRS 630.301(4), Malpractice (Count I); one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Count II); one (1) violation of NRS 630.301(8), Failure to Provide Procedures, Studies, Services, and Referrals (Count III); and one (1) violation of NRS 630.301(7), Violation of Patient Trust for Financial Gain (Count IV).

4. On September 8, 2023, in Case No. 23-12762-3, the IC filed a formal Complaint (Complaint III) charging Respondent with violating the Medical Practice Act. Specifically, Complaint III alleges one (1) violation of NRS 630.301(4), Malpractice (Count I); one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Count II); one (1) violation of NRS 630.301(8), Failure to Provide Procedures, Studies, Services, and Referrals (Count III); one (1) violation of NRS 630.301(7), Violation of Patient Trust for Financial Gain (Count IV); and one (1) violation of NRS 630.301(6), Disruptive Behavior (Count V).

5. On October 4, 2023, in Case No. 23-12762-4, the IC filed a formal Complaint (Complaint IV) charging Respondent with violating the Medical Practice Act. Specifically, Complaint IV alleges one (1) violation of NRS 630.301(4), Malpractice (Count I); one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Count II); one (1) violation of NRS 630.301(8), Failure to Provide Procedures, Studies, Services, and Referrals (Count III); and one (1) violation of NRS 630.301(7), Violation of Patient Trust for Financial Gain (Count IV).

6. On October 6, 2023, in Case No. 23-12762-5, the IC filed a formal Complaint (Complaint V) charging Respondent with violating the Medical Practice Act. Specifically,

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
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Complaint V alleges one (1) violation of NRS 630.301(4), Malpractice (Count I); one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Count II); one (1) violation of NRS 630.306(1)(b)(2) Violation of Standards of Practice – Falsification of Medical Records (Count III); one (1) violation of NRS 630.301(8), Failure to Provide Procedures, Studies, Services, and Referrals (Count IV); and one (1) violation of NRS 630.301(7), Violation of Patient Trust for Financial Gain (Count V).

7. On November 8, 2023, in Case No. 23-12762-6, the IC filed a formal Complaint (Complaint VI) charging Respondent with violating the Medical Practice Act. Specifically, Complaint VI alleges two (2) violations of NRS 630.301(4), Malpractice (Counts I-II); one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Count III); one (1) violation of NRS 630.306(1)(b)(2) Violation of Standards of Practice – Falsification of Medical Records (Count IV); one (1) violation of NRS 630.301(8), Failure to Provide Procedures, Studies, Services, and Referrals (Count V); and one (1) violation of NRS 630.301(7), Violation of Patient Trust for Financial Gain (Count VI).

8. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

9. On February 26, 2025, through February 28, 2025, a formal Hearing was conducted for Complaint I, in which the Hearing Officer found by a preponderance of the evidence that Counts I-II and Counts V-VIII were proven.

10. Respondent was properly served with a copy of the Complaints, has reviewed and understands these Complaints, and has had the opportunity to consult with competent counsel concerning the nature and significance of these Complaints.

11. Respondent is hereby advised of his rights regarding these administrative matters, and of his opportunity to defend against the allegations in the Complaints. Specifically, Respondent has certain rights in these administrative matters as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B and 622A. These rights include the right to

formal hearings on the allegations in the Complaints, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decisions of the Board, and the right to judicial review of the Board's orders, if the decisions are adverse to him.

12. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

13. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaints, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaints has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel, and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in these matters materially changes prior to entering into this Agreement and for the duration of this

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Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with these administrative matters. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaints filed in these matters, including defense of the Complaints, adjudication of the allegations set forth in the Complaints, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaints as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaints II-VI remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges Respondent is not admitting that the IC's claims/counts as alleged in the Complaints have merit and Respondent is agreeing to resolve these matters to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if these matters were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaints, but for the purposes of resolving these matters and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve the Complaints pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent

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9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. For the purposes of this Agreement, Respondent admits that sufficient evidence exists, and the Hearing Officer has found that specifically Respondent committed two (2) violations of NRS 630.301(4), Malpractice (Count I-II); one (1) violation of NRS 630.306(1)(p) Unsafe or Unprofessional Conduct (Count V); one (1) violation of NRS 630.306(1)(b)(1) Deceptive Conduct (Count VI); one (1) violation of NRS 630.301(7) Violation of Patient Trust for Financial Gain (Count VII); and one (1) violation of NRS 630.306(1)(b)(2) Violation of Standards of Practice – Falsification of Medical Records (Count VIII).

b. In order to resolve Complaints II-VI pending against Respondent, Respondent does not admit any of the counts, but Respondent acknowledges that sufficient evidence may be presented at a hearing, such that the Board could conclude that the counts in Complaints II-VI were proven, and he agrees that the Board may enter a finding that he violated the counts in Complaints II-VI as part of this agreement.

c. Respondent hereby agrees that his license to practice medicine is hereby revoked. Respondent shall not reapply for a license for a period of five (5) years after the date of the Board's acceptance, adoption and approval of this Agreement.

d. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matters in the amount of sixty-five thousand dollars ($65,000). Respondent shall pay the aforementioned costs and expenses by way of six (6) payments, the first of five (5) payments in the amount of ten thousand eight hundred thirty-three dollars and thirty-three cents ($10,833.33) is due on or before July 15, 2025, the second payment is due on or before August 15, 2025, the third payment is due on or before September 15, 2025, the fourth payment is due on or before October 15, 2025, the fifth payment is due on or before November 15, 2025. The sixth and final payment of ten thousand eight hundred thirty-three dollars and thirty-five cents ($10,833.35) is due on or before December 15, 2025. The costs and

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

expenses as well as the payment plan are subject to the Board's acceptance, adoption, and approval of this Agreement.

e. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

f. Respondent shall receive a Public Letter of Reprimand.

g. The remaining counts of Complaint I, and any other claims arising from the Board's corresponding investigative case files in Complaints I-VI, shall be dismissed with prejudice. This agreement shall also encompass any other investigatory matters pending against Respondent.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the cases referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of these Complaints. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board

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Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaints and any and all information of every nature whatsoever related to these matters. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the cases shall be closed and all remaining claims arising out of the Complaints shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering these Complaints and from participating in disciplinary proceedings against Respondent, including adjudication of these cases; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, which constitutes a failure to comply with an order of the Board, and may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a). Additionally, failure to pay any fines, costs, expenses or fees owed to the Board pursuant to this Agreement will result in additional disciplinary action, unless within ten (10) calendar days of the payment due date, Respondent notifies the Board in writing of the inability to comply with the payment terms and requests to appear before the Board at the next regularly scheduled Board meeting to request a modification to any payments ordered in this Agreement. Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 30th day of May, 2025.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

DEONNE E. CONTINE
General Counsel
IAN J. CUMINGS
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dcontine@medboard.nv.gov
icumings@medboard.nv.gov
Attorneys for the Investigative Committee

DATED this 30th day of May, 2025.

By: _____

SAMUEL RODOLFO CHACON, M.D.,
Nevada License No. 9105
Respondent

DATED this 30th day of May, 2025.

FREEMAN, MATHIS & GARY LLP

By: _____

ERIC K. STRYKER, ESQ.
770 East Warm Springs Road, Suite 360
Las Vegas, NV 89119
Tel: (725) 330-2096
Email: eric.stryker@fmglaw.com
Attorney for Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case Nos. 23-12762-1, 23-12762-2, 23-12762-3, 23-12762-4, 23-12762-5, 23-12762-6) was approved and accepted by the Nevada State Board of Medical Examiners on the 6th day of June, 2025.

DATED this 6th day of June, 2025.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

NICK M. SPIRTOS, M.D., F.A.C.O.G.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 895521
(775) 688-2559

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE Rx,** **Pharmacy License No. PH04215,** **Respondent.**	**CASE NO. 23-411-PH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Revive Rx, Pharmacy License No. PH04215, located in Houston, Texas, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. From October 10, 2023, through January 10, 2024, Respondent compounded and dispensed drug products to Nevada patients using active ingredients that (1) do not have a United States Pharmacopoeia-National Formulary monograph; (2) are not a part of an FDA approved drug product, or (3) are not authorized to be used in pharmacy compounding pursuant to 21 USC § 353a(b)(1) or the regulations adopted pursuant thereto. Specifically, Respondent dispensed compounded injectable peptides, including, without limitation, AOD9604, Ipamorelin, Kisspeptin, and MOTs-C Acetate. Respondent also dispensed KPV 500mcg/BPX-157 20mcg and Dihexa in capsule form and Selank 7.5mg in a nasal spray.

3. Respondent compounded and dispensed high-risk sterile products to Nevada patients with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD.

APPLICABLE LAW

4. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661 -.690, *inclusive*, and related federal law, 21 U.S.C. § 353a, establishing national standards for compounding medications.

5. Any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

7. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

8. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

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COUNT ONE

Violation of Federal and State Compounding Law/Unprofessional Conduct

9. Respondent, Respondent's owner(s), and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated various provisions of 21 U.S.C. § 353a, NAC 639.67019, NAC 639.67067, NAC 639.67071 and/or NAC 639.757 and related provisions of 21 U.S.C. § 353a as alleged in paragraphs 2-3 herein. Respondent is responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

Signed this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE Rx,** **Pharmacy License No. PH04215,** **Respondent.**	**Case No. 23-411-PH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Lane
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE Rx,** **Pharmacy License No. PH04215,** **Respondent.**	**Case No. 23-411-PH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR REVIVE RX

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Revive Rx
3831 Golf Dr #A
Houston, TX 77018

Philip E. M. Crooker, Esq.
PO Box 339
Tigerville, SC 29688

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **INJURED WORKERS PHARMACY, Pharmacy License No. PH02281,** **Respondent.**	**CASE NO. 23-428-PH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Injured Workers Pharmacy, LLC, Pharmacy License No. PH02281, located in Andover, Massachusetts, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. In June of 2023 Respondent entered into a settlement agreement with the U.S. Department of Justice, the Drug Enforcement Administration, and the Department of Labor, resolving Respondent's violations of federal law related to dispensing of controlled substances (Settlement Agreement - SEE EXHBIT A HERETO).

3. In 2022, Respondent dispensed 1,573 controlled substance prescriptions to Nevada patients in 2022 and dispensed 2, 196 controlled substance prescriptions to Nevada patients in 2023.

APPLICABLE LAW

4. A pharmacy engaged in the practice of dispensing controlled substances in Nevada shall comply in pertinent part with the provisions of the Controlled Substances Act

(CSA), Title 21 United States Code (21 U.S.C.) 801-971, and DEA regulations, Title 21, Code of Federal Regulations (21 CFR) Parts 1300 to 1316.

5. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

7. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Controlled Substances Act/Unprofessional Conduct

8. Respondent, Respondent's owner(s), and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated various provisions of the Controlled Substances Act (CSA), Title 21 United States Code (21 U.S.C.) 801-971, and DEA regulations, Title 21, Code of Federal Regulations (21 CFR) Parts 1300 to 1316, as detailed in the Settlement Agreement. Respondent is responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of this Respondent.

Signed this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

Exhibit A

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into by and between the United States of America, acting through the United States Department of Justice, the Drug Enforcement Administration ("DEA"), and the Department of Labor (collectively, the "United States"); and Injured Workers Pharmacy LLC ("IWP"). The United States and IWP are each referred to herein as a "Party" and collectively as the "Parties."

RECITALS

A. IWP is a mail-order pharmacy that is located at 300 Federal St, Andover, Massachusetts. IWP dispenses and ships prescription drugs, including controlled substances, across the United States, primarily to workers who have been injured on the job. IWP is a pharmacy registered with the DEA.

B. The DEA is the Department of Justice component agency primarily responsible for enforcing the Controlled Substances Act ("CSA"), 21 U.S.C. § 801, et seq., and is vested with the responsibility of investigating violations of the CSA.

C. The United States Attorney General, through the United States Attorney's Office, has primary authority to bring civil actions to enforce the CSA. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

D. The Department of Labor's Office of Worker Compensation Programs administers workers compensation claims under the Federal Workers Compensation Act. Each pharmacy submitting claims for payment to the Department of Labor pursuant to that Act "signifies that the service for which reimbursement is sought was performed as described, necessary, appropriate and properly billed in accordance with accepted industry standards." 20 C.F.R. § 10.801(d). In 2018, the Department of Labor began requiring pharmacies to pre-

adjudicate federal workers compensation prescription claims electronically through a pharmacy benefit manager. The Department of Labor required pre-adjudication to curtail opioid abuse among injured federal workers.

E. Each DEA registrant is required to conduct its operations in accordance with the CSA and the regulations promulgated thereunder. Under the CSA, a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The prescriber has a responsibility for proper prescribing, "but a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.*

F. Beginning in or around June 2018, the United States and the Attorney General for the Commonwealth of Massachusetts (the "Massachusetts AG") began investigating, among other things, IWP's processes and documentation relating to the dispensing of controlled substances. The two investigations proceeded in parallel until June 2020, when IWP resolved the Massachusetts AG's investigation by settling with the Massachusetts AG for $11 million and agreeing to permanent injunctive relief in a stipulated consent judgment (the "Massachusetts AG Consent Judgment"). The settlement with the Massachusetts AG concerned IWP's dispensing practices from 2008 to 2019. The United States' investigation concerned IWP's dispensing practices, as discussed further below, from 2014 through 2019.

G. Prior to and in connection with the Massachusetts AG Consent Judgment, IWP implemented changes to its policies and procedures concerning dispensing controlled substances, including opioids.

H. IWP admits, acknowledges, and accepts its responsibility for the following facts:

a. Between January 1, 2014, and July 31, 2019, IWP received numerous

prescriptions with "red flags," including high doses of opioids, early refills, and "Holy Trinities." A Holy Trinity occurs when an opioid, a benzodiazepine, and a muscle relaxant are prescribed simultaneously to a patient. "Red flags" may indicate a prescriber issued a prescription for a reason other than a legitimate medical purpose, such as abuse or diversion. Pharmacists must review and resolve such "red flags" before filling any prescription. When IWP received prescriptions with "red flags" between January 1, 2014, and July 31, 2019, IWP pharmacists did not always resolve the "red flags" before filling those prescriptions. Even though IWP implemented process improvements beginning in 2017, IWP pharmacists did not have a consistent process or documentation with respect to resolving "red flags."

b. IWP dispensed medications to injured federal workers and submitted claims for payment to the Department of Labor. Between December 12, 2017, and September 26, 2019, the Department of Labor's pharmacy benefit manager issued drug utilization review ("DUR") alerts for 1,456 claims for federal workers' prescriptions for issues such as drug interactions, potential allergic reactions, and therapeutic duplication of opioids. A DUR helps pharmacists ensure that prescribed drugs are appropriate and medically necessary. To clear those DUR rejections and ultimately receive payment from the Department of Labor, IWP's non-pharmacy, claims employees routinely submitted override codes representing that IWP had consulted with prescribers about the DUR alerts. The IWP claims employees, who lacked clinical pharmacy experience and training, submitted the overrides without consulting with IWP pharmacists. Because IWP pharmacists were not aware of the rejections, they did not consult with prescribers in response to the DUR alerts received from the Department of Labor, as represented by IWP claims employees. The foregoing conduct set out in subparagraphs (a) through (b) of Paragraph H is referred to below as the "Covered Conduct."

I. In May 2020, IWP self-disclosed to the Department of Labor that the DUR alerts issue affected 821 claims and offered to repay 256 of them.

J. The United States contends that it has certain civil and administrative claims for civil monetary penalties, injunctive relief, and administrative remedies against IWP under the CSA and its implementing regulations based upon the Covered Conduct. Such civil and administrative claims under the CSA include violations of 21 U.S.C. §§ 827(a)(3), 842(a)(1), 843(a)(2), and the following implementing regulations: 21 C.F.R. §§ 1301.19(b), 1301.71(a), 1304.21(a), 1306.04(a), 1306.05(a). 1306.06, and 1307.02.

K. The United States also contends that it has certain federal civil claims against IWP for submitting or causing the submission of false claims for payment to the Department of Labor.

In consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. IWP shall pay to the United States the sum of Ten Million Dollars ($10,000,000), plus interest at a rate of 3.6% per annum from February 13, 2023 ("Settlement Amount"), of which $318,341.40 is restitution. Within fifteen (15) calendar days of the Effective date of this agreement. IWP shall pay One Million Two Hundred Fifty Thousand Dollars ($1,250,000), plus interest accrued.

a. Over a period of five years, IWP will pay the remaining Eight Million, Seven Hundred Fifty Thousand Dollars ($8,750,000), plus interest at 3.6% per annum, pursuant to the payment schedule attached at Exhibit A. If a prepayment occurs under either paragraph 1.d or paragraph 7 of this Agreement, the parties agree that the principal balance will be adjusted

accordingly and that the computation and allocation of interest set forth in Exhibit A will be adjusted consistant with the remaining principal balance.

b. Interest shall accrue on the unpaid Settlement Amount as indicated in Exhibit A. Collectively the Settlement Amount and interest received by the United States shall be referred to as the "Settlement Payments."

c. If IWP or any of its affiliates is sold, merged, or transferred, or a significant portion of the assets of IWP or of any of its affiliates is sold, merged, or transferred into another non-affiliated entity, IWP shall promptly notify the United States, and all remaining payments owed pursuant to the Agreement shall be accelerated and become immediately due and payable.

d. The Settlement Amount may be prepaid, in whole or in part, without penalty or premium.

e. IWP shall pay the Settlement Payments, or any portion thereof, by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts.

2. No later than five business days after the Effective Date of this agreement, IWP and the DEA will enter into the Corrective Action Plan ("CAP").

3. Subject to the exceptions in Paragraph 4 (concerning reserved claims) and Paragraph 5 (injunctive relief) below, and conditioned upon the United States' receipt of the Settlement Amount, and upon IWP complying with Paragraph 2, the United States releases IWP, its predecessors, its current and former parents, divisions, subsidiaries, successors, and assigns from any civil or administrative monetary claim the United States has for the Covered Conduct under Controlled Substances Act; the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program

Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

4. Notwithstanding the release given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, or any administrative remedy, including the suspension and debarment rights of any federal agency;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for failure to deliver goods or services due; and

h. Any liability for personal injury or property damages or for other consequential damages arising from the Covered Conduct.

5. The United States reserves the right to seek injunctive relief pursuant to 21 U.S.C. § 843(f) if IWP fails to pay the Settlement Amount, or fails to comply with the obligations of the CAP.

6. IWP has provided financial disclosures and supporting documents ("Financial Disclosures") to the United States, and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. IWP warrants that the

Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which IWP had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy IWP's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by IWP on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by One Million Dollars ($1,000,000) or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of IWP's previously undisclosed assets. IWP agrees not to contest any collection action undertaken by the United States pursuant to this provision and agrees that it will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected in the collection action as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States, pursuant to this paragraph rescinds this Agreement, IWP waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to IWP that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement.

7. In the event IWP receives proceeds from any insurance policy on account of the Settlement Amount in this Agreement or the Covered Conduct at any time before the Settlement

Amount has been paid in full, IWP agrees to remit those insurance proceeds to the United States within fifteen (15) days, and that amount shall be credited against future payments, with the schedule of remaining payments to be adjusted as described in paragraph 1.a. IWP need not remit to the United States more insurance proceeds than necessary to pay the Settlement Amount in full. This paragraph does not apply to IWP's receipt of proceeds from any insurance policy on account of its legal expenses.

8. IWP waives and shall not assert any defenses it may have to any criminal prosecution relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. IWP fully and finally releases the United States and its agencies, officers, agents, employees, and servants from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that IWP has asserted, could have asserted, or may assert in the future against the United States or its agencies, officers, agents, employees, or servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. IWP agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of IWP, and its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement:

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) IWP's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement; and

(5) the payment IWP makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by IWP, and IWP shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, IWP shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by IWP or any of its subsidiaries or affiliates from the United States. IWP agrees that the United States, at a minimum, shall be entitled to recoup from IWP any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine IWP's books and records and to disagree with any calculations submitted by IWP or

any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by IWP, or the effect of any such Unallowable Costs on the amount of such payments.

11. The obligations imposed upon IWP pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon IWP pursuant to all applicable federal, state, and local laws and regulations, including but not limited to the requirements set forth in Title 21 of the United States Code and the regulations promulgated thereunder.

12. IWP agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, IWP shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. IWP further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

13. The Settlement Amount and Settlement Payments represent the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to IWP's financial condition as reflected in the Financial Disclosures referenced in Paragraph 6.

a. In the event that IWP fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above and in Exhibit A, IWP shall be in Default of IWP's payment obligations ("Default"). The United States will provide a written Notice of

Default, and IWP shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Agreement up to the date of payment. Notice of Default will be delivered to IWP, or to such other representative as IWP shall designate in advance in writing. If IWP fails to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule ("Uncured Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

14. In the event of Uncured Default, IWP agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against IWP for the claims that would otherwise be covered by the releases provided in Paragraph 4 above, with any recovery reduced by the amount of any payments previously made by IWP to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to IWP and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, IWP agrees immediately to pay the United States the greater of (i) a

ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, IWP waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that are (i) filed by the United States against IWP within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date. IWP agrees not to contest any offset, recoupment, and/or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

15. In exchange for valuable consideration provided in this Agreement, IWP acknowledges the following:

a. IWP has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to IWP, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which IWP was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If any of IWP's payments or obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, IWP or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of IWP's debts, or to adjudicate IWP as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for IWP or for all or any substantial part of IWP's assets:

(i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against IWP for the claims that would otherwise be covered by the releases provided in Paragraph 4 above; and

(ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against IWP in the amount of Eleven Million Two-Hundred Twenty-Six Thousand Sixty-Two Dollars and Seventy-One Cents ($11,226,062.71), plus first payment handshake interest, per Paragraph 1, less any payments received pursuant to Paragraph 1 of this Agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by a receiver, trustee, creditor, custodian, or similar official.

f. IWP agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 17.E is not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States' police and regulatory power. IWP shall not argue or otherwise contend that the United States' claim,

action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). IWP waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to IWP that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the Effective Date.

16. This Agreement is intended to be for the benefit of the Parties only.

17. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each Party represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. This Agreement shall be deemed to have been drafted by all Parties to this Agreement and, therefore, shall not be construed against any Party for that reason in any subsequent dispute.

20. The Agreement contains the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

21. The undersigned represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on IWP's successors, transferees, heirs, and assigns.

24. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

25. The Parties may execute this Agreement via facsimile and/or by portable document format (.pdf), both of which shall be deemed the equivalent of an original signature.

26. This Agreement shall become effective on the date of the signature of the last signatory to the Agreement ("Effective Date" of this Agreement).

SIGNATURES TO FOLLOW ON NEXT PAGE

THE UNITED STATES OF AMERICA

DATED: 6/26/2023

BY: _____

BRIAN M. LAMACCHIA
JESSICA J. WEBER
Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 6/13/2023

BY: _____

JENNIFER VALDIVIESO
Deputy Director for Program and
System Integrity
Division of Federal Employees', Longshore
and Harbor Workers' Compensation
Office of Workers' Compensation Programs
United States Department of Labor

INJURED WORKERS PHARMACY LLC

DATED: 6/23/23

BY: _____
M. Gavin
CEO

DATED: 6/23/2023

BY: _____
ERIC P. CHRISTOFFERSON
BRIAN H. BENJET
DLA Piper LLP
Counsel for Injured Workers Pharmacy LLC

Exhibit A

Year	Payment #	Due Date	Principal	Interest	Payment	Balance
						$10,000,000.00
0	1	Effective Date of Agreement	$1,250,000.00	Handshake interest to be calculated per Para. 1 based on payment date	$1,250,000.00, plus handshake interest	$8,750,000.00
1	2	One year after First Payment	$935,000.00	$315,000.00	$1,250,000.00	$7,815,000.00
2	3	Two years after First Payment	$968,660.00	$281,340.00	$1,250,000.00	$6,846,340.00
3	4	Three years after First Payment	$1,003,531.76	$246,468.24	$1,250,000.00	$5,842,808.24
4	5	Four years after First Payment	$1,039,658.90	$210,341.10	$1,250,000.00	$4,803,149.34
5	6	Five years after First Payment	$4,803,149.34	$172,913.38	$4,976,062.71	$0.00
		TOTAL	$10,000,000.00	$1,226,062.72, plus handshake interest	$11,226,062.71, plus handshake interest	

Attachment 1 - Corrective Action Plan

This Corrective Action Plan ("CAP") between the Injured Worker's Pharmacy ("IWP") and the U.S. Drug Enforcement Administration ("DEA") memorializes the policies and procedures that IWP and the DEA (jointly, the "Parties") have agreed upon to advance IWP's efforts to ensure compliance with the Controlled Substances Act (the "Act") and to enhance IWP's ability to prevent, detect, and address drug diversion. IWP is registered with the DEA as a Retail Pharmacy authorized to handle Schedule II-V controlled substances under DEA #BI7566245.

1. This CAP is incorporated by reference at paragraph 2 of the Settlement Agreement between IWP and the United States executed contemporaneously with this CAP (the "Settlement Agreement").

2. This CAP pertains to the "Covered Conduct" described in Recital H of the Settlement Agreement and in the United States' contentions in Recital I of the Settlement Agreement.

3. DEA agrees to take no further administrative action against IWP, along with their respective directors, officers, managers, employees, successors and assigns related to the Covered Conduct. However, should IWP violate this CAP, IWP understands that DEA may institute further administrative action, including but not limited to seeking revocation of IWP's DEA registration for any new violation, as well as for the Covered Conduct. DEA may also seek injunctive relief to enforce the terms of the CAP pursuant to 21 U.S.C. § 843 (f), as stated in Paragraph 5 of the Settlement Agreement.

4. The period of this CAP shall be five (5) years, starting on the Effective Date of the Settlement Agreement.

5. Whenever this CAP requires notice to the DEA, the persons to be notified will be Taylor McCarty (571-362-9087) Taylor.A.McCarty@dea.gov and Heather Danner-Ryan (571-362-9035) Heather.A.Danner-Ryan@dea.gov. Whenever this CAP requires notice to IWP, the persons to be notified will be Jayne Kresac (888-321-7945) jkresac@iwpharmacy.com and Brian Benjet (215-656-3311) brian.benjet@dlapiper.com. Either party may change the name and or contact information of its contact person(s) by so notifying the other party's contact person(s).

6. Prior to, in connection with, and following the Massachusetts AG Consent Judgment, IWP has implemented several changes to their controlled substance handling procedures, including, but not limited to, the following:

   a. In 2018, IWP released a High-Risk Prescribing Regimens Standard of Procedure ("SOP"), which requires pharmacists to conduct a thorough review of prescriptions that are identified as part of a high-risk drug combination. As later amended, this SOP requires the Pain Management Specialty Pharmacist to contact the prescribers of the identified high-risk prescriptions to confirm awareness and accuracy of the prescribed dosages and treatment plan.

   b. In 2020, IWP implemented an Initial High-Risk Opioid Prescription Policy and Procedure, which expands the clinical checks conducted prior to initial dispensing, by including a process for documenting the authenticity of high-risk prescriptions before dispensing the medication and a process for providing specific counseling to patients regarding alternatives to high-risk prescriptions. IWP also implemented training regarding the identification of initial high-risk opioid prescriptions, the review process, and the documentation process. In

addition, IWP implemented an At-Risk Patient Process that requires holistic review of patient profiles for high-risk medications.

c. IWP has implemented other new and revised pharmacy policies and procedures. IWP has provided the DEA with copies of its current policies and procedures that pertain to:

i. At-Risk Patient Chronic Pain Counseling
ii. CII Room Operation
iii. Controlled Substance Inventory
iv. Controlled Substances Workflow (CIII-CV)
v. Drug Utilization Review (DUR)
vi. Clinical Intervention: High Risk Prescribing Regimens
vii. Initial High-Risk Opioid Prescriptions
viii. Naloxone Standing Order
ix. New At-Risk Patient Auditing Procedure
x. PDMP Query
xi. Prescription Authentication Practices
xii. Processing Pharmacist Responsibilities & Preserving Pharmacist's Judgement
xiii. Professional License Verification (MedPro)
xiv. Receipt of Pharmaceutical Inventory
xv. Pharmacy Record Retention
xvi. Pharmacy Risk Evaluation and Mitigation Strategy (REMS)
xvii. Schedule II Narcotic Non-Contiguous States
xviii. PMSP Program Provider Monitoring

7. Since 2017, IWP has either hired new personnel or created new positions including: a Chief Compliance Officer that reports to the Board of Directors as well as the Chief Executive Officer, Pain Management Specialty Pharmacist, replacing its Chief Executive Officer, and hiring new executive and clinical leadership. IWP's new Chief Compliance Officer has since designed and implemented a new compliance program.

8. IWP agrees that it will continue utilizing the changes that it undertook, as those changes are listed out in paragraph 6 in order to address the Covered Conduct, and to remain in compliance with Title 21 of the Code of Federal Regulations.

9. During the CAP Period, IWP:

a. Agrees to abide by all federal, state and local statutes and regulations relating to controlled substances.

b. Agrees to allow DEA personnel to enter the registered location at any time during regular business hours, without prior notice, and without requiring DEA to obtain an administrative inspection warrant, search warrant, or other means of entry, in order to verify compliance with the Controlled Substances Act (Title 21 United States Code §801, et seq.), its implement regulations, and this CAP.

c. Agrees to maintain complete and accurate records relating to controlled substances, and to maintain copies of these records for a period of five years, from the effective date of this CAP, which will be available to DEA for inspection and copying, and inventories as required by 21 C.F.R. § 1304.04(a), except that, during the CAP Period only, the time period for which records and inventories must be maintained is extended to five (5) years from the date of such records or inventories.

d. Agrees to be truthful and accurate in all information that it submits to the DEA and that any notifications, as required by this CAP and DEA rules and regulations, are timely submitted.

e. Agrees that if any state agency or entity conducts an inspection or any investigation of IWP by seeking any records or documents from IWP, IWP hereby gives its unrestricted consent to the state agency or entity to share

any and all reports, documents, evidence and information of whatever nature or kind with the DEA.

f. Agree to continue implementing SOP's to ensure compliance with its obligations under 21 CFR 1306.04(a).

g. Agrees to maintain SOPs to ensure compliance with its obligations under 21 CFR § 1306.04(a).

h. Agrees that it shall maintain SOPs to ensure the pharmacy complies with the requirements of 21 CFR § 1306.05, including by ensuring prescriptions contain all the required information.

i. Agrees to maintain, on a current basis, a complete and accurate record of each controlled substance received, sold, delivered, dispensed or otherwise disposed of, as required by 21 CFR § 1304.21(a).

j. Agrees that only IWP pharmacists will make clinical determinations relating to Drug Utilization Review ("DUR") alerts for prescriptions that are flagged for issues such as drug interactions, potential allergic reactions, dangerous drug combinations and therapeutic duplication of opioids, to ensure that the prescribed drugs are appropriate and medically necessary prior to filling.

k. Agrees to emphasize the identification of potential safety concerns, red flags, and potentially illegitimate prescriptions.

l. Agrees to not make any decision relating to a pharmacist's performance review, compensation, promotion, work hours, hiring, or termination that relies in whole or in part on dispensing rates, whether measured individually or in aggregate. This restriction shall not be interpreted to limit IWP's ability

to reassign pharmacists to different responsibilities based on operational considerations, or to prohibit employment decisions based upon non-performance (e.g., absenteeism, failure to complete essential job responsibilities) or significant underperformance, as compared to peers and taking into account best dispensing practices.

m. Agrees to provide controlled substance training to all new employees who handle controlled substances or records related to controlled substances. This training shall be conducted within one week of hire. This training shall include, but not be limited to the following: (1) the proper handling, recordkeeping, security, and storage procedures for controlled substances (2) how to identify and handle prescription red flags to ensure patient safety and prescription legitimacy (3) how to identify potentially dangerous medication combinations (4) current CDC prescription guidelines and (5) controlled substance abuse and prevention.

n. Agrees to provide controlled substance training to all current employees who handle controlled substances or records related to controlled substances. This training shall be conducted at least, but not limited to, annually. This training shall include, but not be limited to the following: (1) the proper handling, recordkeeping, security, and storage procedures for controlled substances (2) how to identify and handle prescription red flags to ensure patient safety and prescription legitimacy (3) how to identify potentially dangerous medication combinations (4) current CDC prescription guidelines and (5) controlled substance abuse and prevention.

o. Agrees to maintain a drug diversion team consisting of employees in compliance, pharmacy, security and operations roles. This drug diversion team shall be tasked with establishing, maintaining, and, if appropriate, advancing various diversion controls throughout IWP.

p. Will send a copy of this CAP, in its entirety, to the Massachusetts Department of Public Health Drug Control Program, within ten days of the full execution of this Agreement.

q. At least once every 12 months following the Effective Date of the Settlement Agreement, IWP will conduct a self-evaluation to review compliance with all requirements of the Act, this CAP and its corresponding commitments to maintain SOPs and a compliance program directed at IWP's obligations under the Act. At the completion of each evaluation, the Pharmacy Manager of Record and/or the Chief Compliance Officer will certify that he/she has completed the evaluation and document any corrective action to be taken. IWP will retain the letters of certification, and make them available to the DEA upon request, for two years following the expiration of this CAP.

r. IWP will promptly and thoroughly investigate all thefts, significant losses, and other potential diversions of controlled substances. IWP will establish protocols to reduce the number of in-transit losses of controlled substances and will promptly report all such thefts, significant losses, and other diversions to DEA. DEA is aware that IWP has additional reporting duties to licensure boards, and all other relevant agencies.

10. IWP will comply at all times with the Act and the regulations issued thereunder. To the extent that any requirements in the Act or regulations are greater than those imposed by this CAP, the stricter requirements will apply.

11. Each Party and signatory to this CAP represents that it/he/she freely and voluntarily enters into this CAP without any degree of duress or compulsion.

12. This CAP is intended for the benefit of the Parties only; it does not create any rights or benefits for third parties.

13. This CAP is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this CAP is the United States District Court for the District of Massachusetts. This CAP shall be deemed to have been drafted by both Parties and shall not, therefore, be construed against either Party in any subsequent dispute.

14. This CAP and the Settlement Agreement constitute the complete agreement between the DEA and IWP relating to the matters addressed herein. This CAP may be amended only by a writing signed by both DEA and IWP.

15. The undersigned signatories represent and warrant that it is fully authorized to execute this CAP on behalf of the parties.

16. This CAP may be executed in two counterparts, each of which constitutes an original and both of which constitute one and the same agreement.

17. This CAP is binding on IWP's successors, transferees, and assigns.

SIGNATURES TO FOLLOW ON NEXT PAGE

On Behalf of IWP:

Brian H. Benjet
DLA Piper LLP (US)
Counsel for Injured Workers Pharmacy LLC

Date: 6-23-2023

Michael Gavin
Chief Executive Officer
Injured Workers Pharmacy LLC

Date: 6/23/23

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

BRIAN BOYLE
Digitally signed by BRIAN BOYLE
Date: 2023.06.23 17:46:30 -04'00'

Brian D. Boyle
Special Agent in Charge
Drug Enforcement Administration
New England Field Division

Date:

MARK RUBBINS
Digitally signed by MARK RUBBINS
Date: 2023.06.23 15:28:23 -04'00'

Mark J. Rubbins
Diversion Program Manager
Drug Enforcement Administration
New England Field Division

Date:

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **INJURED WORKERS PHARMACY,** **Pharmacy License No. PH02281,** **Respondent.**	**Case No. 23-428-PH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **INJURED WORKERS PHARMACY,** **Pharmacy License No. PH02281,** **Respondent.**	**Case No. 23-428-PH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR INJURED WORKERS PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

INJURED WORKERS PHARMACY
300 Federal Street
Andover, MA 01810

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
MAY 0 2 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. INJURED WORKERS PHARMACY, Pharmacy License No. PH02281, Respondent.	Case No. 23-428-PH-O **ANSWER AND NOTICE OF DEFENSE**

Injured Workers Pharmacy, LLC ("IWP" and "Respondent"), by and through its attorneys, the Law Offices of Lyn E. Beggs, PLLC and DLA Piper (US), in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

JURISDICTION

1. Paragraph 1 of the Notice of Intended Action and Accusation contains legal arguments and/or conclusions to which no response is required. To the extent a response is required, Respondent acknowledges that it does not presently intend to challenge the Nevada State Board of Pharmacy's jurisdiction over this matter.

FACTUAL ALLEGATIONS

2. Admitted in part and denied in part. Respondent admits that it entered into a settlement agreement with the U.S. Department of Justice, the Drug Enforcement Administration, and the Department of Labor in June 2023. Respondent denies that there were any "violations of federal law related to dispensing of controlled substances."

3. Admitted.

APPLICABLE LAW

4. Paragraph 4 of the Notice of Intended Action and Accusation contains legal arguments and/or conclusions to which no response is required.

5. Paragraph 5 of the Notice of Intended Action and Accusation contains legal arguments and/or conclusions to which no response is required.

6. Paragraph 6 of the Notice of Intended Action and Accusation contains legal arguments and/or conclusions to which no response is required.

7. Paragraph 7 of the Notice of Intended Action and Accusation contains legal arguments and/or conclusions to which no response is required.

COUNT ONE

8. Respondent denies the allegations in Paragraph 8 of the Notice of Intended Action and Accusation.

FACTUAL DEFENSE AND MITIGATING FACTORS

9. In 2020, the Massachusetts Attorney General ("MA AG") investigated IWP's historical dispensing practices from 2008 to 2019. That investigation was resolved in June 2020 by means of a Consent Judgment entered by the Superior Court for the Commonwealth of Massachusetts on July 3, 2020. (Exhibit A.) Notice of the Consent Judgment was provided to the Nevada Board of Pharmacy on June 26, 2020. (Exhibit B.) There was no finding by the MA AG that any illegitimate prescription was filled by IWP.

10. As part of the Consent Judgment with the Massachusetts AG, IWP agreed to, *inter alia*, implement enhanced policies and procedures to further safeguard against improper and unlawful dispensing and engage an independent auditor to audit and report on IWP's compliance with the Consent Judgment. In October 2021, an independent auditor concluded that IWP was in

compliance with the stipulated consent judgment in all material aspects. These enhanced policies and procedures remain in place.

11. Just as IWP provided notice of the MA AG Consent Judgment resolution to the Nevada Board of Pharmacy, IWP also provided formal notice of the MA AG Consent Judgment resolution to the Massachusetts Board of Pharmacy. In light of the resolution of the matter brought by the MA AG, the Massachusetts Board of Pharmacy, IWP's home regulator, concluded that no additional disciplinary actions were warranted.

12. The June 27, 2023 Settlement Agreement entered into by and between the United States of America, acting through the United States Department of Justice, the Drug Enforcement Administration ("DEA"), and the Department of Labor, and IWP (referred to in the Notice of Intended Action and Accusation) did not raise new issues with respect to IWP's historical dispensing practices, but was instead coextensive with the same conduct that was investigated by and resolved with the MA AG. (Exhibit C.) The United States' investigation concerned IWP's dispensing practices from 2014 through 2019. As part of the Settlement Agreement, IWP and the DEA entered into a separate Corrective Action Plan to ensure continued compliance with the Controlled Substances Act and to enhance IWP's ability to prevent, detect, and address drug diversion. The Corrective Action Plan largely incorporated and/or restated the provisions of the June 24, 2020 Consent Judgment with the MA AG that had already been implemented in 2020. Notice of the Settlement Agreement was provided to the Nevada Board of Pharmacy on June 28, 2023. (Exhibit D.) IWP has fully complied with the terms of the June 27, 2023 Settlement Agreement.

13. Like the MA AG settlement, neither the DEA nor the DOJ found that IWP wrongfully filled any prescription.

14. As with the MA AG settlement, the Massachusetts Board of Pharmacy, IWP's home regulator, concluded that no additional disciplinary actions were warranted as a result of the Settlement Agreement.

15. IWP remains committed to ensuring compliance with federal and state laws and to enhancing its ability to prevent, detect, and address drug diversion.

16. Further, the controlled substance prescriptions that IWP dispensed in 2022 and 2023 were properly filled and followed IWP's policies and procedures concerning the dispensing of controlled substances. After the MA AG Settlement in 2020, IWP implemented several enhancements, including clinical, operational, diversion and security, and compliance enhancements. (*See* Exhibit E (letter from Neil Welch); Exhibit F (letter from Jaclyn McNulty).) The efficacy of the implementation of those enhancements was validated by an independent third-party auditor. Thus, all of the controlled substance prescriptions in 2022 and 2023, as identified in Paragraph 3 of the Notice of Intended Action, were dispensed in accordance with those enhancements and in compliance with the Controlled Substances Act.

17. Accordingly, there is no basis for Count One, Violation of Federal Controlled Substances Act/Unprofessional Conduct with respect to prescriptions filled and dispensed in 2022 and 2023. Moreover, neither the Consent Judgment or the Settlement Agreement contained any finding of wrongful conduct in 2022 and 2023. (*See, e.g.* Exhibit A ¶ 81.) Rather, the Corrective Action Plan was made "to advance IWP's efforts to ensure compliance with the Controlled Substances Act . . . and to enhance IWP's ability to prevent, detect, and address drug diversion." (*See* Exhibit C, Corrective Action Plan at 1.) Prescriptions dispensed in 2022 and 2023 prescriptions were never at issue in the MA AG or United States' investigations.

DATED: May 2, 2025

Respectfully submitted,

Lyn E. Beggs

Lyn E. Beggs, Esq.
Law Offices of Lyn E. Beggs, PLLC
316 California Ave. #863
Reno, NV 89509
lyn@lbeggslaw.com

Brian H. Benjet
DLA Piper LLP (US)
One Liberty Place
1650 Market Street, Suite 5000
Philadelphia, PA 19103-7300
brian.benjet@us.dlapiper.com

Attorneys for Injured Workers Pharmacy, LLC

NOTIFY

V6/30

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COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT
CIVIL ACTION NO.
20-1348H

COMMONWEALTH OF MASSACHUSETTS,

Plaintiff,

v.

INJURED WORKERS PHARMACY, LLC

Defendant.

Ohio
mt
7-3-20
SF
HDC
MASD

CONSENT JUDGMENT

WHEREAS, Plaintiff, the Commonwealth of Massachusetts ("Commonwealth"), acting by and through the Attorney General, alleges that Defendant Injured Workers Pharmacy ("IWP") violated the Massachusetts Consumer Protection Act, G.L. c. 93A, § 2 by, *inter alia*: (a) failing to implement adequate policies and procedures to safeguard against improper and unlawful dispensing of controlled substances; (b) filling controlled substance prescriptions without sufficient regard for whether they were issued for a legitimate medical purpose; and (c) engaging in unfair sales tactics, including paying certain third parties to refer patients to IWP;

WHEREAS, the Commonwealth and IWP (collectively, the "Parties") have agreed to resolve the claims alleged in the Complaint by entering into this Consent Judgment (hereinafter, the "Judgment"); and

WHEREAS, for the reasons set forth in the contemporaneously filed Joint Motion for Entry of Judgment by Consent and for the purpose of avoiding prolonged and costly

JUDGMENT ENTERED ON DOCKET JUL 2 2020
PURSUANT TO THE PROVISIONS OF MASS. R. CIV. P.58(a)
AND NOTICE SENT TO PARTIES PURSUANT TO THE PRO-
VISIONS OF MASS. R. CIV. P. 77(d) AS FOLLOWS

litigation, and in furtherance of the public interest, the Parties consent to the entry of this Judgment;

NOW, THEREFORE, IT IS ADJUDGED, ORDERED AND DECREED:

I. JURISDICTION AND VENUE

1. Defendant consents to this Court's continuing subject matter and personal jurisdiction solely for the purposes of entry, enforcement, and modification of this Judgment or granting such further relief as the Court deems just and proper.

2. Defendant consents to venue in this Court for the purposes of entry, enforcement, and modification of this Judgment.

3. Defendant hereby accepts and expressly waives any defect in connection with service of process in this action and further consents to service of all process in this action in the manner set forth in Section V herein.

II. EFFECT OF JUDGMENT

4. This Judgment fully and finally resolves and disposes of the claims alleged in the Complaint in this matter.

5. The Judgment will, upon its Effective Date, constitute a fully binding and enforceable agreement between the Parties, and the Parties consent to its entry as a final judgment by the Court.

III. MONETARY RELIEF

6. Judgment shall enter against IWP in the amount of $11,000,000 ("the Judgment Amount") to be paid as follows: $6,000,000 within ten business days of the Effective Date; $3,000,000 within one year of the Effective Date; and $2,000,000 upon the earlier of: (a) a transaction resulting in (i) a change of control with respect to the ownership of IWP; (ii) transfer of all or substantially all of the assets of IWP; or (iii) a recapitalization or other transaction in

which the owners of IWP immediately prior to such transaction do not own a majority of the equity interests of the surviving entity after the closing of such transaction; or (b) five years of the Effective Date. IWP covenants and agrees that it shall not make any distributions to any of the owners of IWP or any related entities or affiliates until such time as the Judgment Amount has been paid in full and satisfied. The Judgment Amount shall be allocated as follows: (a) $9,000,000 as civil penalties pursuant to G.L. c. 93A, § 4; (b) $1,500,000 to be deposited to an account or accounts held by the Office of the Attorney General ("AGO") for the purpose of assisting the AGO to discharge its duties, in accordance with G.L. c. 12 § 4A, and to be used in the sole discretion of the AGO to: (i) promote initiatives designed to improve care and treatment related to prescription medications or otherwise assist Massachusetts health care consumers, or (ii) support efforts to enforce compliance with state and federal laws and regulations that protect such individuals, including, but not limited to, through grants or other distributions to one or more political subdivisions of the Commonwealth, non-profit organizations, or to the Local Consumer Aid Fund, as established by G.L. c 12, § 11G; and (c) $500,000 for the reasonable attorney's fees and expenses incurred in investigating and resolving this matter.

7. If IWP fails to pay the Judgment Amount in accordance with this Judgment, it shall be in default of this Judgment. Upon receipt of written notice of the default from the AGO, IWP shall have the opportunity to cure such default within 5 business days from the date of receipt of the notice. If IWP fails to cure such default within 5 business days of receiving the notice of default, the remaining unpaid balance of the Judgment Amount and any interest then accrued shall become accelerated and immediately due and payable, and interest shall accrue at a simple rate of 12 percent per annum from the date of default until the date of payment.

8. The Effective Date of this Judgment shall be deemed the date that this Judgment

is entered on the Court docket ("Effective Date").

9. If within 91 days of the Effective Date of this Judgment or of any payment made under this Judgment, IWP or a third party commences any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking an order for relief of IWP's debts, or seeking to adjudicate IWP as bankrupt or insolvent, or seeking appointment of a receiver, trustee, custodian, or other similar official for IWP or for all or any substantial part of IWP's assets, IWP shall not argue or otherwise take the position, directly or indirectly, that: (a) its obligations under this Judgment may be avoided under 11 U.S.C. § 547; (b) it was insolvent at the time this Judgment was entered into, or became insolvent as a result of a payment made pursuant to the Judgment; or (c) the mutual promises, covenants, and obligations set forth in this Judgment do not constitute a contemporaneous exchange for new value given to IWP.

10. If IWP's obligations under this Judgment are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Commonwealth, at its option, may rescind the releases in this Judgment and bring any claim, action, or proceeding against IWP for the claims that would otherwise be covered by the release provided herein. IWP shall not argue or otherwise take the position that the Commonwealth's claims are subject to stay, including pursuant to 11 U.S.C. §§ 105 or 362(a), or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, except to the extent such defenses were available on the date this Judgment entered.

IV. PERMANENT INJUNCTIVE RELIEF

The following injunctive relief shall apply to IWP and those otherwise bound pursuant Mass. R. Civ. P. 65(d):

A. DEFINITIONS

11. "At-Risk Patient" means any patient in one or more of the following categories:

    a. A patient with one or more opioid prescriptions that, in aggregate, total 100 MME/day or more;

    b. A patient with one or more opioid prescriptions who has also been prescribed a benzodiazepine, either simultaneously or within an overlapping duration; or

    c. A patient who has been prescribed opioids for use every day for at least 90 consecutive days.

12. "Audit Report" refers to the report, together with any attachments thereto, prepared by the Independent Auditor, pursuant to Section IV.H herein.

13. "Independent Auditor" refers to the person hired to audit and report on IWP's compliance with this Judgment, consistent with the terms described in Section IV.H herein.

14. "Audit Period" refers to the one-year period from the Effective Date.

15. "Corresponding Responsibility" shall be interpreted as it is used in state and federal law governing the practice of pharmacy. *See* G.L. c. 94C, § 19(a); 21 CFR § 1306.04(a).

16. "Dispensing Pharmacist" refers to the IWP pharmacist responsible for authorizing the dispensing of a particular prescription, including fulfilling Corresponding Responsibility obligations.

17. "Initial High-Risk Prescription" means any prescription for a Schedule II opioid that includes at least one of the following, as confirmed via IWP fill history and a patient's PDMP profile:

a. An initial prescription for an opioid that exceeds a 7-day supply for an opioid-naïve patient;

b. An initial prescription for an extended-release or long-acting opioid for an opioid-naïve patient;

c. An initial prescription for an opioid that exceeds 50 MME/day for an opioid-naïve patient; or

d. A set of prescriptions that together initiate a patient on a combination of a benzodiazepine and an opioid.

18. "MME" means morphine milligram equivalents, as used by the U.S. Centers for Disease Control and Prevention. *See* Guideline for Prescribing Opioids for Chronic Pain, U.S. CDC, available at https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

19. "MME/day" means the total MME of all prescribed doses of opioid medications that a patient may take in a single day, when taking medications as directed.

20. "Opioid-Naïve" means a patient who has not been prescribed and/or dispensed opioids for use on more than seven consecutive days during the previous thirty days.

21. "Referral Source" refers to any person or entity that refers or may refer patients to IWP, including prescribers and lawyers.

B. GENERAL TERMS

22. IWP shall not engage in unfair or deceptive acts or practices.

23. IWP shall implement adequate policies and procedures to safeguard against improper and unlawful dispensing.

24. IWP shall not fill any controlled substance prescription that IWP knows was not issued for a legitimate medical purpose, or that, with reasonable best efforts consistent with the provisions of this agreement, IWP should have identified was not issued for a legitimate medical purpose.

25. IWP shall not fill any controlled substance prescription without verifying it, as required by, *inter alia*, G.L. c. 94C, § 18.

26. IWP shall not fill any new prescription without conducting a Drug Utilization Review pursuant to 247 CMR 9.07.

27. IWP shall not fill any prescription without verifying the patient's address.

28. IWP shall not offer or pay any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, to induce any person to recommend a patient fill a prescription at IWP. Nothing in this paragraph shall be interpreted to prohibit IWP from compensating persons or entities under the safe harbor provision of 42 U.S.C. § 1320a-7b(b)(3).

29. The requirements of this injunction are in addition to, and not in lieu of, any other requirements of state or federal law, including requirements concerning pharmacists' Corresponding Responsibility. Nothing in this injunction shall be construed as relieving IWP of the obligation to comply with all local, state, and federal laws, regulations, or rules, nor shall any of the provisions of this injunction be deemed as permission for IWP to engage in any acts or practices prohibited by such laws, regulations, or rules.

30. IWP shall use reasonable best efforts to meet the deadlines herein and shall report any delays to the AGO, including delays in implementation resulting from the COVID-19 pandemic.

31. IWP shall provide a copy of this Consent Judgment to its officers, directors, and supervisors in IWP's verification, enrollment and pharmacy departments promptly following the Effective Date. IWP shall provide the AGO with signed acknowledgements of receipt from all such officers, directors, and supervisors within 30 days of the Effective Date. In addition, upon hiring, IWP shall ensure that appropriate IWP personnel necessary to fulfill IWP's obligations under this Judgment are aware of the relevant provisions.

C. POLICIES AND PROCEDURES FOR DISPENSING

32. IWP shall not dispense an Initial High-Risk Prescription unless and until the Dispensing Pharmacist has:

a. Verified that the prescription is authentic, if a written prescription is presented;

b. Ascertained the circumstances necessitating the Initial High-Risk Prescription; and

c. Ascertained whether a less-risky alternative treatment plan was considered.

d. Documented each of (a)-(c) in writing in the patient's records.

33. Except as otherwise permitted herein, IWP shall not dispense an Initial High-Risk Prescription unless and until the Dispensing Pharmacist contacts the patient (and documents the contact) to attempt to:

a. Advise the patient of the risks associated with the Initial High-Risk Prescription, including risks of addiction, overdose and death;

b. Counsel the patients on safe consumption and storage practices; and

c. Offer to dispense to the patient a naloxone rescue kit pursuant to Board of Registration in Pharmacy Policy No. 2018-04: Naloxone Dispensing via Standing Order, at no cost to the patient, consistent with IWP billing practices for the underlying Initial High-Risk Prescription.

34. IWP may dispense an Initial High-Risk Prescription after making an unsuccessful attempt using reasonable best efforts to contact and verbally counsel the patient in accordance with Paragraph 33, provided that IWP makes such counseling available upon patient request and effectively communicates to the patient that such counseling is available.

35. IWP shall continue to provide written counseling to every patient who receives any prescription for a Schedule II or III drug (whether an Initial High-Risk Prescription or not), by providing an Opioid Prescription Drug Fact Sheet with each prescription delivery, as mandated by Massachusetts law, as well as a written offer to dispense to the patient a Naloxone Rescue Kit pursuant to Board of Registration in Pharmacy Policy No. 2018-04: Naloxone Dispensing via Standing Order, at no cost to the patient, consistent with IWP billing practices for the underlying prescription.

36. Nothing in this Judgment precludes IWP from: (a) seeking reimbursement from insurers for Naloxone Rescue Kits it dispenses to patients; or (b) seeking to amend this Judgment to allow it to charge patients the cost of the Naloxone Rescue Kits it dispenses pursuant to the Standing Order, if a change in reimbursement practices results in widespread denial of coverage for such Naloxone Rescue Kits.

37. IWP shall not dispense a controlled substance prescription unless and until the Dispensing Pharmacist, either manually or through an automated system, verifies the DEA number and the state license(s) for the prescriber immediately prior to dispensing the drugs.

38. IWP shall not dispense a controlled substance prescription unless and until the Dispensing Pharmacist consults the applicable state's Prescription Drug Monitoring Program (except as permitted by 105 CMR 700.012(H) or similar state regulations), where the applicable state allows pharmacists to do so.

39. IWP shall not dispense a Schedule II narcotic prescription written by a physician, nurse practitioner, or physician assistant from any Massachusetts pharmacy location unless the prescriber is licensed to practice medicine and registered in the same state or a contiguous state to where the prescription is to be delivered, in accordance with G.L. c. 94C, § 18(d½)(2).

40. IWP shall enable all pharmacy staff to access a provider's entire IWP dispensing history without the need to request a special report from other departments.

41. IWP shall make any necessary changes to its pharmacy software to comply with the obligations in this Judgment within a reasonable time, including changes that block pharmacists from dispensing opioid prescriptions in violation of these sections.

D. MAINTENANCE OF RECORDS

42. IWP shall maintain records reflecting its compliance with the injunctive relief in this Judgment, including any and all information and documentation received from prescribers and patients, for every controlled substance prescription for at least ten years, in a manner that is accessible to IWP staff and consistent with applicable privacy laws. This provision shall not apply to the maintenance of telephone call recordings pursuant to paragraph 44 herein.

43. IWP shall request and record in its pharmacy software ICD-10 codes and physician specialty information for all patients filling Initial High-Risk Prescriptions. Provided however, that IWP may dispense a Schedule II prescription other than an Initial High-Risk Prescription in the absence of receipt of an ICD-10 Code if in the professional judgment of the Dispensing Pharmacist, the ICD-10 code is not required to fulfill his or her Corresponding Responsibility with respect to that prescription.

44. IWP shall record all phone calls between pharmacists and prescribers and all phone calls between pharmacists and patients. IWP shall advise prescribers and patients at the beginning of each phone call that the phone calls are being recorded. The audio recordings of all phone calls shall be maintained for at least two years in a manner that is accessible to IWP staff and consistent with applicable privacy laws.

45. IWP shall ensure that the primary pharmacist who was charged with exercising professional judgment as to the propriety and appropriateness of filling a prescription is recorded in its pharmacy software as a Dispensing Pharmacist.

46. IWP shall make any necessary changes to ensure it uses pharmacy software that implements the record keeping obligations in this Judgment.

E. CHANGES TO STAFFING

47. Within 90 days of the Effective Date, IWP shall hire a sufficient number of full-time Pain Management Specialty Pharmacists and supporting data analytics resources to accurately and reasonably identify and counsel At-Risk Patients. The Pain Management Specialty Pharmacist(s) shall report to the Pharmacist Manager of Record as defined by IWP's Massachusetts pharmacy license, but shall have specific and independent direct access to the Chief Compliance Officer and shall have full independent access to IWP's pharmacy software, as

well as the ability to sort the data by characteristics such as dosage, patient state, prescriber state, and payer.

48. The Pain Management Specialty Pharmacist(s) shall work with supporting data analytics resources to:

a. Review dispensing data at least monthly, as necessary to timely identify At-Risk Patients;

b. Review dispensing data at least monthly, as necessary to timely identify prescribers exhibiting suspicious or dangerous prescribing patterns and behaviors and notify the Chief Compliance Officer, the Dispensing Pharmacist(s) and the Pharmacist in Charge, in writing, of any findings; and

c. Prepare and issue monthly reports to the Chief Compliance Officer and all pharmacy staff concerning Initial High-Risk Prescriptions, At-Risk Patients, and suspected suspicious prescriber behavior, including failure or refusal by prescribers to meaningfully engage with the Pain Management Specialty Pharmacist(s). IWP may also use these reports to assist with training efforts as appropriate.

49. The Pain Management Specialty Pharmacist(s) shall use reasonable best efforts to promptly speak with and counsel each At-Risk Patient and his or her prescriber(s) no later than 30 days after dispensing the prescription at issue, except as permitted in paragraph 50, to discuss: the risks of addiction, overdose and death associated with their existing prescriptions; a treatment plan to, where appropriate, safely lower the patient's opioid dosage over time, safely remove dangerous drug combinations, and/or taper the patient off opioids completely, consistent with evidence-based guidelines and in consultation with relevant specialists; and the advisability of co-

prescribing/co-dispensing Naloxone Rescue Kits. The Pain Management Specialty Pharmacist(s) shall document these efforts. To the extent At-Risk Patients are also patients receiving Initial High-Risk Prescriptions, paragraphs 32 and 33 shall also apply.

50. With respect to preexisting At-Risk Patients (i.e., At-Risk Patients as of the time of the Effective Date) and their prescribers, the obligations in paragraph 49 shall be satisfied if the Pain Management Specialty Pharmacist(s) makes the required contact attempts, by the following deadlines, provided that IWP agrees to use reasonable best efforts to make these contacts as set forth below:

a. By 180 days after the Effective Date, the Pain Management Specialty Pharmacist(s) shall have satisfied the requirements of paragraph 49 for all At-Risk Patients who satisfy all three definitional criteria in Paragraph 11.

b. Within 270 days of the Effective Date, in addition to those At-Risk Patients who satisfy all three criteria of the definition in Paragraph 11, the Pain Management Specialty Pharmacist(s) shall also have satisfied the requirements of paragraph 49 with respect to all other At-Risk Patients who satisfy Paragraph 11(c).

c. Within one year of the Effective Date, the Pain Management Specialty Pharmacist(s) shall have satisfied the requirements of paragraph 49 with respect to all preexisting At-Risk Patients.

51. For avoidance of doubt, nothing in this Judgment relieves IWP or its Dispensing Pharmacists from exercising Corresponding Responsibility when dispensing an Initial High-Risk Prescription or a prescription to an At-Risk Patient.

52. Reports prepared by the Pain Management Specialty Pharmacist shall be available to the AGO upon request and shall be treated as confidential consistent with paragraph 73, below.

53. IWP shall hire a full-time Chief Compliance Officer who reports directly to IWP's Board to oversee and direct IWP's compliance with the law and with this injunction, together with adequate staff, in training and in number. The Chief Compliance Officer shall also have a dotted-line reporting relationship with the Chief Executive Officer. The Chief Compliance Officer, or those working under her supervision, shall:

a. Track all relevant laws, rules, and regulations for each state into which IWP dispenses controlled substances, making changes to IWP's policies, procedures, and software to ensure compliance with such laws, and keep IWP's policies and procedures up to date with changes in such laws;

b. Design and administer training programs for IWP staff on compliance-related topics; and

c. Receive, investigate and document reports of suspicious prescriber behavior, help assess whether IWP should cease filling prescriptions for such suspicious prescribers, and, where appropriate, report such prescribers to an appropriate law enforcement agency.

54. IWP shall train all new employees – including pharmacy staff, sales representatives, enrollment specialists, and collection workers – on Corresponding Responsibility and identifying suspicious prescriber behavior, including but not limited to "red flags" identified by the Drug Enforcement Administration and the National Association of Boards of Pharmacy. Examples of such "red flags" include: (a) "pattern" prescribing – repeated

prescriptions from the same doctor to multiple patients for the same drugs and the same quantities, often for the same diagnosis; (b) prescribing certain dangerous combinations of controlled substances; (c) geographic anomalies such as unexplained distances between the patient, doctor, and pharmacy and shared addresses among multiple patients; (d) disproportionate prescribing of controlled substances relative to other drugs; (e) quantity and strength of the prescription; (f) customers paying cash; and (g) prescriptions written by doctors for diagnoses inconsistent with their specialty.

55. All pharmacy, enrollment, sales, and collections employees shall receive quarterly training on problematic prescribing trends identified by the Pain Management Specialty Pharmacist and other employees.

56. IWP shall require all employees who become aware of suspicious or dangerous prescriber behavior or patterns to report it to the Chief Compliance Officer.

F. BAN ON PAYMENTS TO REFERRAL SOURCES

57. IWP shall comply with all applicable federal and state laws governing compensation for referrals.

58. IWP shall implement a written reporting system for its relationships with Referral Sources, which will require IWP employees interacting with a Referral Source to report the following information:

a. Descriptions of any meetings or communications with a Referral Source;

b. Descriptions of any items of value given to a Referral Source; and

c. Any patients referred by the Referral Source to IWP.

59. The Chief Compliance Officer shall be responsible for maintaining the reporting system in Paragraph 58.

G. OTHER POLICIES AND PROCEDURES

60. IWP shall not implement any incentive or bonus compensation plans that reward IWP employees and staff based on volume of Schedule II and III controlled substance prescriptions referred to or filled by IWP.

61. IWP shall not make any decision relating to a pharmacist's performance review, compensation, promotion, work hours, hiring, or termination that relies in whole or in part on dispensing rates, whether measured individually or in aggregate. This restriction shall not be interpreted to limit IWP's ability to reassign pharmacists to different responsibilities based on operational considerations, or to prohibit employment decisions based upon non-performance (e.g., absenteeism, failure to complete essential job responsibilities) or significant underperformance, as compared to peers and taking into account best dispensing practices.

62. IWP shall post notices advising employees of their rights and obligations. These notices shall include federal and state law establishing the pharmacist's Corresponding Responsibility, contact information for the Drug Enforcement Administration to report suspicious or dangerous prescriber behavior or patterns, contact information for the Attorney General's Health Care Division and the Board of Registration in Pharmacy to report violations of laws governing pharmacies, and specific examples of management practices that would inhibit pharmacists' ability to full their responsibility, including:

a. pressure to increase dispensing rates through threats, intimidation, or the withholding of compensation or promotions;

b. malfunctioning software, or software that does not comply with the other requirements of this injunction; and

c. inadequate training for pharmacy or non-pharmacy staff in identifying red flags.

63. The above notice shall comply with the formatting and placement requirements of 29 CFR § 1903.2(a), which governs notices advising employees of their rights under the Occupational Safety and Health Act. These requirements include a minimum poster size of 8.5 inches by 14 inches, minimum heading caption font size of 36 points, minimum font size for all other text of 10 points, and placement of the poster in a "conspicuous place or places where notices to employees are customarily posted." The phone number for the Drug Enforcement Administration, the Attorney General's Health Care Division, and the Board of Registration in Pharmacy shall be printed in 36-point font or larger.

H. INDEPENDENT COMPLIANCE AUDIT

64. IWP shall engage, at its sole expense, an Independent Auditor to audit and report on IWP's compliance with the Judgment during the Audit Period. The Independent Auditor shall deliver a final Audit Report to the AGO and IWP no later than sixty days after the Independent Auditor is engaged unless otherwise agreed to by IWP and the AGO.

65. By the one-year anniversary of the Effective Date of this Judgment, IWP shall propose to the AGO an Independent Auditor with: (a) experience related to the practice of pharmacy and knowledge of compliance programs addressing policies, procedures, and practices for dispensing controlled substances and (b) sufficient independence from IWP to ensure effective and impartial performance of the Independent Auditor's duties. IWP shall provide the AGO with the proposed Independent Auditor's name, resume or curriculum vitae, and contact information, and shall obtain information in response to inquiries from the AGO concerning the proposed Independent Auditor's qualifications. If the AGO determines, in good faith, that the

proposed Independent Auditor is not qualified, or is otherwise not satisfied with IWP's proposed candidate, IWP shall propose alternate candidates until an Independent Auditor acceptable to both IWP and the AGO is chosen, provided that IWP and the AGO shall use best efforts to complete the selection process within thirty (30) days after the one-year anniversary of the Effective Date. The AGO shall not unreasonably withhold approval of IWP's proposed candidate.

66. Upon approval by the AGO, IWP shall engage the Independent Auditor to perform the duties set forth in this Judgment and on terms consistent with this Judgment. The terms of the engagement shall be subject to AGO approval. IWP shall designate the AGO a third-party beneficiary to its engagement agreement with the Independent Auditor.

67. The Independent Auditor shall audit and report on IWP's compliance with the terms contained in this Judgment. The Independent Auditor shall review IWP's actual ongoing operations, inside and outside the pharmacy. The Independent Auditor shall prepare a work plan for its audit and report, which shall be approved by the AGO and IWP. The Independent Auditor's review shall not be limited to reviewing IWP's stated policies and practices. IWP shall provide the Independent Auditor appropriate access to all data, documents and information necessary to complete the Audit Report, including, without limitation, reports by the Pain Management Specialty Pharmacist(s) and reports by licensing and law enforcement authorities.

68. IWP shall make available for meetings and/or interviews current employees, executives, and officers necessary for the completion of the Audit Report. Upon the Independent Auditor's request, IWP will use its reasonable best efforts to arrange meetings or interviews with former IWP employees, executives and officers and use its reasonable best efforts to provide the

Independent Auditor with access to IWP's third-party vendors, agents and consultants, if necessary, to complete the Audit.

69. IWP shall be under no obligation to provide or disclose to the Independent Auditor any documents, materials, or information subject to the Attorney Client Privilege or the Attorney Work Product Doctrine. IWP waives any confidentiality obligations owed to it on the part of any third party who may have records of IWP or other information that may be relevant to the Independent Auditor's work pursuant to this Judgment, except to the extent that such information is subject to the Attorney Client Privilege or the Attorney Work Product Doctrine.

70. The Audit Report shall, without limitation:

a. describe in detail the work undertaken to produce the Audit Report, in accordance with the approved work plan described in paragraph 67;

b. identify, for the Audit Period, the number of Initial High-Risk Prescriptions dispensed, the number of At-Risk Patients and related prescribers counseled, an accounting of all Naloxone kits requested and dispensed, and all prescribers IWP deactivated in its system;

c. describe in detail the nature of any instance in which the Independent Auditor believes that IWP was or is not in compliance with the terms of this Judgment, and a detailed explanation as to why the Independent Auditor has formulated this conclusion; and

d. describe in detail the nature of and basis for any concerns the Independent Auditor has regarding IWP's compliance or non-compliance with federal or state law, based on observations during the course of its Audit.

71. The Audit Report shall not contain Protected Health Information, as defined in 45 CFR § 160.103, unless such Protected Health Information is reasonably necessary to illustrate IWP's compliance or noncompliance with the terms of this Judgment.

72. The AGO may request from the Independent Auditor, and the Independent Auditor shall share, any documents or information related to the Independent Auditor's work, including confidential information obtained from IWP. The AGO agrees that it will provide confidential treatment for any IWP confidential information disclosed to it by the Independent Auditor, consistent with Paragraph 73. The AGO will notify IWP of any such contact with the Independent Auditor within five (5) days of any such contact.

73. Any report by the Independent Auditor provided pursuant to this paragraph and all information contained therein shall be treated by the AGO as confidential and exempt from public disclosure to the extent legally permissible or required under the relevant laws of the Commonwealth and the United States, provided, however, that nothing herein precludes the AGO from sharing the Audit Report with relevant state and federal licensing and law enforcement authorities or from using the Audit Report in an action to enforce this Judgment.

74. In the event that the AGO receives any public records request for the report from the Independent Auditor or other documents produced to the AGO under this Judgment and believes that such information is subject to disclosure under the relevant public records laws, the AGO agrees to provide IWP with at least ten (10) days' advance notice (consistent with Section V herein) before producing any information so that IWP may take appropriate action to defend against the disclosure of such information. Nothing contained in this subparagraph shall alter or limit the obligations of the AGO that may be imposed by the relevant public records laws of the Commonwealth, or by order of any court, regarding the maintenance or disclosure of documents

and information supplied to the AGO except with respect to the obligation to notify IWP of any potential disclosure.

75. The AGO's receipt of the report from the Independent Auditor, whether or not it represents that IWP is in compliance with laws relating to controlled substances and with the terms of this Judgment, shall not be construed as a ratification of IWP's policies or practices by the AGO, and shall not relieve IWP of the obligation to comply with all local, state, and federal laws, regulations, or rules, nor shall a lack of immediate enforcement action by the AGO be deemed as permission for IWP to engage in any acts or practices prohibited by this injunction or by such laws, regulations, or rules.

V. REPORTING AND NOTICES

76. IWP shall promptly respond to the AGO's reasonable inquiries about relief set forth herein and shall provide the AGO with contact information for purposes of such inquiries.

77. Any notices required to be sent to the AGO or IWP under this Judgment may be sent by e-mail to the addresses provided below. The notices or documents shall be sent to the following addresses:

For the Commonwealth:

Gillian Feiner
Office of the Massachusetts Attorney General
One Ashburton Place, 18th Floor
Boston, MA 02108
Gillian.Feiner@mass.gov

For IWP:
Jayne Kresac
General Counsel
Injured Workers Pharmacy, LLC
300 Federal Street
Andover, MA 01810

With email copies to:

Brian Benjet (Brian.Benjet@dlapiper.com)
Eric Christofferson (Eric.Christofferson@dlapiper.com)
Frank Libby (falibby@libbyhoopes.com)

VI. RELEASES

78. Except as otherwise provided in paragraph 79, following full payment of the Judgment Amount, the Commonwealth shall release and discharge IWP and its current and former directors, officers, employees, affiliates, successors, and assigns from any and all claims which were or could have been brought under G.L. c. 93A or for common law claims concerning unfair, deceptive, or fraudulent trade practices resulting from the activities described in the Complaint, including but not limited to claims, actions or proceedings seeking restitution, injunctive relief, fines, penalties, multiple damages, attorney's fees, or costs.

79. The Judgment is without prejudice to and the Commonwealth expressly reserves:

a. any administrative or licensing claims;

b. any claims arising under Massachusetts tax laws;

c. any claims for the violation of securities laws;

d. any claims for the violation of antitrust laws;

e. any claims for the violation of G.L. c. 12 § 5B, G.L. c. 118E §§ 39-41;

f. any criminal liability; and

g. any action to enforce this Judgment and subsequent, related orders or judgments.

80. IWP fully and finally releases the Commonwealth, its agencies, officers, agents, employees, and servants from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that they have asserted, could have asserted, or may assert in the future against the Commonwealth, its agencies, officers, agents, employees, and servants related

to the AGO's investigation of the conduct alleged in the contemporaneously filed Complaint or this Judgment.

VII. NO ADMISSION OF LIABILITY

81. IWP's consent to entry of this Judgment is not an admission of liability or of any facts alleged in the Judgment or in the Complaint. IWP is consenting to entry of this Judgment solely for the purpose of settlement, and nothing contained herein may be taken or construed to be an admission, concession, disciplinary action, finding, or conclusion of any violation of law, rule, or regulation, or of any other matter of fact or law, or any adverse final action or other final action, or of any liability or wrongdoing, all of which IWP expressly denies.

VIII. MISCELLANEOUS

82. This Judgment shall be construed in accordance with the laws of the Commonwealth.

83. Nothing in this Judgment releases any private rights of action asserted by entities or persons not releasing claims under this Judgment.

84. This Judgment shall be enforceable by the Commonwealth.

85. Any failure by any party to this Judgment to insist upon the strict performance by any other party of any of the provisions of this Judgment shall not be deemed a waiver of any of the provisions of this Judgment.

86. This Judgment, which constitutes a continuing obligation, is binding upon the Commonwealth and IWP, and any of IWP's respective successors, assigns, or other entities or persons otherwise bound by law.

87. Aside from any action stemming from compliance with this Judgment, the Parties waive all rights of appeal or to re-argue or re-hear any judicial proceedings upon this Judgment,

any right they may possess to a jury trial, and any and all challenges in law or equity to the entry of this Judgment.

88. The terms of this Judgment may be modified only by a subsequent written agreement signed by the Parties and approved by the Court.

89. Consent to this Judgment does not constitute an approval by the Commonwealth of IWP's business acts and practices, and IWP shall not represent this Judgment as such an approval.

90. IWP shall not take any action or make any statement denying, directly or indirectly, the propriety of this Judgment, including by expressing the view that the Judgment or its substance is without factual basis.

91. Nothing in this Judgment shall preclude any party from commencing an action to pursue any remedy or sanction that may be available to that party upon its determination that another party has failed to comply with any of the requirements of this Judgment.

92. Nothing in this Judgment shall create or give rise to a private right of action of any kind or create any right in a non-party to enforce any aspect of this Judgment or claim any legal or equitable injury for a violation of this Judgment. The exclusive right to enforce any violation or breach of this Judgment shall be with the Parties to this Judgment and the Court.

93. Nothing in this Judgment shall relieve IWP of its obligation to comply with all federal, state or local law and regulations.

94. If any portion of this Judgment is held invalid by operation of law, the remaining terms of this Judgment shall not be affected and shall remain in full force and effect.

95. This Judgment supersedes all prior communications, discussions or understandings, if any, of the Parties, whether oral or in writing.

96. If the AGO reasonably believes that IWP has failed to comply with any of Paragraphs 6 to 75 of this Judgment, and if in the AGO's sole discretion the failure to comply does not threaten the health or safety of the citizens of the Commonwealth and/or does not create an emergency requiring immediate action, the AGO shall provide notice to IWP of such alleged failure to comply and IWP shall have at least ten (10) days from receipt of such notice to provide a good faith written response, including either a statement that IWP believes it is in full compliance with the relevant provision or a statement explaining how the violation occurred, how it has been addressed or when it will be addressed, and what IWP will do to make sure the violation does not occur again. The AGO may agree to provide IWP with more than ten (10) days to respond. The AGO shall receive and consider the response from IWP prior to initiating a proceeding for any alleged failure to comply with this Judgment.

IT IS SO ORDERED. JUDGMENT is hereby entered in accordance with the foregoing.

By the Court:

JUSTICE, SUPERIOR COURT

Dated: 6/30/20

June 26, 2020

VIA OVERNIGHT MAIL

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

RE: Injured Workers Pharmacy, LLC-Non-Resident Pharmacy License PH02281

To Whom It May Concern:

On June 7, 2018, Injured Workers Pharmacy, LLC ("IWP"), a Massachusetts limited liability company, received a Civil Investigative Demand for Documents from the Massachusetts Attorney General relating to IWP's dispensing practices beginning January 1, 2010. IWP is registered with the Nevada State Board of Pharmacy as a Non-Resident Pharmacy under License No. PH02281.

In order to avoid prolonged and on-going costly litigation, IWP reached a settlement with the Massachusetts Attorney General (the "**Matter**") with respect to any and all outstanding inquiries and matters on June 24, 2020. IWP has agreed to a voluntary Consent Judgment including IWP's payment of a monetary fine. IWP expects that the Consent Judgment will be entered by the Court in the next several days. Notably, the Consent Judgment expressly states, in pertinent part:

> IWP is entering into this Judgment solely for the purpose of settlement, and nothing contained herein may be taken or construed to be an admission, concession, disciplinary action, finding, or conclusion of any violation of law, rule, or regulation, or of any other matter of fact or law, or any adverse final action or other final action, or of any liability or wrongdoing, all of which IWP expressly denies."

IWP values its relationship and privilege to facilitate care to its patients and trusts this letter fully satisfies any notification or reporting obligations to the Nevada State Board of Pharmacy under applicable state law.

Please let me know if you require any additional information regarding this Matter. You may reach me by phone toll-free at 888-321-7945, extension 3014, or via e-mail addressed to kprince@iwpharmacy.com.

Sincerely,

Kerrin Prince
Manager of Compliance

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into by and between the United States of America, acting through the United States Department of Justice, the Drug Enforcement Administration ("DEA"), and the Department of Labor (collectively, the "United States"); and Injured Workers Pharmacy LLC ("IWP"). The United States and IWP are each referred to herein as a "Party" and collectively as the "Parties."

RECITALS

A. IWP is a mail-order pharmacy that is located at 300 Federal St, Andover, Massachusetts. IWP dispenses and ships prescription drugs, including controlled substances, across the United States, primarily to workers who have been injured on the job. IWP is a pharmacy registered with the DEA.

B. The DEA is the Department of Justice component agency primarily responsible for enforcing the Controlled Substances Act ("CSA"), 21 U.S.C. § 801, et seq., and is vested with the responsibility of investigating violations of the CSA.

C. The United States Attorney General, through the United States Attorney's Office, has primary authority to bring civil actions to enforce the CSA. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

D. The Department of Labor's Office of Worker Compensation Programs administers workers compensation claims under the Federal Workers Compensation Act. Each pharmacy submitting claims for payment to the Department of Labor pursuant to that Act "signifies that the service for which reimbursement is sought was performed as described, necessary, appropriate and properly billed in accordance with accepted industry standards." 20 C.F.R. § 10.801(d). In 2018, the Department of Labor began requiring pharmacies to pre-

adjudicate federal workers compensation prescription claims electronically through a pharmacy benefit manager. The Department of Labor required pre-adjudication to curtail opioid abuse among injured federal workers.

E. Each DEA registrant is required to conduct its operations in accordance with the CSA and the regulations promulgated thereunder. Under the CSA, a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The prescriber has a responsibility for proper prescribing, "but a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.*

F. Beginning in or around June 2018, the United States and the Attorney General for the Commonwealth of Massachusetts (the "Massachusetts AG") began investigating, among other things, IWP's processes and documentation relating to the dispensing of controlled substances. The two investigations proceeded in parallel until June 2020, when IWP resolved the Massachusetts AG's investigation by settling with the Massachusetts AG for $11 million and agreeing to permanent injunctive relief in a stipulated consent judgment (the "Massachusetts AG Consent Judgment"). The settlement with the Massachusetts AG concerned IWP's dispensing practices from 2008 to 2019. The United States' investigation concerned IWP's dispensing practices, as discussed further below, from 2014 through 2019.

G. Prior to and in connection with the Massachusetts AG Consent Judgment, IWP implemented changes to its policies and procedures concerning dispensing controlled substances, including opioids.

H. IWP admits, acknowledges, and accepts its responsibility for the following facts:

a. Between January 1, 2014, and July 31, 2019, IWP received numerous

prescriptions with "red flags," including high doses of opioids, early refills, and "Holy Trinities." A Holy Trinity occurs when an opioid, a benzodiazepine, and a muscle relaxant are prescribed simultaneously to a patient. "Red flags" may indicate a prescriber issued a prescription for a reason other than a legitimate medical purpose, such as abuse or diversion. Pharmacists must review and resolve such "red flags" before filling any prescription. When IWP received prescriptions with "red flags" between January 1, 2014, and July 31, 2019, IWP pharmacists did not always resolve the "red flags" before filling those prescriptions. Even though IWP implemented process improvements beginning in 2017, IWP pharmacists did not have a consistent process or documentation with respect to resolving "red flags."

b. IWP dispensed medications to injured federal workers and submitted claims for payment to the Department of Labor. Between December 12, 2017, and September 26, 2019, the Department of Labor's pharmacy benefit manager issued drug utilization review ("DUR") alerts for 1,456 claims for federal workers' prescriptions for issues such as drug interactions, potential allergic reactions, and therapeutic duplication of opioids. A DUR helps pharmacists ensure that prescribed drugs are appropriate and medically necessary. To clear those DUR rejections and ultimately receive payment from the Department of Labor, IWP's non-pharmacy, claims employees routinely submitted override codes representing that IWP had consulted with prescribers about the DUR alerts. The IWP claims employees, who lacked clinical pharmacy experience and training, submitted the overrides without consulting with IWP pharmacists. Because IWP pharmacists were not aware of the rejections, they did not consult with prescribers in response to the DUR alerts received from the Department of Labor, as represented by IWP claims employees. The foregoing conduct set out in subparagraphs (a) through (b) of Paragraph H is referred to below as the "Covered Conduct."

I. In May 2020, IWP self-disclosed to the Department of Labor that the DUR alerts issue affected 821 claims and offered to repay 256 of them.

J. The United States contends that it has certain civil and administrative claims for civil monetary penalties, injunctive relief, and administrative remedies against IWP under the CSA and its implementing regulations based upon the Covered Conduct. Such civil and administrative claims under the CSA include violations of 21 U.S.C. §§ 827(a)(3), 842(a)(1), 843(a)(2), and the following implementing regulations: 21 C.F.R. §§ 1301.19(b), 1301.71(a), 1304.21(a), 1306.04(a), 1306.05(a), 1306.06, and 1307.02.

K. The United States also contends that it has certain federal civil claims against IWP for submitting or causing the submission of false claims for payment to the Department of Labor.

In consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. IWP shall pay to the United States the sum of Ten Million Dollars ($10,000,000), plus interest at a rate of 3.6% per annum from February 13, 2023 ("Settlement Amount"), of which $318,341.40 is restitution. Within fifteen (15) calendar days of the Effective date of this agreement, IWP shall pay One Million Two Hundred Fifty Thousand Dollars ($1,250,000), plus interest accrued.

a. Over a period of five years, IWP will pay the remaining Eight Million, Seven Hundred Fifty Thousand Dollars ($8,750,000), plus interest at 3.6% per annum, pursuant to the payment schedule attached at Exhibit A. If a prepayment occurs under either paragraph 1.d or paragraph 7 of this Agreement, the parties agree that the principal balance will be adjusted

accordingly and that the computation and allocation of interest set forth in Exhibit A will be adjusted consistent with the remaining principal balance.

b. Interest shall accrue on the unpaid Settlement Amount as indicated in Exhibit A. Collectively the Settlement Amount and interest received by the United States shall be referred to as the "Settlement Payments."

c. If IWP or any of its affiliates is sold, merged, or transferred, or a significant portion of the assets of IWP or of any of its affiliates is sold, merged, or transferred into another non-affiliated entity, IWP shall promptly notify the United States, and all remaining payments owed pursuant to the Agreement shall be accelerated and become immediately due and payable.

d. The Settlement Amount may be prepaid, in whole or in part, without penalty or premium.

e. IWP shall pay the Settlement Payments, or any portion thereof, by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts.

2. No later than five business days after the Effective Date of this agreement, IWP and the DEA will enter into the Corrective Action Plan ("CAP").

3. Subject to the exceptions in Paragraph 4 (concerning reserved claims) and Paragraph 5 (injunctive relief) below, and conditioned upon the United States' receipt of the Settlement Amount, and upon IWP complying with Paragraph 2, the United States releases IWP, its predecessors, its current and former parents, divisions, subsidiaries, successors, and assigns from any civil or administrative monetary claim the United States has for the Covered Conduct under Controlled Substances Act; the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program

Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

4. Notwithstanding the release given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, or any administrative remedy, including the suspension and debarment rights of any federal agency;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for failure to deliver goods or services due; and

h. Any liability for personal injury or property damages or for other consequential damages arising from the Covered Conduct.

5. The United States reserves the right to seek injunctive relief pursuant to 21 U.S.C. § 843(f) if IWP fails to pay the Settlement Amount, or fails to comply with the obligations of the CAP.

6. IWP has provided financial disclosures and supporting documents ("Financial Disclosures") to the United States, and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. IWP warrants that the

Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which IWP had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy IWP's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by IWP on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by One Million Dollars ($1,000,000) or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of IWP's previously undisclosed assets. IWP agrees not to contest any collection action undertaken by the United States pursuant to this provision and agrees that it will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected in the collection action, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States, pursuant to this paragraph rescinds this Agreement, IWP waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to IWP that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement.

7. In the event IWP receives proceeds from any insurance policy on account of the Settlement Amount in this Agreement or the Covered Conduct at any time before the Settlement

Amount has been paid in full, IWP agrees to remit those insurance proceeds to the United States within fifteen (15) days, and that amount shall be credited against future payments, with the schedule of remaining payments to be adjusted as described in paragraph 1.a. IWP need not remit to the United States more insurance proceeds than necessary to pay the Settlement Amount in full. This paragraph does not apply to IWP's receipt of proceeds from any insurance policy on account of its legal expenses.

8. IWP waives and shall not assert any defenses it may have to any criminal prosecution relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. IWP fully and finally releases the United States and its agencies, officers, agents, employees, and servants from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that IWP has asserted, could have asserted, or may assert in the future against the United States or its agencies, officers, agents, employees, or servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. IWP agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of IWP, and its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) IWP's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement; and

(5) the payment IWP makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by IWP, and IWP shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, IWP shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by IWP or any of its subsidiaries or affiliates from the United States. IWP agrees that the United States, at a minimum, shall be entitled to recoup from IWP any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine IWP's books and records and to disagree with any calculations submitted by IWP or

any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by IWP, or the effect of any such Unallowable Costs on the amount of such payments.

11. The obligations imposed upon IWP pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon IWP pursuant to all applicable federal, state, and local laws and regulations, including but not limited to the requirements set forth in Title 21 of the United States Code and the regulations promulgated thereunder.

12. IWP agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, IWP shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. 1WP further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

13. The Settlement Amount and Settlement Payments represent the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to IWP's financial condition as reflected in the Financial Disclosures referenced in Paragraph 6.

a. In the event that IWP fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above and in Exhibit A, IWP shall be in Default of IWP's payment obligations ("Default"). The United States will provide a written Notice of

Default, and IWP shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Agreement up to the date of payment. Notice of Default will be delivered to IWP, or to such other representative as IWP shall designate in advance in writing. If IWP fails to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule ("Uncured Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

14. In the event of Uncured Default, IWP agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against IWP for the claims that would otherwise be covered by the releases provided in Paragraph 4 above, with any recovery reduced by the amount of any payments previously made by IWP to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to IWP and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, IWP agrees immediately to pay the United States the greater of (i) a

ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, IWP waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that are (i) filed by the United States against IWP within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date. IWP agrees not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

15. In exchange for valuable consideration provided in this Agreement, IWP acknowledges the following:

a. IWP has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to IWP, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which IWP was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If any of IWP's payments or obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, IWP or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of IWP's debts, or to adjudicate IWP as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for IWP or for all or any substantial part of IWP's assets:

(i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against IWP for the claims that would otherwise be covered by the releases provided in Paragraph 4 above; and

(ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against IWP in the amount of Eleven Million Two-Hundred Twenty-Six Thousand Sixty-Two Dollars and Seventy-One Cents ($11,226,062.71), plus first payment handshake interest, per Paragraph 1, less any payments received pursuant to Paragraph 1 of this Agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by a receiver, trustee, creditor, custodian, or similar official.

f. IWP agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 17.E is not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States' police and regulatory power. IWP shall not argue or otherwise contend that the United States' claim,

action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). IWP waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to IWP that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the Effective Date.

16. This Agreement is intended to be for the benefit of the Parties only.

17. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each Party represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. This Agreement shall be deemed to have been drafted by all Parties to this Agreement and, therefore, shall not be construed against any Party for that reason in any subsequent dispute.

20. The Agreement contains the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

21. The undersigned represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on IWP's successors, transferees, heirs, and assigns.

24. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

25. The Parties may execute this Agreement via facsimile and/or by portable document format (.pdf), both of which shall be deemed the equivalent of an original signature.

26. This Agreement shall become effective on the date of the signature of the last signatory to the Agreement ("Effective Date" of this Agreement).

SIGNATURES TO FOLLOW ON NEXT PAGE

THE UNITED STATES OF AMERICA

DATED: 6/27/2023

BY: _____

BRIAN M. LAMACCHIA
JESSICA J. WEBER
Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 6/13/2023

BY: _____

JENNIFER VALDIVIESO
Deputy Director for Program and
System Integrity
Division of Federal Employees', Longshore
and Harbor Workers' Compensation
Office of Workers' Compensation Programs
United States Department of Labor

INJURED WORKERS PHARMACY LLC

DATED: 6/23/23

BY: _____
M. Gavin
CEO

DATED: 6/23/2023

BY: _____
ERIC P. CHRISTOFFERSON
BRIAN H. BENJET
DLA Piper LLP
Counsel for Injured Workers Pharmacy LLC

Exhibit A

Year	Payment #	Due Date	Principal	Interest	Payment	Balance
						$10,000,000.00
0	1	Effective Date of Agreement	$1,250,000.00	Handshake interest to be calculated per Para. 1 based on payment date	$1,250,000.00, plus handshake interest	$8,750,000.00
1	2	One year after First Payment	$935,000.00	$315,000.00	$1,250,000.00	$7,815,000.00
2	3	Two years after First Payment	$968,660.00	$281,340.00	$1,250,000.00	$6,846,340.00
3	4	Three years after First Payment	$1,003,531.76	$246,468.24	$1,250,000.00	$5,842,808.24
4	5	Four years after First Payment	$1,039,658.90	$210,341.10	$1,250,000.00	$4,803,149.34
5	6	Five years after First Payment	$4,803,149.34	$172,913.38	$4,976,062.71	$0.00
		TOTAL	$10,000,000.00	$1,226,062.72, plus handshake interest	$11,226,062.71, plus handshake interest	

Attachment 1 - Corrective Action Plan

This Corrective Action Plan ("CAP") between the Injured Worker's Pharmacy ("IWP") and the U.S. Drug Enforcement Administration ("DEA") memorializes the policies and procedures that IWP and the DEA (jointly, the "Parties") have agreed upon to advance IWP's efforts to ensure compliance with the Controlled Substances Act (the "Act") and to enhance IWP's ability to prevent, detect, and address drug diversion. IWP is registered with the DEA as a Retail Pharmacy authorized to handle Schedule II-V controlled substances under DEA [redacted].

1. This CAP is incorporated by reference at paragraph 2 of the Settlement Agreement between IWP and the United States executed contemporaneously with this CAP (the "Settlement Agreement").

2. This CAP pertains to the "Covered Conduct" described in Recital H of the Settlement Agreement and in the United States' contentions in Recital I of the Settlement Agreement.

3. DEA agrees to take no further administrative action against IWP, along with their respective directors, officers, managers, employees, successors and assigns related to the Covered Conduct. However, should IWP violate this CAP, IWP understands that DEA may institute further administrative action, including but not limited to seeking revocation of IWP's DEA registration for any new violation, as well as for the Covered Conduct. DEA may also seek injunctive relief to enforce the terms of the CAP pursuant to 21 U.S.C. § 843 (f), as stated in Paragraph 5 of the Settlement Agreement.

4. The period of this CAP shall be five (5) years, starting on the Effective Date of the Settlement Agreement.

5. Whenever this CAP requires notice to the DEA, the persons to be notified will be Taylor McCarty [redacted] and Heather Danner-Ryan [redacted]. Whenever this CAP requires notice to IWP, the persons to be notified will be Jayne Kresac [redacted] and Brian Benjet [redacted]. Either party may change the name and/or contact information of its contact person(s) by so notifying the other party's contact person(s).

6. Prior to, in connection with, and following the Massachusetts AG Consent Judgment, IWP has implemented several changes to their controlled substance handling procedures, including, but not limited to, the following:

   a. In 2018, IWP released a High-Risk Prescribing Regimens Standard of Procedure ("SOP"), which requires pharmacists to conduct a thorough review of prescriptions that are identified as part of a high-risk drug combination. As later amended, this SOP requires the Pain Management Specialty Pharmacist to contact the prescribers of the identified high-risk prescriptions to confirm awareness and accuracy of the prescribed dosages and treatment plan.

   b. In 2020, IWP implemented an Initial High-Risk Opioid Prescription Policy and Procedure, which expands the clinical checks conducted prior to initial dispensing, by including a process for documenting the authenticity of high-risk prescriptions before dispensing the medication and a process for providing specific counseling to patients regarding alternatives to high-risk prescriptions. IWP also implemented training regarding the identification of initial high-risk opioid prescriptions, the review process, and the documentation process. In

addition, IWP implemented an At-Risk Patient Process that requires holistic review of patient profiles for high-risk medications.

c. IWP has implemented other new and revised pharmacy policies and procedures. IWP has provided the DEA with copies of its current policies and procedures that pertain to:

i. At-Risk Patient Chronic Pain Counseling
ii. CII Room Operation
iii. Controlled Substance Inventory
iv. Controlled Substances Workflow (CIII-CV)
v. Drug Utilization Review (DUR)
vi. Clinical Intervention: High Risk Prescribing Regimens
vii. Initial High-Risk Opioid Prescriptions
viii. Naloxone Standing Order
ix. New At-Risk Patient Auditing Procedure
x. PDMP Query
xi. Prescription Authentication Practices
xii. Processing Pharmacist Responsibilities & Preserving Pharmacist's Judgement
xiii. Professional License Verification (MedPro)
xiv. Receipt of Pharmaceutical Inventory
xv. Pharmacy Record Retention
xvi. Pharmacy Risk Evaluation and Mitigation Strategy (REMS)
xvii. Schedule II Narcotic Non-Contiguous States
xviii. PMSP Program Provider Monitoring

7. Since 2017, IWP has either hired new personnel or created new positions including: a Chief Compliance Officer that reports to the Board of Directors as well as the Chief Executive Officer, Pain Management Specialty Pharmacist, replacing its Chief Executive Officer, and hiring new executive and clinical leadership. IWP's new Chief Compliance Officer has since designed and implemented a new compliance program.

8. IWP agrees that it will continue utilizing the changes that it undertook, as those changes are listed out in paragraph 6 in order to address the Covered Conduct, and to remain in compliance with Title 21 of the Code of Federal Regulations.

9. During the CAP Period, IWP:

a. Agrees to abide by all federal, state and local statutes and regulations relating to controlled substances.

b. Agrees to allow DEA personnel to enter the registered location at any time during regular business hours, without prior notice, and without requiring DEA to obtain an administrative inspection warrant, search warrant, or other means of entry, in order to verify compliance with the Controlled Substances Act (Title 21 United States Code §801, et seq.), its implement regulations, and this CAP.

c. Agrees to maintain complete and accurate records relating to controlled substances, and to maintain copies of these records for a period of five years, from the effective date of this CAP, which will be available to DEA for inspection and copying, and inventories as required by 21 C.F.R. § 1304.04(a), except that, during the CAP Period only, the time period for which records and inventories must be maintained is extended to five (5) years from the date of such records or inventories.

d. Agrees to be truthful and accurate in all information that it submits to the DEA and that any notifications, as required by this CAP and DEA rules and regulations, are timely submitted.

e. Agrees that if any state agency or entity conducts an inspection or any investigation of IWP by seeking any records or documents from IWP, IWP hereby gives its unrestricted consent to the state agency or entity to share

any and all reports, documents, evidence and information of whatever nature or kind with the DEA.

f. Agree to continue implementing SOP's to ensure compliance with its obligations under 21 CFR 1306.04(a).

g. Agrees to maintain SOPs to ensure compliance with its obligations under 21 CFR § 1306.04(a).

h. Agrees that it shall maintain SOPs to ensure the pharmacy complies with the requirements of 21 CFR § 1306.05, including by ensuring prescriptions contain all the required information.

i. Agrees to maintain, on a current basis, a complete and accurate record of each controlled substance received, sold, delivered, dispensed or otherwise disposed of, as required by 21 CFR § 1304.21(a).

j. Agrees that only IWP pharmacists will make clinical determinations relating to Drug Utilization Review ("DUR") alerts for prescriptions that are flagged for issues such as drug interactions, potential allergic reactions, dangerous drug combinations and therapeutic duplication of opioids, to ensure that the prescribed drugs are appropriate and medically necessary prior to filling.

k. Agrees to emphasize the identification of potential safety concerns, red flags, and potentially illegitimate prescriptions.

l. Agrees to not make any decision relating to a pharmacist's performance review, compensation, promotion, work hours, hiring, or termination that relies in whole or in part on dispensing rates, whether measured individually or in aggregate. This restriction shall not be interpreted to limit IWP's ability

to reassign pharmacists to different responsibilities based on operational considerations, or to prohibit employment decisions based upon non-performance (e.g., absenteeism, failure to complete essential job responsibilities) or significant underperformance, as compared to peers and taking into account best dispensing practices.

m. Agrees to provide controlled substance training to all new employees who handle controlled substances or records related to controlled substances. This training shall be conducted within one week of hire. This training shall include, but not be limited to the following: (1) the proper handling, recordkeeping, security, and storage procedures for controlled substances (2) how to identify and handle prescription red flags to ensure patient safety and prescription legitimacy (3) how to identify potentially dangerous medication combinations (4) current CDC prescription guidelines and (5) controlled substance abuse and prevention.

n. Agrees to provide controlled substance training to all current employees who handle controlled substances or records related to controlled substances. This training shall be conducted at least, but not limited to, annually. This training shall include, but not be limited to the following: (1) the proper handling, recordkeeping, security, and storage procedures for controlled substances (2) how to identify and handle prescription red flags to ensure patient safety and prescription legitimacy (3) how to identify potentially dangerous medication combinations (4) current CDC prescription guidelines and (5) controlled substance abuse and prevention.

o. Agrees to maintain a drug diversion team consisting of employees in compliance, pharmacy, security and operations roles. This drug diversion team shall be tasked with establishing, maintaining, and, if appropriate, advancing various diversion controls throughout IWP.

p. Will send a copy of this CAP, in its entirety, to the Massachusetts Department of Public Health Drug Control Program, within ten days of the full execution of this Agreement.

q. At least once every 12 months following the Effective Date of the Settlement Agreement, IWP will conduct a self-evaluation to review compliance with all requirements of the Act, this CAP and its corresponding commitments to maintain SOPs and a compliance program directed at IWP's obligations under the Act. At the completion of each evaluation, the Pharmacy Manager of Record and/or the Chief Compliance Officer will certify that he/she has completed the evaluation and document any corrective action to be taken. IWP will retain the letters of certification, and make them available to the DEA upon request, for two years following the expiration of this CAP.

r. IWP will promptly and thoroughly investigate all thefts, significant losses, and other potential diversions of controlled substances. IWP will establish protocols to reduce the number of in-transit losses of controlled substances and will promptly report all such thefts, significant losses, and other diversions to DEA. DEA is aware that IWP has additional reporting duties to licensure boards, and all other relevant agencies.

10. IWP will comply at all times with the Act and the regulations issued thereunder. To the extent that any requirements in the Act or regulations are greater than those imposed by this CAP, the stricter requirements will apply.

11. Each Party and signatory to this CAP represents that it/he/she freely and voluntarily enters into this CAP without any degree of duress or compulsion.

12. This CAP is intended for the benefit of the Parties only; it does not create any rights or benefits for third parties.

13. This CAP is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this CAP is the United States District Court for the District of Massachusetts. This CAP shall be deemed to have been drafted by both Parties and shall not, therefore, be construed against either Party in any subsequent dispute.

14. This CAP and the Settlement Agreement constitute the complete agreement between the DEA and IWP relating to the matters addressed herein. This CAP may be amended only by a writing signed by both DEA and IWP.

15. The undersigned signatories represent and warrant that it is fully authorized to execute this CAP on behalf of the parties.

16. This CAP may be executed in two counterparts, each of which constitutes an original and both of which constitute one and the same agreement.

17. This CAP is binding on IWP's successors, transferees, and assigns.

SIGNATURES TO FOLLOW ON NEXT PAGE

On Behalf of IWP:

Brian Benjet

Date: 6-23-2023

Brian H. Benjet
DLA Piper LLP (US)
Counsel for Injured Workers Pharmacy LLC

Date: 6/23/23

Michael Gavin
Chief Executive Officer
Injured Workers Pharmacy LLC

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

BRIAN BOYLE
Digitally signed by BRIAN BOYLE
Date: 2023.06.23 17:46:30 -04'00'

Date:

Brian D. Boyle
Special Agent in Charge
Drug Enforcement Administration
New England Field Division

MARK RUBBINS
Digitally signed by MARK RUBBINS
Date: 2023.06.23 15:28:24 -04'00'

Date:

Mark J. Rubbins
Diversion Program Manager
Drug Enforcement Administration
New England Field Division

June 28, 2023

VIA OVERNIGHT MAIL

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Re: Injured Workers Pharmacy, LLC
Pharmacy License No. PH02281

To Whom It May Concern,

On July 1, 2020, Injured Workers Pharmacy, LLC ("IWP") provided notice to the Nevada State Board of Pharmacy that IWP had resolved an investigation by the Massachusetts Attorney General ("MA AG") into IWP's historical practices for the dispensing of controlled substances. I write today to notify you that, on June 23, 2023, IWP resolved a parallel investigation by the U.S. Department of Justice and the Drug Enforcement Administration ("DEA") regarding IWP's historical practices for the dispensing of controlled substances.

As noted in the settlement agreement, federal authorities conducted this investigation in parallel with the MA AG until June 2020, when IWP resolved the MA AG's investigation in a stipulated consent judgment. In October 2021, an independent auditor concluded that IWP was in compliance with the MA AG stipulated consent judgment in all material aspects. The federal and state investigations concerned IWP's historical dispensing practices through 2019. The settlement agreement recognizes that, prior to and in connection with the MA AG consent judgment, IWP implemented changes to its policies and procedures concerning the dispensing of controlled substances, including opioids. IWP has agreed to continue utilizing these enhancements as part of the federal resolution. IWP remains committed to ensuring compliance with federal and state laws, including with respect to the identification of high-risk prescriptions.

In bringing the federal portion of the investigation to a close, IWP agreed to pay $10 million to the United States and agreed to abide by the terms of a Corrective Action Plan ("CAP") for a period of five years. The DEA agreed to take no further administrative action against IWP as long

as it abides by the terms of the CAP, which in large part incorporates the policies and procedures that IWP implemented following the conclusion of the MA AG investigation to advance IWP's efforts to ensure compliance with the Controlled Substances Act and enhance IWP's ability to prevent, detect, and address drug diversion.

IWP is registered with the Nevada State Board of Pharmacy as a Pharmacy under License No. PH02281

Please let me know if you require any additional information. You may reach me by phone at (978) 771-0361 or via e-mail at jtorres@iwpharmacy.com.

Sincerely,

Jeffrey Torres
Chief Compliance Officer

BE FREE WITH IWP

February 16, 2024

Nevada Board of Pharmacy
1140 N Town Center Dr. Ste 300
Las Vegas, NV 89144
Attn: Kenneth Scheuber, Investigator

Dear Mr. Scheuber,

On June 7, 2018, IWP received a Civil Investigative Demand for Documents from the Massachusetts Attorney General relating to Injured Workers Pharmacy (IWP). To avoid prolonged and on-going costly litigation, IWP reached a settlement with the Massachusetts Attorney General with respect to any and all outstanding inquiries and matters. On June 24, 2020, IWP agreed to a voluntary Consent Judgment including IWP's payment of a monetary fine ($11,000,000) and has undertaken remedial changes to its operations and compliance program consistent with the requirements of the Consent Judgment. IWP implemented changes to its policies and procedures concerning the dispensing of controlled substances, including opioids. Specific changes to IWP's clinical program include the addition of a Pain Management Specialty Pharmacist position to identify and counsel at-risk patients, checking all controlled substance prescriptions through the prescription drug monitoring program of the state we are shipping into at each fill, and proactive prescriber and patient outreach for initial opioid prescriptions for opioid naïve patients that exceed CDC guidelines, as well as enhanced monitoring and analytics around prescribers that IWP does business with. In addition, IWP hired a Compliance Officer whose responsibilities include tracking of relevant laws and regulations, administering training programs on compliance-related topics and investigating and documenting reports of suspicious prescriber behavior. IWP has agreed to continue utilizing these enhancements and remains committed to ensuring compliance with federal and state laws, including with respect to the identification of high-risk prescriptions. In October 2021, an independent auditor concluded that IWP is in compliance with the Massachusetts Attorney General's stipulated consent judgment in all material aspects.

If you have any further questions regarding this matter, please feel free to contact me.

Sincerely,

Neil F. Welch
Pharmacist-in-Charge

April 3, 2025

Nevada Board of Pharmacy
1140 N Town Center Dr. Ste 300
Las Vegas, NV 89144
Attn: J. David Wuest, RPh., Executive Secretary Nevada State Board of Pharmacy
Re: Case No. 23-428-PH-O

Dear Dr. Wuest:

This letter and the accompanying materials are submitted on behalf of Injured Workers Pharmacy, LLC ("IWP") in response to the "Notice of Intended Action and Accusation" filed by the Nevada State Board of Pharmacy on March 11, 2025. Please note that due to the sensitive and confidential information contained within this letter and the documents being produced today, these materials should be considered confidential and designated accordingly.

As background, IWP has a unique business model that sets it apart from retail pharmacies. Patients are required to complete an enrollment process and have a verified Workers Compensation claim to be able to receive services from our pharmacy.

IWP undertook remedial changes to its operations and compliance program consistent with the requirements of the Consent Judgment. IWP implemented changes to its policies and procedures concerning the dispensing of controlled substances, including opioids.

I would like to outline some of the improvements that were made to IWP's Clinical and Compliance programs that continue to be strengthened and improved.

- Employment of a designated Pain Management Specialty Pharmacist (PMSP) whose key responsibilities include leading clinical initiatives and implementing procedures to ensure the safe dispensing of prescriptions to IWP's patients on chronic or high-dose opioid regimens or dangerous drug combinations. Key areas of focus include, but are not limited to the following:
    - Patient counselling and education on the risks associated with opioid medications and how to use safely
    - Provider consultation to review and discuss patients' treatment plans, make clinically appropriate recommendations and/or discuss red flags identified during review of the patient's medication history
    - Review and assess provider prescribing patterns, identify red flag concerns associated with various "high-risk" prescribing patterns

- Employment of a Compliance Officer whose responsibilities include tracking of relevant laws and regulations, administering training programs on compliance-related topics and investigating and documenting reports of suspicious prescriber behavior
- Creation of an At-Risk Patient program to counsel patients and their prescribers who are taking high dose and/or chronic opioids
- Establishment of an Initial High Risk prescription program to proactively provide counselling to patients and enhanced due diligence around prescriptions written for opioid naïve patients that exceed CDC initial dosing guidelines
- Requirement for review of the Prescription Drug Monitoring Program (PDMP) by a pharmacist prior to dispensing all controlled substance prescription
- An exhaustive prescriber monitoring program to ensure we are monitoring prescriber licensing not only prior to filling every prescription but also monitoring prescriber behavior retroactively using Injured Workers Pharmacy's dispensing data
- A Drug Diversion Committee that continually monitors and makes recommendations for enhancements to IWP employee and patient diversion policies and procedures

Program enhancements to ensure we remain in compliance in addition to what is noted above, include:

- Clinical Enhancements
    - Aligning our At-Risk program to the new CDC Opioid Clinical Practice Guidelines updating our At-Risk program inclusion criteria by lowering the threshold for chronic opioid use from 90 days to 60 days and inclusion of alternate dangerous drug combinations in addition to the opioid/benzodiazepine combination. Enhancements include additional monitoring of patients being co-prescribed CNS depressants, CNS stimulants, controlled sedatives and/or high dose gabapentinoids ensuring we are providing counselling on the risks associated with the medications and education on how to safely and properly use their medications to our patients who are being treated with a high-risk drug combination.
    - Aligning our Initial High-Risk program to the new CDC Opioid Clinical Practice Guidelines, lowering the MME threshold leading to enhanced due diligence and providing clinical counselling to more patients through this program
    - Implementation of a clinical program to provide patient and provider counselling for patients receiving Schedule II stimulants
    - Implementation of Naloxone follow-up program to complete patient outreach for patients who have previously received a naloxone emergency kit two or more years ago that is at risk of being expired

- Creating a process to counsel patients and the prescribers of patients who have had a clinically significant dosage increase and/or addition of drugs of concern to ensure appropriateness
- Ability of the Pain Management Specialty Pharmacist to flag patient's account for additional review prior to prescription fulfillment for additional due diligence and review of clinical appropriateness
- Terminating relationships with prescribers that upon our review were not exhibiting sound clinical judgement
- Placing prescribers with previous disciplinary action on a quarterly monitoring program in which the Pain Management Specialty Pharmacist reviews the providers prescribing history at IWP to monitor for any clinically concerning trends. Identified prescribers are reviewed on a quarterly basis to ensure there are no clinical or regulatory concerns observed with their prescribing history at IWP.
- Redesign of the Pharmacy's Drug Utilization Review "DUR" module to improve the clinical data presented to IWP Pharmacists for review when evaluating new and refill prescriptions for clinical appropriateness

- Operational Enhancements
  - Ensuring adequate staffing of the pharmacy to maintain a low ratio of prescriptions filled per pharmacist per day (currently 110-120 Rxs/RPh/day), significantly lower than the average retail pharmacy
  - Engaging with industry experts on an inspection tool to monitor compliance with the Controlled Substance Act; and by instituting best practices as recommended
  - Specialized annual training on best practices for the receipt, storage, and handling of controlled substances for all pharmacy staff
  - Creation and execution of clinical audit protocols to evaluate the clinical effectiveness of staff pharmacists
  - Creation and maintenance of an extensive policy library that contains written policies and procedures which, among other activities of pharmacy practice, document the pharmacy's complete efforts with regards to controlled substance ordering, dispensing, handling and accountability
  - Continued use of MedPro real time prescriber licensure checks to verify prescriber's state licensure and DEA registration, and review possible sanctions prior to fulfillment of each prescription
  - Pharmacists perform PDMP checks for all controlled substances (C2-C5) at each and every fill
- Diversion and Security Enhancements

- Perpetual inventory system of all controlled substances including regular reconciliation
- Installation of upgraded security camera system, including the use of over 10 high resolution cameras throughout the pharmacy space
- Use of technology for dispensing of controlled substances to ensure accuracy such as EyeCon® and ScriptPro® machines
- Enhanced employee screening protocols including initial and yearly criminal background checks for all employees with access to the licensed pharmacy space
- Quarterly training for personnel on identification of patient and prescriber red flags as it pertains to potential misuse, abuse and diversion

- Compliance Enhancements
  - The Compliance Officer and PMSP Pharmacist meet regularly to review the Pain Management Specialty Program to ensure IWP continues to meet all requirements
  - Present a summary of the PMSP metrics to both the internal Compliance Committee and IWP's Board of Directors
  - Robust auditing program that includes an annual Pharmacy Audit

IWP agreed to continue utilizing these enhancements and remains committed to ensuring compliance with federal and state laws, including with respect to the identification of high-risk prescriptions. In October 2021, an independent auditor concluded that IWP is in compliance with the Massachusetts Attorney General's stipulated consent judgment in all material aspects.

If you have any further questions regarding this matter, please feel free to contact me.

Thank you,
Sincerely,

Jaclyn McNulty, PharmD, RPh- Director of Pharmacy Operations

jmcnulty@iwpharmacy.com
Phone: 888-321-7945
Fax: 800-497-4276

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **INJURED WORKERS PHARMACY,** **Pharmacy License No. PH02281,** **Respondent.**	**CASE NO. 23-428-PH-O** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Injured Workers Pharmacy, LLC, Pharmacy License No. PH02281, by and through counsel, Law Offices of Lyn E. Beggs, PLLC and DLA Piper LLP (US), **HEREBY STIPULATE AND AGREE THAT**:

1. On or about June 25, 2025, Respondent was served with the First Amended Notice of Intended Action and Accusation (Amended Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. Respondent is entering into this Stipulation in lieu of filing an Answer and Notice of Defense to the Amended Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Amended Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Amended Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. In June of 2023 Respondent entered into a Settlement Agreement with the U.S. Department of Justice, the Drug Enforcement Administration, and the Department of Labor (DOJ). In the Settlement Agreement, Respondent made no admissions to any violation of federal law related to dispensing controlled substances from approximately 2014-2019, rather Respondent admitted to certain facts related to the need for enhanced policies and procedures to safeguard against improper and unlawful dispensing as addressed in a Consent Judgement entered into with the Massachusetts Attorney General in June 2020. No new issues were raised in the DOJ case and in the Settlement Agreement, it was acknowledged that Respondent had addressed the deficiencies in its policies through the engagement of an independent auditor and implementation of the enhanced policies and procedures. Per the terms of the DOJ Settlement Agreement, Respondent paid a substantial fine and agreed to enter into a Corrective Action Plan in which Respondent agreed to continue compliance with the Controlled Substances Act through a general restatement of the terms of the Massachusetts Consent Judgment;

B. Based on the language of the DOJ Settlement Agreement, Respondent, Respondent's owner(s), and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated various provisions of the Controlled Substances Act (CSA), Title 21 United States Code (21 U.S.C.) 801-971, and DEA regulations, Title 21, Code of Federal

Regulations (21 CFR) Parts 1300 to 1316, as detailed in the Settlement Agreement, although neither the DOJ Settlement Agreement nor the Massachusetts Consent Judgment indicate any direct nexus to prescriptions dispensed to patients in Nevada; and

C. Respondent is responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

7. Those violations are pled with particularity in the Amended Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The pharmacy license of Injured Workers Pharmacy, LLC, Pharmacy License No. PH02281, is suspended for a period of one (1) year pursuant to NRS 639.255(1)(c). The suspension is stayed, and Respondent is placed on probation subject to the following conditions:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Ten Thousand Dollars ($10,000.00) for the violations by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2025; and

B. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2025; and

C. Respondent shall have no new charges filed against Injured Workers Pharmacy, LLC, while on probation.

Upon successful completion of probation, Respondent's License No. PH02281 will be fully restored.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay of suspension and immediately suspend Respondent's License No. PH02281and may impose additional discipline upon that Respondent not inconsistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 3, 2025. Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Amended Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *First Amended Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2025

Michael Gavin (Aug 1, 2025 16:44:38 EDT)

INJURED WORKERS PHARMACY
Pharmacy License No. PH02281

Signed this ___ day of _____ 2025

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 1st day of August 2025

Counsel for Respondent

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Injured Workers Pharmacy, LLC, Pharmacy License No. PH02281, in Case No. 23-428-PH-O, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2025.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FRANK A. SHALLENBERGER, MD, Certificate of Registration No. CS20566,** **Respondent.**	**Case No. 23-515-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Frank A. Shallenberger, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS20566, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about December 1, 2023, the Nevada State Board of Medical Examiners (NSBME) and Respondent entered a settlement agreement in Case No. 23-7127-1, imposing discipline on Respondent's NSBME License No. 4951 to practice medicine for cause, relating in pertinent part to Respondent unlawfully prescribing a controlled substance for his own personal use.

3. Respondent failed to disclose to the Board the disciplinary order in NSBDE Case No. 23-7127-1 on his 2024 biennial renewal application for Certificate of Registration No. CS20566.

APPLICABLE LAW

4. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in conformance with the requirements federal and state law. 21 CFR § 1306.04(a); NRS 453.381(1).

5. It is a category E felony for an individual practitioner to dispense a substance included in schedule II, III or IV for the practitioner's own personal use except in a medical emergency. NRS 453.256(5) and (6).

6. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

7. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

8. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

9. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

10. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

11. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

12. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has furnished false or fraudulent material information in an application or committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(a) and (e) and NRS 453.241(1).

COUNT ONE

Violation of State Controlled Substances Act

13. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 23-7127-1, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.256(5) and/or NRS 453.381(1) and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

14. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 23-7127-1 and by violating NRS 453.256(5) and/or NRS 453.381(1), Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(4).

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COUNT THREE
Furnishing False Material Information to Board/
Obtaining Registration by False or Fraudulent Application

15. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 23-7127-1 on his 2024 biennial renewal application for Certificate of Registration No. CS20566, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a), NRS 453.241(1) and/or NRS 639.210(9), (10) and/or (12).

COUNT FOUR
Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 23-7127-1 by violating NRS 453.256(5) and/or NRS 453.381(1), Respondent has committed acts that render his registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 26th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FRANK A. SHALLENBERGER, MD,** **Certificate of Registration No. CS20566,** **Respondent.**	**Case No. 23-515-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FRANK A. SHALLENBERGER, MD,** **Certificate of Registration No. CS20566,** **Respondent.**	**Case No. 23-515-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Frank A. Shallenberger, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Frank A. Shallenberger, MD
[redacted]
Carson City, NV [redacted]

Frank A. Shallenberger, MD
c/o Nevada Center
1231 Country Club Dr
Carson City, NV 89703

Lyn Beggs, Esq.
316 California Ave #863
Reno, NV 89509

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DEBRA RENEE MCCURTAINMURRY, APRN,** **Certificate of Registration No. CS31659,** **Respondent.**	**CASE NOS. 24-131-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because, at the time of the events alleged herein, Respondent Debra Renee McCurtain, APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS31659, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about February 22, 2024, the California Board of Registered Nursing, Department of Consumer Affairs entered a Default Decision and Order in Case No. 4002021005914, revoking Respondent's Registered Nurse License No. 469635, Nurse Practitioner Certificate No. 8738, and Nurse Practitioner Furnishing Certificate No. 8738 for cause, finding that Respondent committed acts of gross negligence when she coded patients within normal weight parameters as obese, inappropriately prescribed phentermine to non-obese patients, failed to track signs and symptoms of potentially adverse cardiac and psychogenic events in her patients, prescribed medications outside of procedural standards, mailed Schedule IV controlled substances labeled as "supplements" and demonstrated unprofessional conduct.

3. As of April 17, 2024, Respondent's DEA registration No. MM6416235 and License No. 826028 with the Nevada State Board of Nursing (NSBN) were no longer active in good standing.

4. On or about April 27, 2024, Board staff served Respondent with notice that her Certificate of Registration No. CS31659 with the Board was suspended pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

APPLICABLE LAW

5. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NAC 453.210; NRS 639.100(1); NRS 639.235(1).

6. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

7. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(10).

8. The Board may suspend or revoke a registration if the holder has had a certificate, license or permit suspended or revoked in another state on grounds which would cause suspension or revocation of a certificate, license or permit in this State. NRS 639.210(14).

9. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration

inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

10. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

11. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Violations of State Law

12. By her violations of law as detailed in the California Board of Registered Nursing's Order in Case No. 4002021005914, Respondent is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(10) and/or NRS 639.210(12).

COUNT TWO
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

13. By her violations of law as detailed in the California Board of Registered Nursing's Order in Case No. 4002021005914, Respondent performed her duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(4) and/or NRS 639.210(4).

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COUNT THREE

Revocation of California Licenses for Cause

14. By the revocation of her California Registered Nurse License No. 469635, Nurse Practitioner Certificate No. 8738, and Nurse Practitioner Furnishing Certificate No. 8738 for cause, Respondent is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(14).

COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

15. By her violations of law as detailed in the California Board of Registered Nursing's Order in Case No. 4002021005914, Respondent has committed acts that render her registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

COUNT FIVE

Not Qualified for Registration

16. Because her DEA registration No. MM6416235 and NSBN License No. 826028 are no longer active in good standing, Respondent no longer qualifies for registration to dispense controlled substances under federal or state law and her Certificate of Registration No. CS31659 is subject to revocation pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DEBRA RENEE MCCURTAINMURRY, APRN,** **Certificate of Registration No. CS31659,** **Respondent.**	**CASE NOS. 24-131-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DEBRA RENEE MCCURTAINMURRY, APRN,** **Certificate of Registration No. CS31659,** **Respondent.**	**CASE NOS. 24-131-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Debra Renee McCurtainMurry, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Debra R. McCurtainMurry
[redacted]
Henderson, NV [redacted]

Nevada Weight Loss & Wellness Inc.
c/o Debra R. McCurtainMurry
2501 N. Green Valley Pkwy #101D
3068 Box 2
Henderson, NV 89014

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

I hereby certify the
foregoing to be a true copy
of the documents on file in our office.
BOARD OF REGISTERED NURSING
Loretta Melby RN, MSN
Loretta Melby, RN, MSN
Executive Officer

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **DEBRA RENEE MCCURTAIN, aka DEBRA RENEE MCCURTAIN-MURRY, aka DEBRA R. MCCURTAIN-MURRY, aka DEBRA RENEE MCCURTAINMURRY, aka DEBRA MCCURTAIN-MURRY, aka DEBRA R. MCCURTAINMURRY** **790 Craigmark Court** **Henderson, NV 89002** **Registered Nurse License Number 469635** **Nurse Practitioner Certificate Number 8738** **Nurse Practitioner Furnishing Certificate Number 8738** Respondent.	Case Number 4002021005914 **DEFAULT DECISION AND ORDER** [Gov. Code, §11520]

FINDINGS OF FACT

1. On or about December 7, 2023, Complainant Loretta Melby, R.N., M.S.N., in her official capacity as the Executive Officer of the Board of Registered Nursing (Board), Department of Consumer Affairs, filed Accusation Number 4002021005914 against Debra Renee McCurtain, also known as (aka) Debra Renee McCurtain-Murry, aka Debra R. McCurtain-Murry,

aka Debra Renee McCurtainmurry, aka Debra McCurtain-Murry, aka Debra R. McCurtainmurry (Respondent) before the Board of Registered Nursing. (Accusation attached as Exhibit A.)

2. On or about August 31, 1991, the Board issued Registered Nurse License Number 469635 to Respondent. The Registered Nurse License was in full force and effect at all times relevant to the charges brought in Accusation Number 4002021005914 and will expire on April 30, 2025, unless renewed.

3. On or about October 7, 1996, the Board issued Nurse Practitioner Certificate Number 8738 to Respondent. The Nurse Practitioner Certificate was in full force and effect at all times relevant to the charges brought in Accusation Number 4002021005914 and will expire on April 30, 2025, unless renewed.

4. On or about July 22, 1997, the Board issued Nurse Practitioner Furnishing Certificate Number 8738 to Respondent. The Nurse Practitioner Furnishing Certificate was in full force and effect at all times relevant to the charges brought in Accusation No. 4002021005914 and will expire on April 30, 2025, unless renewed.

5. On or about December 15, 2023, Respondent was served by Certified and First Class Mail copies of the Accusation Number 4002021005914, Statement to Respondent, Notice of Defense, Request for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6, and 11507.7) at Respondent's address of record which, pursuant to California Code of Regulations, title 16, section 1409.1, is required to be reported and maintained with the Board. Respondent's address of record was and is:

790 Craigmark Court

Henderson, NV 89002.

6. Service of the Accusation was effective as a matter of law under the provisions of Government Code section 11505(c) and/or Business and Professions Code section 124.

7. Government Code section 11506(c) states, in pertinent part:

> (c) The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense . . . and the notice shall be deemed a specific denial of all parts of the accusation . . . not expressly admitted. Failure to file a notice of defense . . . shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.

8. The Board takes official notice of its records and the fact that Respondent failed to file a Notice of Defense within 15 days after service upon her of the Accusation, and therefore waived her right to a hearing on the merits of Accusation Number 4002021005914.

9. California Government Code section 11520(a) states, in pertinent part:

> (a) If the respondent either fails to file a notice of defense . . . or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence without any notice to respondent . . . .

10. Pursuant to its authority under Government Code section 11520, the Board finds Respondent is in default. The Board will take action without further hearing and, based on the relevant evidence contained in the Default Decision Investigatory Evidence Packet in this matter, finds that the charges and allegations in Accusation Number 4002021005914, are separately and severally, found to be true and correct by clear and convincing evidence.

DETERMINATION OF ISSUES

1. Based on the foregoing findings of fact, Respondent Debra Renee McCurtain, also known as (aka) Debra Renee McCurtain-Murry, aka Debra R. McCurtain-Murry, aka Debra Renee McCurtainmurry, aka Debra McCurtain-Murry, aka Debra R. McCurtainmurry has subjected her Registered Nurse License Number 469635, Nurse Practitioner Certificate Number 8738, and Nurse Practitioner Furnishing Certificate Number 8738 to discipline.

2. The agency has jurisdiction to adjudicate this case by default.

3. The Board of Registered Nursing is authorized to revoke Respondent's Registered Nurse License, Nurse Practitioner Certificate and Nurse Practitioner Furnishing Certificate based upon the following violations alleged in the Accusation which are supported by the evidence contained in the Default Decision Investigatory Evidence Packet in this case:

a. Respondent violated Business and Professions Code (Code)[1] section 2761, subdivision (a)(1)-(2), within the meaning of title 16 of the California Code of Regulations (CCR) section 1442, in that she committed acts of gross negligence when she coded patients within

[1] At the time the Accusation was filed, the 2023 version of the Business and Professions Code was in effect, and the original citation was to Code section 2761, subdivision (a)(1).

normal weight parameters as obese, inappropriately prescribed Phentermine to non-obese patients, failed to track signs and symptoms of potential adverse cardiac and psychogenic events in her patients, prescribed medications outside of procedural standards, and mailed Scheduled IV controlled substances labeled as "supplements."

b. Respondent violated Code section 2761, subdivision (a)(5),[2] in conjunction with Code sections 2725 and 2836.1, and CCR section 1474, in that Respondent and her staff regularly performed standardized procedure functions, including conducting good faith examinations and issuing controlled substance prescriptions, without any standardized procedures in place.

c. Respondent violated Code section 2761, subdivision (a)(1),[3] for unprofessional conduct as defined in Code section 2762, subdivision (e), in that Respondent falsified, made grossly incorrect, grossly inconsistent, or unintelligible entries in hospital or patient records.

d. Respondent violated Code section 2761, subdivision (a)(1),[4] in that Respondent demonstrated unprofessional conduct.

ORDER

IT IS SO ORDERED that Registered Nurse License Number 469635, Nurse Practitioner Certificate Number 8738, and Nurse Practitioner Furnishing Certificate Number 8738, issued to Respondent Debra Renee McCurtain, also known as (aka) Debra Renee McCurtain-Murry, aka Debra R. McCurtain-Murry, aka Debra Renee McCurtainmurry, aka Debra McCurtain-Murry, aka Debra R. McCurtainmurry are revoked.

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[2] At the time the Accusation was filed, the 2023 version of the Business and Professions Code was in effect, and the original citation was to Code section 2761, subdivision (d).

[3] At the time the Accusation was filed, the 2023 version of the Business and Professions Code was in effect, and the original citation was to Code section 2761, subdivision (a).

[4] At the time the Accusation was filed, the 2023 version of the Business and Professions Code was in effect, and the original citation was to Code section 2761, subdivision (a).

Pursuant to Government Code section 11520, subdivision (c), Respondent may serve a written motion requesting that the Decision be vacated and stating the grounds relied on within seven (7) days after service of the Decision on Respondent. The agency in its discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

This Decision shall become effective on March 22, 2024.

It is so ORDERED February 22, 2024

FOR THE BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS

37823673.DOCX
DOJ Matter ID:SA2023304887

Attachment:
Exhibit A: Accusation

Exhibit A

Accusation

ROB BONTA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General
PATRICIA WEBBER HEIM
Deputy Attorney General
State Bar No. 230889
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7519
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:** **DEBRA RENEE MCCURTAIN, aka DEBRA RENEE MCCURTAIN-MURRY, aka DEBRA R. MCCURTAIN-MURRY, aka DEBRA RENEE MCCURTAINMURRY, aka DEBRA MCCURTAIN-MURRY, aka DEBRA R. MCCURTAINMURRY** 790 Craigmark Court Henderson, NV 89002 **Registered Nurse License No. 469635** **Nurse Practitioner Certificate No. 8738** **Nurse Practitioner Furnishing Certificate No. 8738** Respondent.	Case No. 4002021005914 **ACCUSATION**

PARTIES

1. Loretta Melby, R.N., M.S.N. (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Registered Nursing (Board), Department of Consumer Affairs.

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LICENSE HISTORY

Registered Nurse License

2. On or about August 31, 1991, the Board issued Registered Nurse License Number 469635 to Debra Renee McCurtain, also known as (aka) Debra Renee McCurtain-Murry, aka Debra R. McCurtain-Murry, aka Debra Renee McCurtainmurry, aka Debra McCurtain-Murry, aka Debra R. McCurtainmurry (Respondent). The Registered Nurse License was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2025, unless renewed.

Nurse Practitioner Certificate

3. On or about October 7, 1996, the Board issued Nurse Practitioner Certificate Number 8738 to Respondent. The Nurse Practitioner Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2025, unless renewed.

Nurse Practitioner Furnishing Certificate

4. On or about July 22, 1997, the Board issued Nurse Practitioner Furnishing Certificate Number 8738 to Respondent. The Nurse Practitioner Furnishing Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2025, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Code section 2750 provides, in pertinent part, that the Board may discipline any licensee, including a licensee holding a temporary or an inactive license, for any reason provided in Article 3 (commencing with Code section 2750) of the Nursing Practice Act.

7. Code section 2764 provides, in pertinent part, that the expiration of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary proceeding against the licensee or to render a decision imposing discipline on the license.

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STATUTORY PROVISIONS

8. Code section 2761 provides, in pertinent part:

The board may take disciplinary action against a certified or licensed nurse or deny an application for a certificate or license for any of the following:

(a) Unprofessional conduct, which includes, but is not limited to, the following:

(1) Incompetence or gross negligence in carrying out usual certified or licensed nursing functions.

…

(d) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violating of, or conspiring to violate any provision or term of this chapter [the Nursing Practice Act] or regulations adopted pursuant to it….

9. Code section 2762 states, in pertinent part:

In addition to other acts constituting unprofessional conduct within the meaning of this chapter [the Nursing Practice Act], it is unprofessional conduct for a person licensed under this chapter to do the following:

…

(e) Falsify, or make grossly incorrect, grossly inconsistent, or unintelligible entries in any hospital, patient, or other record pertaining to the substances described in subdivision (a) of this section.

10. Code section 2725 states, in pertinent part:

…

(b) The practice of nursing within the meaning of this chapter means those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, including all of the following:

(1) Direct and indirect patient care services that ensure the safety, comfort, personal hygiene, and protection of patients; and the performance of disease prevention and restorative measures.

(2) Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code.

(3) The performance of skin tests, immunization techniques, and the withdrawal of human blood from veins and arteries.

(4) Observation of signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and (A) determination of whether the signs, symptoms, reactions, behavior, or general appearance exhibit abnormal characteristics, and (B) implementation, based on observed abnormalities, of appropriate reporting, or referral, or standardized procedures, or changes in treatment regimen in accordance with standardized procedures, or the initiation of emergency procedures.

(c) "Standardized procedures," as used in this section, means either of the following:

(1) Policies and protocols developed by a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code through collaboration among administrators and health professionals including physicians and nurses.

(2) Policies and protocols developed through collaboration among administrators and health professionals, including physicians and nurses, by an organized health care system which is not a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

The policies and protocols shall be subject to any guidelines for standardized procedures that the Division of Licensing of the Medical Board of California and the Board of Registered Nursing may jointly promulgate. If promulgated, the guidelines shall be administered by the Board of Registered Nursing.

(d) Nothing in this section shall be construed to require approval of standardized procedures by the Division of Licensing of the Medical Board of California, or by the Board of Registered Nursing.

(e) No state agency other than the board may define or interpret the practice of nursing for those licensed pursuant to the provisions of this chapter, or develop standardized procedures or protocols pursuant to this chapter, unless so authorized by this chapter, or specifically required under state or federal statute. "State agency" includes every state office, officer, department, division, bureau, board, authority, and commission.

11. Code section 2836.1 states:

Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician and surgeon when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.

(c)(1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.

(2) In addition to the requirements in paragraph (1), for Schedule II controlled substance protocols, the provision for furnishing Schedule II controlled substances shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

…

(f)(1) Drugs or devices furnished or ordered by a nurse practitioner may include Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure.

(2) When Schedule II or III controlled substances, as defined in Sections 11055 and 11056, respectively, of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided, upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order.

(g)(1) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.

(2) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.

…

(h) Use of the term "furnishing" in this section, in health facilities defined in Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.

12. Code section 4022 states, in pertinent part:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-

use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

REGULATORY PROVISIONS

13. California Code of Regulations, title 16 (CCR), section 1442, states:

As used in Section 2761 of the code, "gross negligence" includes an extreme departure from the standard of care which, under similar circumstances, would have ordinarily been exercised by a competent registered nurse. Such an extreme departure means the repeated failure to provide nursing care as required or failure to provide care or to exercise ordinary precaution in a single situation which the nurse knew, or should have known, could have jeopardized the client's health or life.

14. CCR section 1471 states:

For purposes of this article:

(a) "Standardized procedure functions" means those functions specified in Business and Professions Code Section 2725(c) and (d) which are to be performed according to "standardized procedures";

(b) "Organized health care system" means a health facility which is not licensed pursuant to Chapter 2 (commencing with Section 1250), Division 2 of the Health and Safety Code and includes, but is not limited to, clinics, home health agencies, physicians' offices and public or community health services;

(c) "Standardized procedures" means policies and protocols formulated by organized health care systems for the performance of standardized procedure functions.

15. CCR section 1472 states:

An organized health care system must develop standardized procedures before permitting registered nurses to perform standardized procedure functions. A registered nurse may perform standardized procedure functions only under the conditions specified in a health care system's standardized procedures; and must provide the system with satisfactory evidence that the nurse meets its experience, training, and/or education requirements to perform such functions.

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16. CCR section 1474 states:

> Following are the standardized procedure guidelines jointly promulgated by the Medical Board of California and by the Board of Registered Nursing:
>
> (a) Standardized procedures shall include a written description of the method used in developing and approving them and any revision thereof.
>
> (b) Each standardized procedure shall:
>
> (1) Be in writing, dated and signed by the organized health care system personnel authorized to approve it.
>
> (2) Specify which standardized procedure functions registered nurses may perform and under what circumstances.
>
> (3) State any specific requirements which are to be followed by registered nurses in performing particular standardized procedure functions.
>
> (4) Specify any experience, training, and/or education requirements for performance of standardized procedure functions.
>
> (5) Establish a method for initial and continuing evaluation of the competence of those registered nurses authorized to perform standardized procedure functions.
>
> (6) Provide for a method of maintaining a written record of those persons authorized to perform standardized procedure functions.
>
> (7) Specify the scope of supervision required for performance of standardized procedure functions, for example, immediate supervision by a physician.
>
> (8) Set forth any specialized circumstances under which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition.
>
> (9) State the limitations on settings, if any, in which standardized procedure functions may be performed.
>
> (10) Specify patient record keeping requirements.
>
> (11) Provide for a method of periodic review of the standardized procedures.

COST RECOVERY

17. Code section 125.3 provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being

renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUG INFORMATION

18. *Phentermine* is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (f)(4), and is a dangerous drug within the meaning of Code section 4022. Phentermine is used together with diet and exercise to treat obesity.

19. *Tenuate* is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (f)(1), and is dangerous drug within the meaning of Code section 4022. Tenuate is used together with diet and exercise to treat obesity.

FACTUAL ALLEGATIONS

20. On or about April 14, 2021, the Board received a complaint from nurse practitioner B.R. alleging that Respondent, owner of Rocklin Weight Loss (RWL) in Rocklin, California, had been inappropriately prescribing Phentermine and Tenuate to clients of RWL. The complaint stated that on or about April 12, 2021, patients with a normal[1] body mass index (BMI), had requested refills of weight loss medication. B.R, who was working at RWL as a nurse practitioner on that day, did not refill the medication as requested. On or about April 14, 2021, B.R. received a text message from Respondent stating that B.R. should have prescribed the medication even though the patients had normal body weight. In response, B.R. asked Respondent for the clinical protocol approved by the overseeing physician that would allow weight loss prescriptions for patients with normal body weight, however, Respondent refused to provide it.

21. B.R. further alleged that Respondent had been shipping controlled substances to patients labeled as "supplements." In addition, B.R. stated that the clinic was using billing code ICD 10 for obesity, when many of the patients were not obese.

22. A DOI investigation revealed that Respondent had employed nurse practitioners to work at RWL between 2020 and 2021, without nurse practitioner standardized protocols. Multiple employees confirmed that patients had come into the office and received Phentermine without examinations that Phentermine and Tenuate had been shipped to customers, and that

[1] A "normal" body mass index is defined as a score of less than 25.

billing code ICD 10 was used for patients who were not considered obese. Patient records were obtained that showed patients with a BMI of 25 and lower had been receiving Phentermine and that there were no entries of BMI in some medical records. Below is a summary of the patient records.

Patient 1

Visit Date	BMI/Weight/Blood Pressure	Medical Record Notes
04/29/2020	BMI 23.4 and 24.2. Weight and blood pressure charted.	#30 tabs, order shipped
08/10/2020	No BMI. Weight and blood pressure charted.	#60 tabs
11/11/2020	BMI 24.2. Weight and blood pressure charted.	#60 tabs
02/02/2021	BMI 23.8. Weight and blood pressure charted.	#60 tabs
06/25/2021	BMI 23.8. Weight and blood pressure charted.	#60 tabs
09/21/2022	BMI 24.7. Weight and blood pressure charted.	#60 tabs

Patient 2

Visit Date	BMI/Weight/Blood Pressure	Medical Record Notes
03/26/2020	No BMI, weight, or blood pressure charted.	#30 tabs, online order
04/16/2020	No BMI, weight, or blood pressure charted.	#30 tabs, online order shipped
05/04/2020	No BMI, weight, or blood pressure charted.	#30 tabs, online order shipped
06/17/2020	No BMI, weight, or blood pressure charted.	#30 tabs, online order
07/20/2020	No BMI, weight, or blood pressure charted.	#30 tabs, order shipped
08/11/2020	No BMI, weight, or blood pressure charted.	#30 tabs, shipped
09/03/2020	No BMI, weight, or blood pressure charted	#30 tabs, shipped
10/08/2020	BMI 22.5. Weight and blood pressure charted.	#30 tabs
10/27/2020	No BMI, weight, or blood pressure charted.	#30 tabs, online order
11/16/2020	No BMI, weight, or blood pressure charted.	#30 tabs, online order shipped
12/14/2020	No BMI, weight, or blood pressure charted.	#30 tabs, online order shipped
01/07/2021	No BMI, weight, or blood pressure charted.	#30 tabs, online order shipped
02/26/2021	No BMI, weight and blood pressure charted.	#30 tabs
03/12/2021	No BMI, weight, or blood pressure charted.	#30 tabs, online order shipped
03/30/2021	No BMI, weight, or blood pressure charted.	#30 tabs, online order shipped
04/30/2021	No BMI, weight, or blood pressure charted.	#30 tabs, order shipped
07/30/2021	No BMI, weight, or blood pressure charted.	#30 tabs, order shipped
09/02/2021	No BMI, weight, or blood pressure charted.	#30 tabs
09/09/2021	BMI 22.5. No weight or blood pressure.	#30 tabs
10/28/2021	BMI 23.7 and weight charted. No blood pressure charted.	#30 tabs shipped
03/24/2022	BMI 24.3, weight or blood pressure charted.	#60 tabs
05/02/2022	No BMI, weight or blood pressure charted	#60 tabs
05/24/2022	BMI 24 and weight charted. No blood pressure charted.	#60 tabs

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Patient 3

Visit Date	BMI/Weight/Blood Pressure	Medical Record Notes
01/05/2011	BMI 23.7, weight, and blood pressure charted.	#28 tabs
02/04/2011	No BMI. Weight and blood pressure charted	#28 tabs
03/25/2011	No BMI. Weight and blood pressure charted.	#28 tabs
05/10/2011	No BMI. Weight and blood pressure charted	#28 tabs
06/16/2011	No BMI. Weight and blood pressure charted.	#28 tabs
08/09/2011	No BMI. Weight and blood pressure charted	#28 tabs
09/15/2011	No BMI. Weight and blood pressure charted.	#28 tabs
11/18/2011	No BMI. Weight and blood pressure charted.	#28 tabs
12/15/2011	No BMI, weight, or blood pressure charted.	#28 tabs
02/09/2012	No BMI. Weight and blood pressure charted.	#28 tabs
02/22/2012	No BMI, weight, or blood pressure charted.	#28 tabs
05/08/2012	No BMI, weight, or blood pressure charted.	#28 tabs
06/07/2012	No BMI. Weight and blood pressure charted.	#28 tabs
01/03/2013	No BMI. Weight and blood pressure charted.	#28 tabs
02/06/2013	BMI 22.2. Weight and blood pressure charted.	#28 tabs
04/23/2013	No BMI. Weight and blood pressure charted.	#28 tabs
05/17/2013	No BMI. Weight and blood pressure charted.	#28 tabs
06/11/2013	No BMI. Weight and blood pressure charted.	#28 tabs
11/14/2014	BMI 23.9. Weight and blood pressure charted.	#28 tabs
01/07/2015	No BMI. Weight and blood pressure charted.	#28 tabs
02/10/2015	No BMI. Weight and blood pressure charted.	#28 tabs
03/17/2015	No BMI. Weight and blood pressure charted.	#28 tans
05/18/2015	No BMI. Weight and blood pressure charted.	#28 tabs
06/26/2015	No BMI. Weight and blood pressure charted.	#28 tabs
07/24/2015	No BMI. Weight and blood pressure charted.	#28 tabs
08/28/2015	No BMI. Weight and blood pressure charted.	#28 tabs
09/29/2015	No BMI. Weight and blood pressure charted.	#28 tabs
11/09/2015	No BMI. Weight and blood pressure charted.	#28 tabs
01/06/2016	No BMI. Weight and blood pressure charted.	#28 tabs
02/13/2016	No BMI. Weight and blood pressure charted.	#28 tabs
03/15/2016	No BMI. Weight and blood pressure charted.	#28 tabs
05/05/2016	No BMI. Weight and blood pressure charted.	#28 tabs
06/16/2016	No BMI. Weight and blood pressure charted.	#28 tabs
08/30/2016	BMI 24.9. Weight and blood pressure charted.	#28 tabs
10/27/2016	No BMI. Weight and blood pressure charted.	#28 tabs
12/06/2016	No BMI. Weight and blood pressure charted.	#28 tabs
02/25/2017	No BMI. Weight and blood pressure charted.	#28 tabs
05/25/2017	BMI 24. Weight and blood pressure charted.	#30 tabs
01/25/2018	No BMI. Weight and blood pressure charted.	#30 tabs
08/16/2018	No BMI. Weight and blood pressure charted.	#30 tabs
09/25/2018	No BMI. Weight and blood pressure charted.	#30 tabs
10/27/2018	No BMI. Weight and blood pressure charted.	#30 tabs
12/14/2018	No BMI. Weight and blood pressure charted.	#30 tabs
05/24/2019	No BMI. Weight and blood pressure charted.	#30 tabs
07/02/2019	No BMI, weight, or blood pressure charted.	“Grab” #30 tabs
08/10/2019	No BMI. Weight and blood pressure charted.	#30 tabs
09/25/2019	No BMI. Weight and blood pressure charted.	#30 tabs
11/09/2019	No BMI, weight or blood pressure charted.	“Grab and Go” #30 tabs
12/20/2019	No BMI. Weight charted. No blood pressure charted.	#30 tabs

01/20/2020	No BMI. Weight and blood pressure charted.	#30 tabs
03/04/2020	No BMI. Weight and blood pressure charted.	#30 tabs
04/16/2020	No BMI, weight, or blood pressure charted.	"Grab and Go" #60 tabs.
06/26/2020	No BMI, weight, or blood pressure charted.	"Grab and Go" #30 tabs.
08/04/2020	No BMI. Weight and blood pressure charted.	$30 tabs
10/12/2020	No BMI, weight, or blood pressure charted.	#30 tabs
03/23/2021	No BMI. Weight and blood pressure charted.	#30 tabs
05/24/2021	No BMI. Weight charted. No blood pressure charted.	#30 tabs
06/30/2021	No BMI, weight, or blood pressure charted.	"Grab and Go" #30 tabs
08/12/2021	No BMI. Weight and blood pressure charted.	#30 tabs
09/23/2021	No BMI. Weight and blood pressure charted.	#30 tabs

Patient 4

Visit Date	BMI/Weight/Blood Pressure	Medical Record Notes
04/08/2020	No BMI, weight, or blood pressure charted.	#30 tabs purchased online.
05/13/2020	No BMI, weight, or blood pressure charted.	#30 tabs purchased online.
06/26/2020	No BMI, weight, or blood pressure charted.	#30 tabs, order shipped.
08/03/2020	No BMI, weight, or blood pressure charted.	#30 tabs
04/15/2021	BMI 24. Weight and blood pressure charted.	#30 tabs
05/07/2021	No BMI, weight, or blood pressure charted.	#30 tabs

23. On or about June 6, 2023, during an interview with a DOI investigator, Respondent admitted that patients with a BMI of less than 25 had received Phentermine, and further acknowledged that there had been instances where there were no entries of patient BMI in the medical records for patients who were receiving Phentermine. Respondent stated that the nurse practitioner standardized protocols/agreements had been signed by the nurse practitioners who were employed at RWL, however after multiple requests, Respondent did not provide the standardized protocols/agreements to the investigator.

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

24. Respondent is subject to disciplinary action pursuant to Code section 2761, subdivision (a)(1), on the grounds of unprofessional conduct, in that Respondent committed acts constituting gross negligence within the meaning of CCR section 1442, as set forth in paragraphs 20 through 23 above, and as follows:

a. Respondent coded that patients within normal weight parameters, with a BMI of 25 or less, were obese.

b. Respondent prescribed Phentermine without attention to necessary patient

safety parameters, including weight and blood pressure evaluation. Respondent prescribed this medication to patients who were not obese and in larger refill amounts without follow up appointments.

c. Respondent failed to track signs and symptoms of potential adverse cardiac and psychogenic events with her patients.

d. Respondent prescribed medications outside of procedural standards.

e. Respondent mailed Schedule IV controlled substances, labeled as supplements.

SECOND CAUSE FOR DISCIPLINE

(Insufficient Standardized Procedures)

25. Respondent is subject to disciplinary action pursuant to Code section 2761, subdivision (d), in conjunction with Code sections 2725 and 2836.1, and CCR section 1474, in that Respondent and her staff regularly performed standardized procedure functions, including conducting good faith examinations and issuing controlled substance prescriptions, without any standardized procedures in place, as set forth in paragraph 20 through 23, above.

THIRD CAUSE FOR DISCIPLINE

(Incorrect, Grossly Inconsistent, or Unintelligible Entries in Patient Record)

26. Respondent is subject to disciplinary action pursuant to Code section 2761, subdivision (a), on the grounds of unprofessional conduct as defined in Code section 2762, subdivision (e), in that Respondent falsified, made grossly incorrect, grossly inconsistent, or unintelligible entries in hospital or patient records, as set forth in paragraph 22 through 23, above.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

27. Respondent is subject to disciplinary action pursuant to Code section 2761, subdivision (a), on the grounds of unprofessional conduct, in that Respondent demonstrated unprofessional conduct, as set forth in paragraphs 20 through 26, above.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Registered Nursing issue a decision:

1. Revoking or suspending Registered Nurse License Number 469635, issued to Debra Renee McCurtain, also known as (aka) Debra Renee McCurtain-Murry, aka Debra R. McCurtain-Murry, aka Debra Renee McCurtainmurry, aka Debra McCurtain-Murry, aka Debra R. McCurtainmurry;

2. Revoking or suspending Nurse Practitioner Certificate Number 8738, issued to Debra Renee McCurtain, also known as (aka) Debra Renee McCurtain-Murry, aka Debra R. McCurtain-Murry, aka Debra Renee McCurtainmurry, aka Debra McCurtain-Murry, aka Debra R. McCurtainmurry;

3. Revoking or suspending Nurse Practitioner Furnishing Certificate Number 8738, issued to Debra Renee McCurtain, also known as (aka) Debra Renee McCurtain-Murry, aka Debra R. McCurtain-Murry, aka Debra Renee McCurtainmurry, aka Debra McCurtain-Murry, aka Debra R. McCurtainmurry;

4. Ordering Debra Renee McCurtain, also known as (aka) Debra Renee McCurtain-Murry, aka Debra R. McCurtain-Murry, aka Debra Renee McCurtainmurry, aka Debra McCurtain-Murry, aka Debra R. McCurtainmurry to pay the Board of Registered Nursing the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

5. Taking such other and further action as deemed necessary and proper.

DATED: December 7, 2023

for LORETTA MELBY, R.N., M.S.N.
Executive Officer
Board of Registered Nursing
Department of Consumer Affairs
State of California
Complainant

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JOE LOMBARDO
Governor



HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

April 22, 2024

VIA CERTIFIED U.S. MAIL AND EMAIL TO: debramccurtain@gmail.com

Debra Renee McCurtain, APRN
2501 North Green Valley Parkway #101D
3068 Box 2
Henderson, NV 89014

Re: NOTICE OF SUSPENSION - Registration No. CS31659: (Case No. 24-131-CS-S)

Dear Ms. McCurtain:

The Nevada State Board of Pharmacy (Board) has determined that both your DEA registration No. MM6416235 and your License No. 826028 with the Nevada State Board of Nursing (NSBN) are no longer active in good standing. Be advised that an active DEA registration for Nevada and an active license from the NSBN are required to possess, administer, prescribe and dispense controlled substances under your Certification of Registration No. CS31659. *See* 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.126(2); NRS 639.1375(1).

Your Certificate of Registration No. CS31659 is immediately suspended pursuant to NRS 639.2107. You may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until you petition the Board for reinstatement pursuant to NRS 639.2565, present proof of both DEA registrations and an NSBN license active in good standing, and the Board reinstates your Certification of Registration No. CS31659. Your PMP account is also suspended pursuant to NAC 453.078.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABDOLLAH ASSAD, MD,** **Certificate of Registration No. CS12432,** **Respondent.**	**CASE NO. 24-470-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Abdollah Assad, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS12432, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about August 14, 2024, the Nevada State Board of Medical Examiners (NSBME) filed charges in Case Nos 24-28982-1 and 24-28982-2 against Respondent's License No. 10883 to practice medicine for engaging in conduct in violation of NRS Chapter 630.

3. Respondent failed to disclose to the Board the pending charges in NSBME Case Nos 24-28982-1 and 24-28982-2 on his 2024 biennial renewal application for Certificate of Registration No. CS12432.

4. Respondent failed to review the patient utilization report for patient S.D. in the Prescription Monitoring Program (PMP) database prior to issuing a prescription for Adderall, a

Schedule II controlled substance, on August 18, 2024. Respondent subsequently changed the dosage of patient S.D.'s Adderall prescription from 20mg to 30mg on September 9, 2024, and again prescribed Adderall to S.D. on September 19, 2024, each time without reviewing the patient utilization report for patient S.D. in the PMP database.

APPLICABLE LAW

5. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

6. A prescribing practitioner shall only issue a controlled substance prescription after review of a patient's utilization report in the PMP database in conformance with NRS 639.23507.

7. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

8. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

9. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

10. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

11. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has

committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Furnishing False Material Information to Board

12. By failing to disclose to the Board the pending charges in NSBME Case Nos 24-28982-1 and 24-28982-2 on his 2024 biennial renewal application for Certificate of Registration No. CS12432, as detailed in Paragraphs 2 and 3 herein, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

COUNT TWO

Obtaining Registration by False or Fraudulent Application

13. By failing to disclose to the Board the pending charges in NSBME Case Nos 24-28982-1 and 24-28982-2 on his 2024 biennial renewal application for Certificate of Registration No. CS12432, as detailed in Paragraphs 2 and 3 herein, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(10).

COUNT THREE

Violation of State Law when Prescribing a Controlled Substance

14. By failing to review the patient utilization report for patient S.D. in the PMP database prior to issuing controlled substance prescriptions, as detailed in Paragraph 4 herein, Respondent is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

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COUNT FOUR

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

15. By failed to review the patient utilization report for patient S.D. in the PMP database prior to issuing controlled substance prescriptions, as detailed in Paragraph 4 herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(4) and/or NRS 639.23916(3)(b).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By failing to disclose to the Board the pending charges in NSBME Case Nos 24-28982-1 and 24-28982-2 on his 2024 biennial renewal application for Certificate of Registration No. CS124321, and by violating NRS 639.23507, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABDOLLAH ASSAD, MD,** **Certificate of Registration No. CS12432,** **Respondent.**	**Case No. 24-470-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Lane
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABDOLLAH ASSAD, MD,** **Certificate of Registration No. CS12432,** **Respondent.**	**Case No. 24-470-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

Abdollah Assad, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Abdollah Assad, MD
[redacted]
Reno, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KRISTIN A. HESTDALEN, MD,** **Certificate of Registration No. CS38528,** **Respondent.**	**CASE NO. 25-020-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because, at the time of the events alleged herein, Respondent Kristin A. Hestdalen, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS38528, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent has a documented history of substance abuse as detailed in the Stipulation and Order for Recovery Program and Monitoring entered on March 4, 2021, by the Nevada State Board of Medical Examiners (NSBME) in Investigation No. 19-19208.

3. On or about June 17, 2024, the NSBME entered an order granting Respondent's request to return her License No. 10215 to practice medicine to active status with the condition that successfully completed a preceptor plan for twelve (12) months under the supervision of Dr. Byron Czerniski, a Senior Psychiatrist at Lakes Crossing.

4. On or about September 5, 2024, Respondent appeared before the Board and her application for a controlled substance registration was conditionally approved under the terms previously ordered by the NBME.

5. On or about January 14, 2025, the NSBME entered an order in Case No. 25-25351-1, and summarily suspended Respondent's License No. 10215 to practice medicine for cause after Dr. Czerniski terminated his preceptorship on January 6 and reported his concerns about Respondent as she arrived at Lakes Crossing in an "altered" status, was disorganized and smelled of alcohol.

6. On or about January 21, 2025, Board staff served Respondent with notice that the suspension of her NSBME License No. 10215 to practice medicine operated as an immediate suspension of her Certificate of Registration No. CS38528 with the Board pursuant to NRS 639.2107.

APPLICABLE LAW

7. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NAC 453.210; NRS 639.100(1); NRS 639.235(1).

8. The Board may suspend or revoke a controlled substance registration if the holder becomes or is intoxicated or under the influence of liquor, any depressant drug or a controlled substance, unless taken pursuant to a lawfully issued prescription, while on duty in any establishment licensed by the Board. NRS 639.210(3).

9. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

10. Violating any term or condition of an order issued by the Board or the staff of the Board constitutes unprofessional conduct or conduct contrary to the public interest as defined in

NAC 639.945(1)(l) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

11. The Board may suspend or revoke a controlled substance registration upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

12. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

13. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Intoxication While on Duty

14. By reporting to Lakes Crossing in an intoxicated state on January 6,. 2025, Respondent is subject to discipline pursuant to NRS 639.210(3).

COUNT TWO
Unprofessional Conduct – Failure to Comply with Board Order

15. By failing to comply with the terms imposed by the Board for issuance of her controlled substance registration on September 5, 2024, Respondent has violated a Board order and therefore engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(l), and is subject to discipline pursuant to NRS 639.210(4).

COUNT THREE
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

16. By her actions as alleged herein, Respondent performed her duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

17. By her actions as alleged herein, Respondent has committed acts that render her registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

COUNT FIVE

Not Qualified for Registration

18. By the suspension of her NSBME License No. 10215 to practice medicine, Respondent no longer qualifies for registration to dispense controlled substances under federal or state law and her Certificate of Registration No. CS38528 is subject to revocation pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 24 day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KRISTIN A. HESTDALEN, MD,** **Certificate of Registration No. CS38528,** **Respondent.**	**Case No. 25-020-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KRISTIN A. HESTDALEN, MD,** **Certificate of Registration No. CS38528,** **Respondent.**	**Case No. 25-020-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

KRISTIN A. HESTDALEN, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Kristin Hestdalen c/o Lakes Crossings Center
500 Galletti Way
Sparks, NV 89431

Kristin Hestdalen c/o Lyn E. Beggs, Esq.
Law Offices of Lyn E. Beggs, PLLC
316 California Ave. #863
Reno, NV 89509

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **BERNARD BROOKS, RPH,** **Certificate of Registration No. 20571,** **Respondent.**	**Case No. 25-031-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because, at the time of the events alleged herein, Respondent Bernard Brooks, RPh, Certificate of Registration No. 20571, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. On or about May 22, 2024, pursuant to NRS 639.2895 the Board issued a citation to Respondent in Case No. 24-184-RPH-N and assessed an administrative fine of $500 for failing to complete required continuing education units in violation of NAC 639.330.

3. In 2012, Respondent was convicted on a charge of underage drinking and possession of alcohol in the state of Wisconsin.

4. On or about August 15, 2013, Respondent was convicted on a misdemeanor charge of simple assault in the District of Columbia, Superior Court.

5. Respondent failed to disclose these convictions to the Board on his 2020 application for registration as a pharmacist.

6. Respondent was employed as managing pharmacist at Walgreens Pharmacy #02474, Pharmacy License No. PH01939, located at 3000 Vista Blvd. in Sparks, Nevada, at the time of the events alleged herein.

7. From 2022 through 2024, Walgreens employees routinely observed Respondent intoxicated while performing his duties as managing pharmacist at Walgreens Pharmacy #02474.

8. On multiple occasions Walgreens Pharmacy #02474 had to close early due to Respondent's impaired state and inability to perform his duties as managing pharmacist.

9. On or about April 15, 2025, Respondent was terminated from employment by Walgreens Pharmacy #02474 for cause.

COUNT ONE
Furnishing False Material Information to Board

10. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 639. NRS 639.281(1).

11. By failing to disclose his convictions to the Board on his 2020 application for registration as a pharmacist as alleged in paragraphs 3-5 herein, Respondent violated NRS 639.281(1), and is subject to discipline pursuant to NRS 639.210(9) and/or NRS 639.210(12).

COUNT TWO
Obtaining Registration by False or Fraudulent Application

12. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

13. By failing to disclose his convictions to the Board on his 2020 application for registration as a pharmacist as alleged in paragraphs 3-5 herein, Respondent is subject to discipline pursuant to NRS 639.210(10).

COUNT THREE

Intoxicated While on Duty in Licensed Pharmacy

14. Becoming intoxicated or under the influence of liquor will on duty in any establishment licensed by the Board is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(3).

15. By performing his duties as managing pharmacist at Walgreens Pharmacy #02474 while intoxicated as alleged in paragraphs 6-9 herein, Respondent is subject to discipline pursuant to NRS 639.210(3).

COUNT FOUR

Unprofessional Conduct - Incompetent, Unskillful or Negligent Performance of Duties

16. Performing any duties as the holder of a pharmacist registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

17. By performing his duties as managing pharmacist at Walgreens Pharmacy #02474 while intoxicated as alleged in paragraphs 6-9 herein, Respondent has performed his duties as the holder of a pharmacist registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Violation of State Law

18. It is a misdemeanor crime to sell, dispense or compound any prescription or sell any drug while under the influence of intoxicating liquor. NRS 639.283. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

19. By performing his duties as managing pharmacist at Walgreens Pharmacy #02474 while intoxicated as alleged in paragraphs 6-9 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.293 and is subject to discipline pursuant NRS 639.210(12).

COUNT SIX

Substance Abuse Disorder

20. The Board may suspend or revoke a registration if the holder has a substance use disorder. NRS 639.210(5).

21. By his history of alcohol use disorder as alleged herein, Respondent is subject to discipline pursuant to NRS 639.210(5).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 24 day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **BERNARD BROOKS, RPH,** **Certificate of Registration No. 20571,** **Respondent.**	**Case No. 25-031-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **BERNARD BROOKS, RPH,** **Certificate of Registration No. 20571,** **Respondent.**	**Case No. 25-031-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Bernard Brooks, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Bernard Brooks, RPH
[redacted]
Sparks, NV [redacted]

Bernard Brooks, RPH c/o
Walgreens Pharmacy #02474
3000 Vista Blvd.
Sparks, NV 89436

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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OF PHARMACY

The Switlyk Law Firm, P.A.
Andrew Switlyk, No. 16758
50 West Liberty Street, Suite 1100
Reno, Nevada 89501
Telephone: (775) 264-4955
Email: Andrew@Switlyk.law

Attorney for the Respondent
BERNARD BROOKS, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **BERNARD BROOKS, RPH,** **Certificate of Registration No. 20571,** **Respondent.**	**Case No. 25-031-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent, BERNARD BROOKS, RPH, by and through his attorney, in answer to the Notice of Intended Action and Accusation (hereinafter "Accusation") filed in the above-entitled matter before the Nevada State Board of Pharmacy, hereby answers to the allegation as follows:

JURISDICTION

1. Answering paragraph 1of the Accusation, the Respondent admits he was a registered pharmacist in the timeframes referenced in the factual allegations section of the Accusation. The remainder of this paragraph contain legal conclusions that do not require a response.

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FACTUAL ALLEGATIONS

2. Answering paragraph 2 of the Accusation, the Respondent admits he paid a fine for failing to complete a required continuing education unit on time and that he completed said continuing education two days after the deadline.
3. Answering paragraph 3 of the Accusation, the Respondent denies it on the grounds the allegations contained within it are vague and ambiguous as to the relevant timeframe, what is meant by "conviction", and what authority the alleged charge of underage drinking was brought and by who. The Respondent further asserts that where this paragraph contains a legal conclusion, no response is required.
4. Answering paragraph 4 of the Accusation, the Respondent denies he was convicted of a misdemeanor charge of simple assault in the District of Columbia, Superior Court, on or about August 15, 2013.
5. Answering paragraph 5 of the Accusation, the Respondent admits his 2020 application for registration as a pharmacist did not disclosures that he was convicted of the allegations contained within paragraphs 3 and 4 of the complaint. As to the characterization or classification of those criminal allegations contained referenced by paragraphs 3 and 4, Respondent would repeats and realleges the answers contained within those respective paragraphs. As to all remaining allegations, Respondent denies the same.
6. Answering paragraph 6 of the Accusation, the Respondent admits he was employed as a managing pharmacist at Walgreens Pharmacy #02474.
7. Answering paragraph 7 of the Accusation, the Respondent is without sufficient knowledge of the employees referenced and the nature of their allegations and therefore

denies the same. The Respondent denies he was ever intoxicated while performing his duties as managing pharmacist at Walgreens Pharmacy #02474.

8. Answering paragraph 8 of the Accusation, The Respondent denies that Walgreens Pharmacy #02474 ever had to close early due to him being in an impaired state or inability to perform his duties because of alcohol or any other intoxicating substance.

9. Answering paragraph 9 of the Accusation, the Respondent is without sufficient knowledge or belief as to date and nature of his termination and therefore denies the same.

COUNT ONE
Furnishing False Material Information to Board

10. Answering paragraphs 10 and 11 of the Accusation, the Respondent states that the paragraphs contain legal conclusions that do not require a response. To the extent said allegations are determined to be factual allegations, the Respondent denies the same.

COUNT TWO
Obtaining Registration by False or Fraudulent Application

11. Answering paragraphs 12 and 13 of the Accusation, the Respondent states that the paragraphs contain legal conclusions that do not require a response. To the extent said allegations are determined to be factual allegations, the Respondent denies the same.

COUNT THREE
Intoxicated While on Duty in Licensed Pharmacy

12. Answering paragraphs 14 and 15 of the Accusation, the Respondent states that the paragraphs contain legal conclusions that do not require a response. To the extent said allegations are determined to be factual allegations, the Respondent denies the same.

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COUNT FOUR

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performances of Duties

13. Answering paragraphs 16 and 17 of the Accusation, the Respondent states that the paragraphs contain legal conclusions that do not require a response. To the extent said allegations are determined to be factual allegations, the Respondent denies the same.

COUNT FIVE

Violation of State Law

14. Answering paragraphs 18 and 19 of the Accusation, the Respondent states that the paragraphs contain legal conclusions that do not require a response. To the extent said allegations are determined to be factual allegations, the Respondent denies the same.

COUNT SIX

Substance Abuse Disorder

15. Answering paragraphs 20 and 21 of the Accusation, the Respondent states that the paragraphs contain legal conclusions that do not require a response. To the extent said allegations are determined to be factual allegations, the Respondent denies the same.

PRAYER FOR RELIEF

WHEREFORE, the Respondent prays for the following relief:

1. That the Nevada State Board of Pharmacy take no action against the Respondent and the Accusation be dismissed with prejudice.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge

DATED: August 8, 2025

The Switlyk Law Firm, P.A.

/s/ Andrew Switlyk
Andrew Switlyk, No. 16758
Attorney for the Respondent

CERTIFICATE OF SERVICE

I certify that I am an employee of The Switlyk Law Firm, P.A., and that on this date, I electronically served, via email, this ANSWER AND NOTICE OF DEFENSE to the following:

The Nevada State Board of Pharmacy's coordinating staff
TeamBC@Pharmacy.nv.gov

Brett Kandt, Esq.
The Prosecuting Attorney
bkandt@pharmacy.nv.gov

DATED: this 8th day of August, 2025.

/s/ Emily Switlyk
Emily Switlyk
An employee of The Switlyk Law Firm, P.A.

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #315,** **Pharmacy License No. PH03897,** **ALYSSA MERCEDES GARCIA, PT,** **Certificate of Registration No. PT20499, and** **OCTAVIA LORAINE BROOKS, RPH,** **Certificate of Registration No. 20950,** **Respondents.**	**CASE NOS. 25-076-PH-S** **25-076-PT-S** **25-076-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Alyssa Garcia, PT (Garcia), Certificate of Registration No. PT20499, was a pharmaceutical technician registered with the Board, Respondent Octavia Loraine Brooks, RPh (Brooks), Certificate of Registration No. 20950, was a pharmacist registered with the Board, and Respondent Smith's Pharmacy #315, Pharmacy License No. PH03897, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Garcia was employed as a pharmaceutical technician by Smith's Pharmacy #315, located at 8525 W Warm Springs Road in Las Vegas, and Brooks was employed as managing pharmacist of the pharmacy, at the time of the events alleged herein.

3. On or about February 13, 2025 Smith's Pharmacy #315 submitted DEA Form 106 documentation to the Board reporting the theft of controlled substances after an investigation produced evidence that Garcia diverted 9515 Alprazolam 1mg tablets, 19,908 Alprazolam 2mg tablets, and 1,018 Tramadol 50mg tablets.

4. On or about January 24, 2025, Respondent was terminated from employment by Smith's Pharmacy #315 due to policy violations and unprofessional conduct related to the theft.

5. The investigation revealed that Brooks failed to comply with Smith's Pharmacy policies and procedures to prevent and detect diversion, including, without limitation, failing to maintain balance on hand (BOH) manual changes reports weekly to review for suspicious or unexplainable manual changes for controlled substances, failing to question and/or research suspicious changes, and failing to research inventory discrepancies and report any evidence of theft or unexplainable loss.

6. On or about March 11, 2025, the Board served Garcia with an order of summary suspension of her Certificate of Registration No. PT20499 pursuant to NRS 233B.127(3) and noticed a hearing before the Board on April 16, 2025. Board staff attempted service of the order of summary suspension on Garcia by certified mail, return receipt requested, addressed to Garcia at her last address of record.

7. Garcia failed to appear at the April 16, 2025, hearing, and the Board upheld the suspension of her Certificate of Registration No. PT20499 pending the filing of an accusation.

APPLICABLE LAW

8. It is a felony offense to acquire a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 843(a)(3); 21 U.S.C. § 846; NRS 453.331(1)(d); NRS 453.391(1).

9. It is a felony offense to possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 844; 21 U.S.C. § 846; NRS 453.336(1); NRS 453.381(8)

10. It is a criminal offense to use a controlled substance except as authorized by law. 42 U.S.C. § 12210; NRS 453.411(1).

11. Pharmacies shall establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances. NAC 453.400.

12. Supplying or diverting drugs which are legally sold in pharmacies constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

13. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

16. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

17. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of

any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

18. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Unlawful Acquisition of Controlled Substances
(Respondent Garcia)

19. By diverting and acquiring controlled substances as alleged herein, Garcia violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a), 21 U.S.C. § 843(a)(3), 21 U.S.C. § 846, NRS 453.331(1)(d) and/or NRS 453.391(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT TWO
Unlawful Possession of Controlled Substances
(Respondent Garcia)

20. By diverting and possessing controlled substances as alleged herein, Garcia violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a), 21 U.S.C. § 844, 21 U.S.C. § 846, NRS 453.336(1), NRS 453.381(8) and/or NRS 454.316(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT THREE
Unlawful Use of Controlled Substances
(Respondent Garcia)

21. By diverting and using controlled substances as alleged herein, Garcia violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 42 U.S.C. § 12210 and/or NRS 453.411(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT FOUR
Unprofessional Conduct – Diversion
(Respondent Garcia)

22. By diverting controlled substances as alleged herein, Garcia engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction
(Respondent Garcia)

23. By diverting controlled substances as alleged herein, Garcia was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

COUNT SIX
Managing Pharmacist Responsibility
(Respondent Brooks)

24. As the managing pharmacist of Smith's Pharmacy #315 at the time of the diversion of controlled substances by Garcia and the related violations of law as alleged herein, and by her failure to comply with Smith's Pharmacy policies and procedures to prevent or guard against theft and misuse of controlled substances in violation of NAC 453.400, Brooks is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT SEVEN
Pharmacy/Pharmacy Owner Responsibility
(Respondent Smith's Pharmacy #315)

25. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Smith's Pharmacy #315 is responsible for those violations, including all errors and omissions of Respondents Garcia and Brooks, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and pharmacy license of these Respondents.

Signed this 9th day of June 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #315,** **Pharmacy License No. PH03897,** **Respondent.**	**Case No. 25-076-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, July 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of June 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #315,** **Pharmacy License No. PH03897,** **Respondent.**	**Case No. 25-076-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR SMITH'S PHARMACY #315

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of June 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Smith's Pharmacy #315
8525 W Warm Springs Rd.
Las Vegas, NV 89113

And via Electronic Mail:
Richard Bowman – (richard.boman@SFDC.com)
Paul Howse – (paul.howse@stores.sfdc.com)

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
JUL 24 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #315,** **Pharmacy License No. PH03897,** **Respondent.**	**Case No. 25-076-PH-S** **ANSWER AND NOTICE OF DEFENSE**

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1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

See attached

Quarles & Brady LLP
Attorneys at Law
One Renaissance Square
Two North Central Avenue
Suite 600
Phoenix, AZ 85004-2322
602-229-5200
Fax 602-229-5690

Writer's Direct Dial: 602-229-5439
E-Mail: Nicholas.Meza@quarles.com

July 22, 2025

VIA EMAIL TRANSMISSION

Brett Kandt
Nevada Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

RE: Response to Notice of Intended Action and Accusation - Case No. 25-076-PH-S
Smith's Pharmacy #315 (License No. PH03897)

Dear Mr. Kandt:

This firm represents Smith's Pharmacy #315 (License No. PH03897) ("the Pharmacy"), located at 8525 W Warm Springs Road, in Las Vegas, Nevada. On or about June 12, 2025, the Pharmacy received the Nevada Board of Pharmacy's (the "Board") Notice of Intended Action and Accusation (the "Accusation") in Case No. 25-076-PH-S. Please accept this letter as the Pharmacy's Answer and Notice of Defense and request to negotiate a stipulated settlement agreement. As described below, the facts giving rise to the Accusation are the unfortunate result of now-terminated pharmacy personnels' departure from clear policies and procedures set forth by the Pharmacy. We respectfully ask that the Board consider the Pharmacy's prompt investigation and corrective action as the parties move forward with settlement discussions.

The Factual Allegations

The Pharmacy does not dispute the factual allegations in the Accusation. This matter results from the diversion of controlled substances by Pharmacy Technician Alyssa Garcia ("Garcia") that was reported by the Pharmacy in February 2025 through submission of a DEA Form 106. As the Accusation notes, the Pharmacy promptly terminated Garcia upon discovery of the diversion and investigated Pharmacist-in-Charge Octavia Brooks ("PIC Brooks") for failure to adhere to the Pharmacy's policies and procedures. The Accusation lists five counts against Garcia for her diversion of Alprazolam and Tramadol tablets, one count against PIC Brooks for failure to comply with policies and procedures to safeguard against theft or misuse of controlled substances, and one count against the Pharmacy for the errors and omissions of Garcia and PIC Brooks as employees of the Pharmacy.

Corrective Actions Taken

As Garcia's and PIC Brooks' employer, the Pharmacy recognizes that it is responsible for any violation caused employee conduct. Notably, however, none of the counts relate specifically to the acts or omissions of the Pharmacy itself. Instead, as the factual allegations highlight, the Pharmacy fulfilled its duties to promptly investigate upon notification of a suspicious order and discipline its employees upon confirmation of diversion.

Specifically, on or about January 22, 2025, Mr. Paul Howse, the Pharmacy Practice Coordinator ("PPC"), was contacted by a supplier regarding a suspicious order placed by the Pharmacy for Alprazolam 1 mg. Upon notification, the PPC immediately opened an investigation into the Pharmacy's controlled substance inventory and submitted a covert count on January 22, 2025, the very same day he was notified of the suspicious order. The investigation revealed that between May 1, 2023, and January 22, 2025, 9,515 alprazolam 1 mg, 19,908 alprazolam 2 mg, and 1,018 tramadol 50 mg tablets were unaccounted for.

On January 27, 2025, just three business days after the suspicious order notification, the Pharmacy interviewed pharmacy associates, including Garcia and PIC Brooks. While Garcia did not admit to theft or diversion of the controlled substances, the Pharmacy confirmed that she was likely responsible after reviewing surveillance footage and determining that changes to the Balance on Hand ("BOH") count occurred while she was present in the Pharmacy. Garcia's actions were confirmed after an audit of the BOH changes revealed that Garcia had made multiple count changes between May 1, 2024 and January 22, 2025. During her interview, PIC Brooks admitted to not following the Pharmacy's policies for secure storage and monitoring of controlled substances as alleged in Count Six. While PIC Brooks' became aware of BOH changes during her weekly reviews, she failed to investigate these discrepancies beyond accepting Garcia's statement, without further inquiry, that a glitch in the pharmacy system required Garcia to manually adjust the BOH count. *See* Attachment 1. PIC Brooks' also failed to notify the PPC of unreconciled discrepancies as required by pharmacy policy which further prevented the Pharmacy's discovery of Garcia's diversion. *Id.* Both Garcia and PIC Brooks were suspended pending further investigation on January 27, 2025, the same day that interviews were completed.

Smith's Pharmacy's policies require pharmacy personnel to comply with all applicable federal and state laws, including the federal Controlled Substances Act and similar state laws, regulating the storage, distribution, possession and use of controlled substances. Relevant to this incident, the Pharmacy's Controlled Substance Policy and Procedures clearly establish the process for maintaining the security and distribution of controlled substances through the use of Balance on Hand change reviews by the PIC (SOP 501.4.4), the requirement for two associate check-in upon delivery of controlled substances (SOP 501.5), inventory discrepancy investigations (SOP 501.21), personal item storage near the pharmacy entrance (SOP 501.19.5), and the requirements to dispense a controlled substance only through a valid prescription from

a licensed practitioner. *See* Attachment 2. Further, all pharmacy associates are required to complete annual controlled substance training courses.

After the investigation concluded, the Pharmacy took prompt corrective action by terminating the individuals involved, retraining all pharmacy personnel on controlled substance policies and procedures, and implementing a Corrective Action/Preventive Action ("CAPA") on March 31, 2025. Garcia and PIC Brooks were terminated on February 4, 2025 and February 11, 2025, respectively, and a temporary PIC was appointed on February 12, 2025. The new PIC, Kevin So, was appointed on March 31, 2025. All pharmacy personnel, including the temporary PIC, were retrained immediately on policies related to the two-associate check in procedure for controlled substances, personal item storage, controlled substance inventory discrepancy and loss. Further, PIC So has continued to implement the corrective actions contained in the CAPA.

Offer to Settle

As demonstrated above, the Pharmacy takes compliance with state and federal controlled substance laws seriously. Robust policies and procedures are in place to guard against thefts and diversions and pharmacy personnel are continuously retrained on such procedures. However, even robust policies and procedures are only effective if employees choose to comply. Absent Garcia's illegal actions and PIC Brooks' noncompliance with established policies and procedures, the underlying diversion would not have occurred. Nonetheless, the Pharmacy understands the actions of its employees have a direct impact on its responsibilities and obligations as a licensed pharmacy. To that end, the Pharmacy has taken numerous steps to prevent similar incidents from reoccurring, including terminating the employees involved.

The Pharmacy respectfully requests that the Board consider the swift corrective action taken by the Pharmacy as the parties move forward with settlement negotiations.

Should you have any questions or matters that you wish to discuss regarding this offer, please do not hesitate to contact me at Nicholas.Meza@quarles.com or (602) 229-5439.

Very truly yours,

Nicholas H. Meza

NHM

QB\97465721.1

Attachment 1

Dena M McClish
Nevada State Board of Pharmacy
1140 N Town Center Dr, Ste 300
Las Vegas, NV 89144

Response provided via email to dmcclish@pharmacy.nv.gov on March 24, 2025

RE: Case #25-076

The following statement is being provided pursuant to a written request made by Dena McClish, dated March 10, 2025 and received by Paul Howse via email on March 10, 2025

Statement regarding Requests #1 & #4:

On 01/22/2025 our supplier's (Smith's Food and Drug Centers, Inc. dba Peyton's Phoenix) controlled substance order monitoring associate notified me about a suspicious order placed for alprazolam 1 mg at Smith's #315 based on their monthly tablet fill count versus how much had been ordered recently. Due to this finding, that controlled substance order was cancelled. Upon receiving this information, I went at end of day on 01/22/2025 to complete a covert count and open a review of the pharmacy's alprazolam 1 mg inventory. After the audit was completed on 01/24/2025, it was determined that Smiths #315 had 7,909 alprazolam 1 mg unaccounted for. Upon further review, it was determined that other controlled substances order receipt quantities appeared to have been altered including alprazolam 2 mg and tramadol 50 mg. In addition, I reviewed balance on hand changes between 05/01/2024-01/22/2025 and noticed technician Alyssa Garcia had made multiple count changes, which included, at times, receiving order quantities into the pharmacy system's inventory with lower quantities than what was shipped for alprazolam 1mg, alprazolam 2mg and tramadol 50mg. Further, I reviewed past Cardinal orders for alprazolam 1mg and found that multiple paper invoices were missing from the appropriate file in the pharmacy's controlled substance record's cabinet, despite verification that the orders were shipped in Cardinal's online portal.

On 01/25/2025, I submitted covert physical counts for alprazolam 1 mg, alprazolam 2 mg and tramadol 50 mg taken at the beginning of day on 01/25/2025, along with the annual controlled substance inventories conducted on 4/30/2023, and 5/1/2024 to the Corporate Pharmacy Asset Protection team. An audit using these counts revealed the following discrepancies between 04/30/2023-01/22/2025:

- -9,515 alprazolam 1 mg tablets
- -19,908 alprazolam 2 mg tablets
- -1,018 tramadol 50 mg tablets

During Asset Protection's initial surveillance review done 01/25/2025-01/26/2025 they were unable to affirmatively view any pharmacy staff remove drugs from the pharmacy but observed some behaviors not consistent with policy and procedures from Alyssa Garcia. This included not using the coat closet for personal items such as backpacks, carrying baskets with drug stock bottles to the side storage room, and consuming food/drink without purchase.

Based on the above findings, it was determined that we needed to interview and suspend Alyssa Garcia and pharmacy manager Octavia Brooks. On Monday, 01/27/2025 asset protection manager, Ron Simmons, and I interviewed both Alyssa Garcia and Octavia Brooks regarding the discrepancies (statements provided to the board). During the interview, neither associate admitted to removing the medications from the pharmacy. Both associates were suspended that day pending further investigation. On 02/04/2025 we terminated Alyssa Garcia for consumption of food items without purchase as seen on surveillance video and we terminated Octavia Brooks on 02/11/2025 for consumption of food items before purchase. During this time, we continued to review surveillance footage and discovered additional behaviors not consistent with policy and procedures.

During review of camera footage from 12/23/2024, I witnessed Alyssa Garcia pull two 500-count size bottles from a full Cardinal Health tote at the product dispensing station and put them in a drawer under the counter. She then placed the bottles back into the tote shortly thereafter and proceeded to put the order, including these bottles, away on the drug shelves. Then at approximately 10 am when pharmacy manager Octavia Brooks was in the counsel/vaccine room getting a vaccine ready, Alyssa Garcia checked to make sure Octavia was busy in the room and walked directly to the drug bay grabbing those two 500-count size bottles. She proceeded to walk the bottles to the side storage room in the pharmacy, which is out of camera view, and returned 10 seconds later with no bottles in her hands. When she left at 1 pm that day she grabbed her backpack from the side storage room. One 500 count bottle of alprazolam 1 mg and alprazolam 2 mg was shipped as verified by Cardinal's online portal, but the invoices were missing in the pharmacy's controlled substance records cabinet.

During review of camera footage from 01/02/2025, I observed behaviors from Alyssa Garcia not consistent with policy and procedure while receiving a Cardinal drug order. At 9:56 am Alyssa Garcia tossed an invoice from Cardinal Health in the thrash while receiving the order. At 9:57 am she placed a 500-count size bottle in an empty Cardinal tote and placed that tote on the bottom, stacking 3 empty totes on top of that tote. I was unable to see the drug label since it was placed face down in the tote. At 10:01 am she removed that bottle from the bottom tote and buried it under all the other drug products she had placed in a single Cardinal tote. She then proceeded to move that tote to the product dispensing counter at 10:07 am and immediately put the 500-count bottle on the drug shelf while leaving everything else in the tote on the counter for the next hour. I verified via Cardinal Health website Alprazolam 2 mg was ordered and delivered 01/02/2025, but there was no invoice filed in the pharmacy's controlled substance records cabinet.

Statement regarding Request #2:

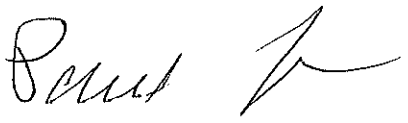
We have policies and procedures in place to prevent and detect diversion as it pertains to inventory adjustments and discrepancies, order receiving and physical security. Relevant policies in matter include the following:

1) The Pharmacy Manager runs and reviews the balance on hand (BOH) manual changes report once a week to review for excessive, suspicious or unexplainable manual changes to balance on hands for controlled substances. The pharmacy manager initials and dates the report indicating they have reviewed the report. Excessive, suspicious, or questionable changes should be researched by the Pharmacy Manager and brought to the attention of the store's Pharmacy Coordinator. The BOH report is kept on file for the prior twelve weeks.
    a) Pharmacy Manager Octavia Brooks failed to maintain her BOH reports in a proper manner. When she did review and sign the BOH changes she either didn't question the BOH changes to do additional research or as she stated when I interviewed her, she trusted technician Alyssa Garcia when she told her there was glitch receiving the order in the pharmacy system which is why she had to adjust the BOH since they never actually received it.
2) Inventory discrepancies will be researched immediately by the pharmacist on duty when discovered and then brought to the attention of the Pharmacy Manager, as soon as possible for review and further research, if necessary, regardless of the outcome of the initial research. Inventory discrepancies will further be investigated by the Pharmacy Manager immediately upon discovery. If there is evidence of theft or unexplainable loss (loss of inventory that has no verifiable documentation), the information must be reported to the Pharmacy Coordinator and Division Health Leader.
    a) Pharmacy Manager Octavia Brooks never properly investigated her inventory discrepancies, and she never informed her Pharmacy Coordinator of unreconciled discrepancies.
3) Controlled substance orders must be checked in by two associates. If two Associates are on duty, then two will check-in the products and indicate as such on the receiving document. If only one (1) Associate (a pharmacist) is on duty at the time of receipt, this Associate will check in the receipt and indicate on the receiving document that there was only one individual on duty at the time of the receipt. A pharmacist must always be involved in checking-in the controlled substance product. The Associates checking in the controlled substances will sign and date the invoice/packing slip and document in a prominent location on the face of the invoice/packing slip document that all controlled substances have been received. If an invoice is available, the invoice will be used to document the receipt. If an invoice is not available, a packing slip will be used, the invoice/packing slip should be transferred to the Record Custodian as soon as possible for filing in the proper folder in the Controlled Substances Filing Cabinet.
    a) Technician Alyssa Garcia failed to properly check in controlled substances by tossing invoices in the trash, hiding controlled substance products that came in and never allowing the pharmacist to review and sign the invoices.

4) Personal items such as coats, purses and backpacks, are prohibited from being brought into the pharmacy drug storage areas. Personal items will be stored in lockers outside the pharmacy, if available. If lockers are unavailable, the Pharmacy Manager will designate an area for storing the items near the entrance of the pharmacy.
    a) Pharmacy Manager Octavia Brooks failed to designate the coat closet at the entrance of the pharmacy as a place for personal items. She allowed pharmacy staff to keep personal items in other areas of the pharmacy. Technician Alyssa Garcia failed to keep her personal items in the closet at the entrance of the pharmacy.

Statement regarding Request #3

I have submitted Balance on Hand Change reports including all received purchased orders (PO) for alprazolam 1 mg, alprazolam 2 mg and tramadol 50 mg. The reports show negative shelf count adjustments and PO's where the amount received was changed from what was delivered before accepting the whole order in the pharmacy system. Most shelf count changes were done by Alyssa Garcia, and all PO receiving changes were done by Alyssa Garcia. For example, looking at alprazolam 1 mg, Alyssa Garcia updated the balance on the shelf by -500 on 11/05/2024 and 11/17/2024. On 01/12/2025 when accepting the PO, she changed the received quantity from 2 bottles to 1 bottle as indicated by the adjustment note stating order quantity 2.0, received quantity 1.0. Most of her adjustments were the result of changing received bottle counts from what was shipped over this time frame.



Paul Howse, PharmD
Pharmacy Practice Coordinator
Smith's Food and Drug Stores

Attachment 2

SOP 501.4: Ordering Controlled Substances

501.4.4 Computer Assisted Ordering Systems – For Pharmacies Utilizing the EPRN Pharmacy System Review of "Balance on Hand" Changes

501.4.4.1 The Pharmacy Manager will run the "Balance on Hand ("BOH") Manual Changes" report once a week and review for excessive, suspicious or unexplainable manual changes to BOHs for controlled substances. The Pharmacy Manager will initial and date the report indicating that they have reviewed the report.

501.4.4.2 In retail pharmacies, excessive, suspicious, or questionable changes should be researched by the Pharmacy Manager and brought to the attention of the store's Coordinator.

501.4.4.3 The report will be maintained in a folder labeled *"Balance on Hand (BOH) Manual Change Report"* for the prior twelve (12) weeks, which is located in the Controlled Substance Filing Cabinet.

501.4.4.4 Orders and BOH changes will be managed from a computer terminal located in the pharmacy area unless approved by the Pharmacy Manager.

SOP 501.5: Checking in Controlled Substances at the Pharmacy

Purpose

The purpose of this procedure is to establish policies for checking in Schedule II through V controlled substances at the pharmacy.

General Information

Scope

This procedure includes all controlled substances received, physical and operational procedures, documentation and internal reporting requirements for shortages. It does not include filing the DEA Form 106 ("Form 106"), which is described in **SOP 501.21** or descriptions of required storage contained in **SOP 501.19**.

Responsibility

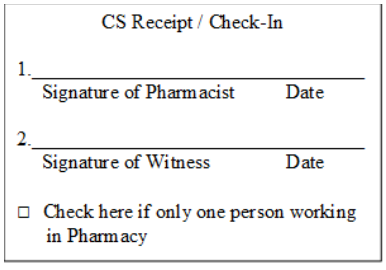
- The Pharmacy Manager is responsible for ensuring compliance with this procedure.

Procedure

501.5.1 Required Personnel

Controlled substances received from other DEA Registrants must be checked-in as described in **SOP 501.5.4**. If two Associates are on duty, then two will check-in the products and indicate as such on the receiving document. If only one (1) Associate (a pharmacist) is on duty at the time of receipt, this Associate will check in the receipt and indicate on the receiving document that there was only one individual on duty at the time of the receipt. **A pharmacist must always be involved in checking-in the controlled substance product.**

In retail pharmacies, this information will be displayed on the incoming documentation with a stamp provided to each pharmacy (see below for example).


CS Receipt / Check-In

1. _____
Signature of Pharmacist Date

2. _____
Signature of Witness Date

☐ Check here if only one person working in Pharmacy

501.5.2 Schedule II Controlled Substances

501.5.2.1 Schedule II controlled substances will be transferred to the secured storage area immediately after receipt, as described in **SOP 501.19.1.** All Schedule II products will be accounted for **by a pharmacist before** signing a release or manifest presented from the supplier/delivery personnel. If it is discovered that items may have been lost in-transit, procedures indicated in **SOP 501.21.5** will be followed.

501.5.2.3 A pharmacist must receive Electronic Orders in the Pharmacy System's inventory receiving application or, if necessary, the supplier's online CSOS application, within 12 hours or at the close of business, whichever occurs first.

If an Order Form is used to order Schedule II controlled substances, mandatory annotation and updates of the Order Form(s) and the Schedule II Perpetual Inventory, as described in **SOP 501.7,** will be completed within 12 hours or at the close of business, whichever occurs first.

501.5.3 Schedule III, IV and V Controlled Substances

Orders containing Schedule III, IV and V controlled substances must be immediately delivered to the pharmacy or another secure, locked area if the shipment is received when the pharmacy is closed. A secure area is an area that can be locked and for which there is limited access. Once the pharmacy is open, the controlled substances will be transferred to the pharmacy. The shipment may remain in the pharmacy area, provided that the tote is strapped or tied, for a period of 12 hours or until the close of business, whichever occurs first. By the close of business, the shipment will be checked-in, and the products dispersed throughout the stock of other legend drugs.

501.5.4 Documentation and Recordkeeping

501.5.4.1 The Associates checking in the controlled substances will sign and date the invoice/packing slip and document in a prominent location on the face of the invoice/packing slip document that all controlled substances have been received as described in **SOP 501.5.1**. If an invoice is available, the invoice will be used to document the receipt. If an invoice is not available, a packing slip will be used. If the Record Custodian or Alternate is not involved in the check-in process, the invoice/packing slip should be transferred to one of them as soon as possible for filing in the proper folder in the Controlled Substances Filing Cabinet.

501.5.4.2 In the case of Schedule III, IV and V controlled substances, the invoice (or if no invoice, the packing slip) will be filed chronologically by date received in the folder labeled *"CIII, CIV and CV Controlled Substances Records of Receipt (invoice/packing slip),"* which is in the Controlled Substance Filing Cabinet. The receiving document must show the date received as well as the name, address and DEA registration number of the supplier. If this information is not on the document, the Pharmacy Manager or other pharmacy staff must call the supplier to get the required information and annotate the invoice with the information.

501.5.4.3 Records of Schedule II controlled substances will be maintained as described in **SOP 501.3.8** and **SOP 501.3.16.**

501.5.5 Reporting Inventory Discrepancies

Inventory discrepancies will be reported per **SOP 501.21.**

SOP 501.21: Reporting Controlled Substance Thefts and Losses

Purpose

The purpose of this procedure is to establish requirements for reporting thefts and significant losses of controlled substances.

General Information

Responsibility

- All Associates are responsible for reporting thefts and/or unexplainable losses of controlled substances to their immediate supervisor, Pharmacy Manager or business unit leadership.
- For retail and high-volume pharmacies:
  - The Pharmacy Manager is responsible for compliance with this procedure, including the evaluation of initial information regarding thefts and significant losses, and notifying the Pharmacy Coordinator and/or the DHL of findings and making reports as required in this SOP.
  - The DHL is responsible for ensuring the Compliance Department has been advised of thefts and significant losses, which are reported to the DEA.

Procedure

501.21.1 Significant Loss

501.21.1.1 The Pharmacy Manager is responsible for reporting a significant loss. Pharmacy Managers will consult with their Pharmacy Coordinator, in deciding whether the loss is significant.

501.21.1.2 When determining whether a loss is significant, DEA Registrants are encouraged to consider the following factors:

- The actual quantity lost in relation to the type of business;
- Whether there has been a pattern of losses and the results of efforts to resolve them; and
- Local trends and other indicators of the potential of the missing drugs.

Specific questions a Registrant should ask are:

- Has a pattern of loss been identified and, if so, would the pattern result in a substantial loss of controlled substances over a period of time?;
- Are specific controlled substances lost or are they random?;
- Are specific controlled substances likely for diversion?; and
- Can losses be associated with specific individuals?

A worksheet that may be used in making this determination and maintained as documentation of this process is attached as **Exhibit 501.21A Significant Loss Determination Worksheet** .

501.21.1.3 If the loss is deemed significant, the worksheet should be filed chronologically with the completed DEA Form 106 in the "*Reports and Theft and Unexplainable Loss (DEA Form 106)"* folder, which is located in the Controlled Substance Record Cabinet.

If the loss is not deemed significant, the worksheet should be filed in *"Additional DEA Notes &, Records"* folder which is in the Controlled Substance Filing Cabinet.

501.21.1.4 If the Pharmacy Manager is still uncertain regarding whether to report the loss, they should consult with their Coordinator and/or DHL.

The Pharmacy Coordinator, DHL may consult with a diversion investigator in a local DEA office for guidance.

501.21.2 Inventory Discrepancies

The DEA does not intend to have registrants report breakage, spillage or unexplainable losses of small amounts in order to "balance their books." Inventory discrepancies will be researched immediately by the pharmacist on duty when discovered and brought to the attention of the Pharmacy Manager as soon as possible for review and further research if necessary, regardless of the outcome of the initial research.

501.21.2.1 Inventory discrepancies will be investigated by the Pharmacy Manager immediately upon discovery. This process includes discrepancies discovered during required inventories pursuant to the procedure in **SOP 501.6.** If the discrepancy is determined to be due to a theft or significant loss, it will be reported to the DEA, in writing, within one (1) business day of making said determination and pursuant to the procedure in **SOP 501.21.3**.

501.21.2.2 If the loss is attributed to breakage, spillage or accounting errors that can be explained, then the errors will be documented and filed chronologically in the *"Additional DEA Notes & Records"* folder, which is located in the Controlled Substance Filing cabinet. A copy of the documentation will also be forwarded to the Coordinator.

501.21.3 Reporting Theft and Significant Loss

If a theft, significant loss or in-transit loss (as described below in **SOP 501.21.5**) is discovered, the following must occur:

501.21.3.1 The information must be reported to the Coordinator and the DHL immediately

501.21.3.2 Notification to the DEA must be accomplished by written notice within one (1) business day of discovery of a theft or significant loss of controlled substance.

501.21.3.3

- For retail and high-volume pharmacies, the Coordinator and/or the DHL, as applicable, will initiate an internal review and, if necessary, report the circumstances regarding the potential theft or significant loss to the Company's Asset Protection Department for possible additional investigation and actions in conjunction with the company's controlled substance compliance program.

501.21.3.4 If it is not clear at the outset that there has been a theft or significant loss, the DEA may advise the Pharmacy Manager to complete the internal investigation prior to preparing a DEA Form 106.

501.21.3.4a

- For retail and high-volume pharmacies: The Pharmacy Manager will report this information to the Coordinator and the DHL, as applicable, and will follow up with an email or facsimile report to the DEA to confirm the instructions provided by the DEA, including the date of the initial telephone call and the name of the Diversion Investigator who provided the instructions.

501.21.3.4b

The local office of the DEA will be advised at least every thirty (30) calendar days (more often if required due to the receipt of additional relevant information) by the Pharmacy Manager, Coordinator or regarding the progress of the internal investigation. These status advisements may be done verbally; however, the name of the Diversion Investigator, date of the

telephone call and a summary of the conversation will be documented and maintained with all official documents relating to the significant loss.

501.21.3.4c

Regardless of the status of the investigation, the Pharmacy Manager must ensure a complete and accurate DEA Form 106 is filed with the Administration within **45 calendar days after discovery of the theft or loss**. This must be accomplished through the DEA Diversion Control Division secure network application as described in **SOP 501.21.4.**

501.21.3.5 If the loss should be resolved within 45 days of the date of discovery and no official reporting on a DEA Form 106 will be necessary, the local office of the DEA should be informed via an email or facsimile that the issue is closed. Paperwork and documentation pertaining to the internal investigation will be filed chronologically in the folder labeled *"Additional DEA Notes & Records,"* which is in the Controlled Substance Filing Cabinet. When applicable, Loss Prevention/Asset Protection will also be notified of the closure.

501.21.4 Use of DEA Form 106

501.21.4.1 If a DEA Form 106 is to be prepared, the Pharmacy Manager will complete and submit it to make the official report to the DEA with the assistance of the Coordinator and/or the DHL.

Electronic form submission is required and will be accomplished through the DEA's Diversion Drug Theft Loss ("DTL") system website: https://apps.deadiversion.usdoj.gov/TLR/. In the event of any technical issues involving the DEA system being down, the Pharmacy Manager can report the issues by calling the DEA Help Center at 1–800–882–9539. If there is a need to submit DEA Form 106 while the DEA system is down, the Pharmacy Manager will document the day and time of their attempted submission(s) and their successful submission and retain these records with other records related to the loss.

501.21.4.1a If, and to the extent required by applicable law, notification of loss will also be made to pertinent state agencies.

501.21.4.2 The date of loss reported on DEA Form 106 must correspond to the date the theft or significant loss was first discovered.

501.21.4.3 If thefts have occurred due to Associate pilferage over a period of time, the estimated beginning and ending dates of the thefts should be noted in the "remarks" section with a brief explanation.

501.21.4.4 For the "Purchase value to Registrant of controlled substances taken", enter the amount the pharmacy paid for the controlled substance(s), not the retail value.

501.21.4.5 Evidence of submission must be kept on file. A copy of the DEA Form 106 and all other information pertaining to the theft or unexplainable loss will be filed chronologically in the folder *"Reports of Theft and Unexplainable Loss (DEA Form 106),"* which is found in the Controlled Substance Filing Cabinet and will be retained in accordance with **SOP 501.2.**

A copy of the DEA Form 106 and any subsequent addendums, where necessary, will be provided to:

- the DHL; and
- the Compliance Department.

501.21.4.6 if required, a member of the Compliance Department will make additional required reports in accordance with relevant terms.

501.21.5 In-transit Losses

501.21.5.1 Reporting of in-transit losses to the DEA are generally the responsibility of the supplier. If the purchaser takes custody of the shipment, however, the shipment is considered to have been received in total and any shortages that are discovered after the transfer of custody are considered losses from the inventory of the recipient. As a result, the pharmacy is required to report the loss.

501.21.5.1a In this case, the supplier and its DEA registration number must be included in the "Loss in Transit" section on the DEA Form 106. When explaining how many losses occurred from the same carrier in the past, do not include the current loss.

501.21.5.2 Pharmacies should not take possession of Schedule II controlled substances until all the substances are checked in as required by **SOP 501.05**.

501.21.5.2a If a discrepancy is identified upon check-in of a Schedule II shipment, a pharmacist must notate on the driver's shipping manifest that the item was not received. The notation shall be initialed and dated by both the pharmacist and the driver.

501.21.5.2b A copy of the notated shipping manifest must be retained and attached to the purchaser's copy of the Order Form and corresponding invoice as noted in **SOP 501.05**.

501.21.5.2c The pharmacist must also contact the supplier to report the discrepancy as soon as possible and report the in-transit loss to the DEA as described in **SOP 501.21.4**.

501.21.6 Associate Theft

Associates who steal controlled substances from Company facilities will be terminated and the facts regarding their illegal activities will be referred to the appropriate law enforcement and regulatory authorities for prosecution.

501.21.7 Robbery and Burglary Procedures

501.21.7.1 In the event of a robbery, burglary or other unlawful entry, the local police will be notified immediately after the incident or upon discovery of burglary.

- For retail and high-volume pharmacies: store management and the Coordinator or DHL, as applicable, will also be notified and the Company's robbery procedures must be followed.

501.21.7.2 In the event of an overnight burglary, the Pharmacy Manager must ensure an inventory count is completed on all controlled substances to assess for potential theft. In addition, the Pharmacy Manager will take inventory of the will call area to assess for theft of any medications awaiting pick up to verify if any product is missing.

501.21.7.3 Any loss of controlled substance must be reported pursuant to this SOP. Any prescriptions determined to be stolen from will call will need to be handled pursuant to HIPAA breach procedures outlined in the **Policy 1000: HIPAA Policies and Procedures**.

501.21.8 Other Agencies

The Board of Pharmacy and the local police will be contacted to report a theft at the time that the DEA is notified. If there are specific state agencies with controlled substance oversight, these agencies will also be contacted.

SOP 501.19: Controlled Substance Product Security

501.19.5 Personal Items

Personal items such as coats, purses and backpacks, are prohibited from being brought into the pharmacy drug storage areas. Personal items will be stored in lockers outside the pharmacy, if available. If lockers are unavailable, the Pharmacy Manager will designate an area for storing the items near the entrance of the pharmacy.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #315,** **Pharmacy License No. PH03897,** **ALYSSA MERCEDES GARCIA, PT,** **Certificate of Registration No. PT20499, and** **OCTAVIA LORAINE BROOKS, RPH,** **Certificate of Registration No. 20950,** **Respondents.**	**CASE NOS. 25-076-PH-S** **25-076-PT-S** **25-076-RPH-S** **STIPULATION AND ORDER [RESPONDENT SMITH'S PHARMACY #315 ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Smith's Pharmacy #315, Pharmacy License No. PH03897, by and through counsel**,** Nicholas Meza, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about June 11, 2025, Board Staff served Respondent with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondents and Notice of Hearing.

2. On or about July 24, 2025, Respondent Smith's Pharmacy #315 filed an Answer and Notice of Defense to the Accusation.

3. Respondent is aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal, and any and all other rights which may be accorded pursuant to NRS Chapter 233B, Nevada Administrative Procedure Act, NRS

Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waive the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit,* that as the pharmacy/pharmacy owner at the time of the diversion of controlled substances by Respondent Alyssa Garcia, PT, Certificate of Registration No. PT20499, and the related violations of law as alleged, Respondent Smith's Pharmacy #315 is responsible for those violations, including all errors and omissions of Garcia and the managing pharmacist, Respondent Octavia Loraine Brooks, RPh, Certificate of Registration No. 20950, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

7. Those violations are pled with particularity in the Amended Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Smith's Pharmacy #315, Pharmacy License No. PH03897, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Smith's Pharmacy #315 Smith's Pharmacy #315 shall pay a fine of Two Thousand Five Hundred Dollars ($2,500.00) for the violations by personal, business, certified or cashier's check or money order

made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by January 1, 2026; and

B. Pursuant to NRS 622.400, Respondent Smith's Pharmacy #315 shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by January 1, 2026.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline consistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 3, 2025. Respondent will appear via teleconference or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms of this Stipulation and any admissions contained herein are made solely for the purpose of settlement of this Accusation. They shall not be deemed an admission for any other purpose and shall not be used or referred to in any other hearing on the merits of this matter, or any other civil or administrative matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 8th **day of** August **2025**

SMITH'S PHARMACY #315
Pharmacy License No. PH03897

APPROVED AS TO FORM AND CONTENT
this 8th **day of** August **2025**

NICHOLAS MEZA, ESQ.
Counsel for Respondents

Signed this ___ day of _____ 2025

BRETT KANDT
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Smith's Pharmacy #315, Pharmacy License No. PH03897, in Case No. 25-076-PH-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ____day of September 2025.

_____

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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FILED
JUN 11 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #315,** **Pharmacy License No. PH03897,** **ALYSSA MERCEDES GARCIA, PT,** **Certificate of Registration No. PT20499, and** **OCTAVIA LORAINE BROOKS, RPH,** **Certificate of Registration No. 20950,** **Respondents.**	**CASE NOS. 25-076-PH-S** **25-076-PT-S** **25-076-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Alyssa Garcia, PT (Garcia), Certificate of Registration No. PT20499, was a pharmaceutical technician registered with the Board, Respondent Octavia Loraine Brooks, RPh (Brooks), Certificate of Registration No. 20950, was a pharmacist registered with the Board, and Respondent Smith's Pharmacy #315, Pharmacy License No. PH03897, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Garcia was employed as a pharmaceutical technician by Smith's Pharmacy #315, located at 8525 W Warm Springs Road in Las Vegas, and Brooks was employed as managing pharmacist of the pharmacy, at the time of the events alleged herein.

3. On or about February 13, 2025 Smith's Pharmacy #315 submitted DEA Form 106 documentation to the Board reporting the theft of controlled substances after an investigation produced evidence that Garcia diverted 9515 Alprazolam 1mg tablets, 19,908 Alprazolam 2mg tablets, and 1,018 Tramadol 50mg tablets.

4. On or about January 24, 2025, Respondent was terminated from employment by Smith's Pharmacy #315 due to policy violations and unprofessional conduct related to the theft.

5. The investigation revealed that Brooks failed to comply with Smith's Pharmacy policies and procedures to prevent and detect diversion, including, without limitation, failing to maintain balance on hand (BOH) manual changes reports weekly to review for suspicious or unexplainable manual changes for controlled substances, failing to question and/or research suspicious changes, and failing to research inventory discrepancies and report any evidence of theft or unexplainable loss.

6. On or about March 11, 2025, the Board served Garcia with an order of summary suspension of her Certificate of Registration No. PT20499 pursuant to NRS 233B.127(3) and noticed a hearing before the Board on April 16, 2025. Board staff attempted service of the order of summary suspension on Garcia by certified mail, return receipt requested, addressed to Garcia at her last address of record.

7. Garcia failed to appear at the April 16, 2025, hearing, and the Board upheld the suspension of her Certificate of Registration No. PT20499 pending the filing of an accusation.

APPLICABLE LAW

8. It is a felony offense to acquire a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 843(a)(3); 21 U.S.C. § 846; NRS 453.331(1)(d); NRS 453.391(1).

9. It is a felony offense to possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 844; 21 U.S.C. § 846; NRS 453.336(1); NRS 453.381(8)

10. It is a criminal offense to use a controlled substance except as authorized by law. 42 U.S.C. § 12210; NRS 453.411(1).

11. Pharmacies shall establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances. NAC 453.400.

12. Supplying or diverting drugs which are legally sold in pharmacies constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

13. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

16. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

17. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of

any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

18. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Unlawful Acquisition of Controlled Substances
(Respondent Garcia)

19. By diverting and acquiring controlled substances as alleged herein, Garcia violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a), 21 U.S.C. § 843(a)(3), 21 U.S.C. § 846, NRS 453.331(1)(d) and/or NRS 453.391(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT TWO
Unlawful Possession of Controlled Substances
(Respondent Garcia)

20. By diverting and possessing controlled substances as alleged herein, Garcia violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a), 21 U.S.C. § 844, 21 U.S.C. § 846, NRS 453.336(1), NRS 453.381(8) and/or NRS 454.316(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT THREE
Unlawful Use of Controlled Substances
(Respondent Garcia)

21. By diverting and using controlled substances as alleged herein, Garcia violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 42 U.S.C. § 12210 and/or NRS 453.411(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT FOUR
Unprofessional Conduct – Diversion
(Respondent Garcia)

22. By diverting controlled substances as alleged herein, Garcia engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction
(Respondent Garcia)

23. By diverting controlled substances as alleged herein, Garcia was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

COUNT SIX
Managing Pharmacist Responsibility
(Respondent Brooks)

24. As the managing pharmacist of Smith's Pharmacy #315 at the time of the diversion of controlled substances by Garcia and the related violations of law as alleged herein, and by her failure to comply with Smith's Pharmacy policies and procedures to prevent or guard against theft and misuse of controlled substances in violation of NAC 453.400, Brooks is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT SEVEN
Pharmacy/Pharmacy Owner Responsibility
(Respondent Smith's Pharmacy #315)

25. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Smith's Pharmacy #315 is responsible for those violations, including all errors and omissions of Respondents Garcia and Brooks, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and pharmacy license of these Respondents.

Signed this 11th day of June 2025.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy,
for and on behalf of J. David Wuest, R.Ph., Executive Secretary of the
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **OCTAVIA LORAINE BROOKS, RPH,** **Certificate of Registration No. 20950,** **Respondent.**	**Case No. 25-076-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, July 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of June 2025.

Yenh Long, Pharm.D.
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **OCTAVIA LORAINE BROOKS, RPH,** **Certificate of Registration No. 20950,** **Respondent.**	**Case No. 25-076-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

OCTAVIA LORAINE BROOKS, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of June 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Octavia Brooks, RPH
[redacted]
Las Vegas, NV [redacted]

Octavia Brooks, RPH c/o
Smith's Food and Drug Pharmacy #315
8525 West Warm Springs Rd.
Las Vegas, NV 89113

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
JUL 19 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #315** **Pharmacy License No. PH03897, and** **ALYSSA MERCEDES GARCIA, PT,** **Certificate of Registration No PT20499, and** **OCTAVIA BROOKS, RPH,** **Certificate of Registration No. 20950,** **Respondents.**	)	**Case Nos. 25-076-PH-S** **25-076-PT-S** **25-076-RPH-S** **ANSWER AND NOTICE OF DEFENSE OF OCTAVIA BROOKS, RPH**

Respondent Octavia Brooks, RPH, hereby files with the Nevada State Board of Pharmacy ("Board"), her Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on June 11, 2025.

ANSWER TO ACCUSATION

Jurisdiction

Ms. Brooks agrees that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation. Ms. Brooks further answers the Factual Allegations set forth in the Accusation as follows:

Factual Allegations: Paragraphs 2-7

Paragraph 2: Ms. Brooks acknowledges that she was the managing pharmacist at Smith's Pharmacy #315 ("Pharmacy") however she acted in this capacity from August 2021 until January 2025. Ms. Brooks asserts that Ms. Garcia was employed as a technician at the Pharmacy prior to Ms. Brooks becoming the managing pharmacist.

Paragraph 3: Ms. Brooks is without sufficient personal knowledge to respond to paragraph 3 and asserts that she no longer worked for the Pharmacy on the date noted.

Paragraph 4: Ms. Brooks is without sufficient personal knowledge to respond to the factual assertions set forth in Paragraph 4 and notes that Paragraph 4 does not specify which Respondent is at issue in the allegation, but based on information contained in the Accusation, Ms. Brooks believes this Paragraph refers to Ms. Garcia.

Paragraph 5: Ms. Brooks denies the factual allegations contained in Paragraph 5 and asserts that she did follow and comply with the Pharmacy's policies and procedures related to prevent and detect diversion and asserts that the systems in place at the Pharmacy to detect diversion were inherently flawed and subject to manipulation.

Paragraph 6: Paragraph 6 is pertains solely to Ms. Brooks and does not require a response from Ms. Brooks.

Paragraph 7: Paragraph 7 is pertains solely to Ms. Brooks and does not require a response from Ms. Brooks.

Applicable Law: Paragraphs 8-18

Paragraph 8: Ms. Brooks agrees that Paragraph 8 accurately reflects the provisions of state and federal law set forth therein, however, asserts that the cited laws do not pertain to her in the instant matter.

Paragraph 9: Ms. Brooks agrees that Paragraph 9 accurately reflects the provisions of state and federal law set forth therein, however asserts that the cited laws do not pertain to her in the instant matter.

Paragraph 10: Ms. Brooks agrees that Paragraph 10 accurately reflects the provisions of federal law noted, however asserts that the cited laws do not pertain to her in the instant matter.

Paragraph 11: Ms. Brooks agrees that Paragraph 11 accurately reflects the provisions of NAC 453.400, however asserts that the cited regulation does not pertain to her in the instant matter.

Paragraph 12: Ms. Brooks agrees that Paragraph 12 accurately reflects the provisions of NRS and NAC Chapter 639 sections noted, however asserts that the cited laws does not pertain to her in the instant matter.

Paragraph 13: Ms. Brooks agrees that Paragraph 13 accurately reflects the provisions of NRS and NAC Chapter 639 sections noted, however asserts that the cited laws does not pertain to her in the instant matter.

Paragraph 14: Ms. Brooks agrees that Paragraph 14 accurately reflects the provisions of NRS 639.210(11).

Paragraph 15: Ms. Brooks agrees that Paragraph 15 accurately reflects the provisions of NRS 639.210(12), however asserts that the cited law does not pertain to her in the instant matter.

Paragraph 16: Ms. Brooks agrees that Paragraph 16 accurately reflects the provisions of NRS and NAC Chapter 639 noted therein.

Paragraph 17: Ms. Brooks agrees that Paragraph 17 accurately reflects the provisions of NRS and NAC Chapter 639 noted therein.

Paragraph 18: Ms. Brooks agrees that Paragraph 18 accurately reflects the provisions of state and federal law noted, however asserts that the cited law does not pertain to her in the instant matter.

Counts: Paragraphs 19-25

Count One (Paragraph 19): The allegations set forth in Count One pertain solely to Respondent Garcia and do not require a response from Ms. Brooks.

Count Two (Paragraph 20): The allegations set forth in Count Two pertain solely to Respondent Garcia and do not require a response from Ms. Brooks.

Count Three (Paragraph 21): The allegations set forth in Count Three pertain solely to Respondent Garcia and do not require a response from Ms. Brooks.

Count Four (Paragraph 22): The allegations set forth in Count Four pertain solely to Respondent Garcia and do not require a response from Ms. Brooks.

Count Five (Paragraph 23): The allegations set forth in Count Five pertain solely to Respondent Garcia and do not require a response from Ms. Brooks.

Count Six (Paragraphs 24): Ms. Brooks denies the allegations contained in Count Six.

Count Seven (Paragraph 25): The allegations set forth in Count Seven pertain solely to Respondent Smith's Pharmacy #315 and do not require a response from Ms. Brooks.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Ms. Brooks worked as managing pharmacist at the Pharmacy between August 2021 and January 2025. Prior to becoming the managing pharmacist, Ms. Brooks worked as an intern pharmacist at the Pharmacy starting in October 2018 until she became the managing pharmacist.

Ms. Brooks was terminated from her position by the store manager in January 2025 after briefly being suspended from her position. No reason was given to her for the suspension and the

reasons provided to her for the termination were unrelated to the instant matter. Ms. Brooks was not advised of the diversion conducted by Ms. Garcia until after she was terminated from her position.

Ms. Brooks would note that no time frame has been provided as to when, or for how long Ms. Garcia had been diverting alprazolam and tramadol resulting in the ultimate number of pills noted in the Accusation as having been diverted and accordingly cannot comment on whether Ms. Garcia's diversion may have been on-going prior to Ms. Brooks becoming managing pharmacist.

Ms. Brooks cannot state with certainty as to how Ms. Garcia may have diverted the drugs in question. However, Ms. Brooks notes that the Electronic Prescription Reference Network (EPRN) used by pharmacies within the Kroger system, of which the Smith's Pharmacy was a part, was known to have occasional glitches which would then impact the quantities on hand; if these were adjusted, this would effect the Balance on Hand (BOH) weekly report. Ms. Brooks acknowledges that she recalls the alprazolam count was off on at least three occasions, but not by amounts that would have caused Ms. Brooks to believe that there was any issue other than an EPRN glitch.

Purchase orders for drugs dispensed by the Pharmacy would be transmitted by the EPRN which would then update the quantity of any one drug in the system based on the purchase order. When drugs were received, controlled substance invoices were signed by the pharmacist and the pharmacy tech and dated. If the drugs received did not match the amount purchased through the purchase order; those numbers would be modified in the EPRN upon acceptance of the drug order. For schedule II controlled substances, the pharmacist on duty would need to accept the drugs received in the system; all other drugs could be accepted into the system by the pharmacy tech.

Ms. Brooks believes it is possible that Ms. Garcia modified invoices at the time that drugs were received at the pharmacy before accepted non-schedule II substances in the system which would then result in a modification to the BOH reports as well. Ms. Brooks cannot be certain that this was the point in the drug acceptance process which Ms. Gracia may have made modifications to the Pharmacy records in an attempt to hide diversion, she believes this to be the most likely time that such modifications would have been made, thus making it difficult to identify discrepancies in the numbers that were attributable to diversion rather than EPRN errors or regular modifications made noting the number of pills received.

Ms. Brooks asserts that she did follow the policies and procedures of Smith's Pharmacy as they relate to this manner, but that she did not identify that possible diversion was taking place as she believes Ms. Garcia was modifying records in a manner that would have appeared consistent with policies related to the receipt and acceptance of drug orders. Ms. Brooks acknowledges that in hindsight she should have follow up more diligently on any and all discrepancies, regardless of the potential cause of that discrepancy.

Respectfully submitted this 18th day of July, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondent, Octavia Brooks, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #315,** **Pharmacy License No. PH03897,** **ALYSSA MERCEDES GARCIA, PT,** **Certificate of Registration No. PT20499, and** **OCTAVIA LORAINE BROOKS, RPH,** **Certificate of Registration No. 20950,** **Respondents.**	**CASE NOS. 25-076-PH-S** **25-076-PT-S** **25-076-RPH-S** **STIPULATION AND ORDER** **[RESPONDENT BROOKS ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Octavia Loraine Brooks, RPh (Brooks), Certificate of Registration No. 20950, by and through counsel, Law Offices of Lyn E. Beggs, PLLC, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about June 11, 2025, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about July 18, 2025, Respondent filed an Answer and Notice of Defense to the Amended Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Amended Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to her pursuant to NRS Chapter 233B (Nevada Administrative Procedure

Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to her by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that as the managing pharmacist of Respondent Smith's Pharmacy #315, Pharmacy License No. PH03897, at the time of the diversion of controlled substances by Respondent Alyssa Garcia, PT, Certificate of Registration No. PT20499, and the related violations of law as alleged, and by her failure to comply with Smith's Pharmacy policies and procedures to prevent or guard against theft and misuse of controlled substances in violation of NAC 453.400, Brooks is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

7. Those violations are pled with particularity in the Amended Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Octavia Loraine Brooks, RPh, Certificate of Registration No. 20950, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Brooks shall pay a fine of Two Thousand Five Hundred Dollars ($2,500.00) for the violations by

personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by January 1, 2026; and

B. Pursuant to NRS 622.400, Respondent Brooks shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by January 1, 2026.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline consistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 3, 2025. Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 28th **day of** July **2025**

OCTAVIA LORAINE BROOKS, RPH
Certificate of Registration No. 20950

Signed this ___ day of _____ 2025

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 29th **day of** July **2025**

LYN E. BEGGS, ESQ.
Counsel for Respondent

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Octavia Loraine Brooks, RPh, Certificate of Registration No. 20950, in Case No. 25-076-RPH-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2025.

_____

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SMITH'S PHARMACY #315,** **Pharmacy License No. PH03897,** **ALYSSA MERCEDES GARCIA, PT,** **Certificate of Registration No. PT20499, and** **OCTAVIA LORAINE BROOKS, RPH,** **Certificate of Registration No. 20950,** **Respondents.**	**CASE NOS. 25-076-PH-S** **25-076-PT-S** **25-076-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Alyssa Garcia, PT (Garcia), Certificate of Registration No. PT20499, was a pharmaceutical technician registered with the Board, Respondent Octavia Loraine Brooks, RPh (Brooks), Certificate of Registration No. 20950, was a pharmacist registered with the Board, and Respondent Smith's Pharmacy #315, Pharmacy License No. PH03897, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Garcia was employed as a pharmaceutical technician by Smith's Pharmacy #315, located at 8525 W Warm Springs Road in Las Vegas, and Brooks was employed as managing pharmacist of the pharmacy, at the time of the events alleged herein.

3. On or about February 13, 2025 Smith's Pharmacy #315 submitted DEA Form 106 documentation to the Board reporting the theft of controlled substances after an investigation produced evidence that Garcia diverted 9515 Alprazolam 1mg tablets, 19,908 Alprazolam 2mg tablets, and 1,018 Tramadol 50mg tablets.

4. On or about January 24, 2025, Respondent was terminated from employment by Smith's Pharmacy #315 due to policy violations and unprofessional conduct related to the theft.

5. The investigation revealed that Brooks failed to comply with Smith's Pharmacy policies and procedures to prevent and detect diversion, including, without limitation, failing to maintain balance on hand (BOH) manual changes reports weekly to review for suspicious or unexplainable manual changes for controlled substances, failing to question and/or research suspicious changes, and failing to research inventory discrepancies and report any evidence of theft or unexplainable loss.

6. On or about March 11, 2025, the Board served Garcia with an order of summary suspension of her Certificate of Registration No. PT20499 pursuant to NRS 233B.127(3) and noticed a hearing before the Board on April 16, 2025. Board staff attempted service of the order of summary suspension on Garcia by certified mail, return receipt requested, addressed to Garcia at her last address of record.

7. Garcia failed to appear at the April 16, 2025, hearing, and the Board upheld the suspension of her Certificate of Registration No. PT20499 pending the filing of an accusation.

APPLICABLE LAW

8. It is a felony offense to acquire a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 843(a)(3); 21 U.S.C. § 846; NRS 453.331(1)(d); NRS 453.391(1).

9. It is a felony offense to possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 844; 21 U.S.C. § 846; NRS 453.336(1); NRS 453.381(8)

10. It is a criminal offense to use a controlled substance except as authorized by law. 42 U.S.C. § 12210; NRS 453.411(1).

11. Pharmacies shall establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances. NAC 453.400.

12. Supplying or diverting drugs which are legally sold in pharmacies constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

13. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

16. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

17. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of

any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

18. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Unlawful Acquisition of Controlled Substances
(Respondent Garcia)

19. By diverting and acquiring controlled substances as alleged herein, Garcia violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a), 21 U.S.C. § 843(a)(3), 21 U.S.C. § 846, NRS 453.331(1)(d) and/or NRS 453.391(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT TWO
Unlawful Possession of Controlled Substances
(Respondent Garcia)

20. By diverting and possessing controlled substances as alleged herein, Garcia violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a), 21 U.S.C. § 844, 21 U.S.C. § 846, NRS 453.336(1), NRS 453.381(8) and/or NRS 454.316(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT THREE
Unlawful Use of Controlled Substances
(Respondent Garcia)

21. By diverting and using controlled substances as alleged herein, Garcia violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 42 U.S.C. § 12210 and/or NRS 453.411(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT FOUR
Unprofessional Conduct – Diversion
(Respondent Garcia)

22. By diverting controlled substances as alleged herein, Garcia engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction
(Respondent Garcia)

23. By diverting controlled substances as alleged herein, Garcia was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

COUNT SIX
Managing Pharmacist Responsibility
(Respondent Brooks)

24. As the managing pharmacist of Smith's Pharmacy #315 at the time of the diversion of controlled substances by Garcia and the related violations of law as alleged herein, and by her failure to comply with Smith's Pharmacy policies and procedures to prevent or guard against theft and misuse of controlled substances in violation of NAC 453.400, Brooks is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT SEVEN
Pharmacy/Pharmacy Owner Responsibility
(Respondent Smith's Pharmacy #315)

25. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Smith's Pharmacy #315 is responsible for those violations, including all errors and omissions of Respondents Garcia and Brooks, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and pharmacy license of these Respondents.

Signed this 9th day of June 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALYSSA MERCEDES GARCIA, PT,** **Certificate of Registration No. PT20499,** **Respondent.**	**Case No. 25-076-PT-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, July 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of JUNE 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALYSSA MERCEDES GARCIA, PT,** **Certificate of Registration No. PT20499,** **Respondent.**	**Case No. 25-076-PT-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

ALYSSA MERCEDES GARCIA, PT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of June 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Alyssa Garcia
[redacted]
Reno, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of June 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Alyssa Garcia
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
APR 16 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALYSSA GARCIA, PT,** **Certificate of Registration No. PT20499,** **Respondent.**	**CASE NO. 25-076-PT-S** **ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, April 16, 2025. Brett Kandt, Esq., prosecuted the case before the Board. Respondent Alyssa Garcia, PT, Certificate of Registration No. PT20499, failed to appear. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The Board finds that probative evidence exists in the record to establish each of the following facts by a preponderance of the evidence:

1. On March 11, 2025, the Executive Secretary of the Nevada State Board of Pharmacy (Board) issued an Order of Summary Suspension of the certificate of registration of Respondent Alyssa Garcia, PT, Certificate of Registration No. PT20499, pursuant to NRS 233B.127(3), and noticed a hearing (See EXHIBIT A hereto).

2. On or about March 11, 2025, Board staff attempted service of the Order of Summary Suspension on Respondent by certified mail, return receipt requested, addressed to the Respondent at her last address of record,.

3. On or about March 19, 2025, Board staff attempted service of the Notice of Hearing on Respondent by certified mail, return receipt requested, addressed to the Respondent at her last address of record.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

1. The Board has jurisdiction over this matter and Respondent, because at the time of the events herein, Respondent held a pharmaceutical technician registration issued by the Board.

2. Board staff satisfied the notice and service requirements of NRS 233B.127(3) and NRS 639.245, and Respondent was given sufficient legal notice of the hearing.

3. If a respondent fails to appear at a scheduled hearing and the Board finds that the respondent was given sufficient legal notice of the hearing, it may accept the allegations as true. NRS 622A.350.

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. The Order of Summary Suspension of the certificate of registration of Respondent Alyssa Garcia, PT, Certificate of Registration No. PT20499, shall remain in effect pending the timely filing and service of a Notice of Intended Action and Accusation, Statement to Respondent and Notice of Hearing, and until such time as an evidentiary hearing on the charges is held.

2. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 17th day of April.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 18th day of April 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Alyssa Garcia, PT
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

Exhibit A

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALYSSA GARCIA, PT,** **Certificate of Registration No. PT20499,** **Respondent.**	**CASE NO. 25-076-PT-S** **ORDER OF SUMMARY SUSPENSION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), has determined that the certificate of registration of Respondent Alyssa Garcia, PT, Certificate of Registration No. PT20499, is subject to summary suspension pursuant to Nevada Revised Statute (NRS) 233B.127(3), based upon the following preliminary findings:

1. Upon information and belief, on or about January 24, 2025, Respondent was terminated from employment by Smith's Pharmacy #315, License No. PH03897, due policy violations and unprofessional conduct related to the theft of 9,515 tablets of Alprazolam 1mg, 19,908 tablets of Alprazolam 2mg, and 1,018 tablets of Tramadol 50mg. Smith's Pharmacy #315 filed a police report with the Las Vegas Metropolitan Police Department and an investigation is ongoing.

2. As of the date of this Order, the Executive Secretary has reasonably determined that the health, safety, or welfare of the public in the State of Nevada is at risk of imminent harm based upon the finding in paragraph 1 above.

3. Based on the foregoing, the Executive Secretary has reasonably determined that a summary suspension of Certificate of Registration No. PT20499 is necessary to remove the risk of imminent harm to the health, safety and welfare of the public.

Accordingly, pursuant to NRS 233B.127(3):

IT IS HEREBY ORDERED that the Certificate of Registration No. PT20499 is **SUMMARILY SUSPENDED** until further order of the Board; and,

IT IS FURTHER ORDERED that pursuant to NRS 233B.127(3), a hearing before the Board on this matter is set for Wednesday, April 16, 2025, at 9:00 AM, or soon thereafter at the following location:

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

Respondent is therefore directed to provide the Board with any evidence or information that would show that either the factual or legal reasons for the summary suspension are incorrect or otherwise demonstrate that her conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Alyssa M. Garcia
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
JUL 28 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HANGER PROSTHETICS AND ORTHOTICS, License No. MP00721, as successor in interest to ABILITY PROSTHETICS AND ORTHOTICS OF NEVADA, LLC, License No. MP01037,** **Respondent.**	**Case No. 23-234-MP-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over Hanger Prosthetics and Orthotics (Respondent), because the Board has licensed Respondent to conduct business as a medical products provider.

FACTUAL ALLEGATIONS

2. Respondent conducts business in Nevada as a medical products provider. As used herein, "medical products provider" has the meaning ascribed to it in NAC 639.6936.

3. Respondent formerly conducted business from a facility at 309 Kirman Avenue in Reno, Nevada.

4. Prior to July 12, 2022, Travis Humphreys, Tina Humphreys and/or Ability Prosthetics and Orthotics of Nevada, LLC, owned the business associated with the facility at 309 Kirman Avenue in Reno, Nevada.

5. Prior to July 12, 2022, Tina Humphreys served as the administrator for the licensed facility at 309 Kirman Avenue in Reno, Nevada. That facility operated under license no. MP01037.

6. On or about July 12, 2022, Respondent acquired the assets and/or 100% of the ownership interests formerly associated with the facility at 309 Kirman Avenue in Reno, Nevada. On information and belief, Respondent purchased said assets and/or ownership interests from Travis Humphreys, Tina Humphreys and/or Ability Prosthetics and Orthotics of Nevada, LLC.

7. On or about July 12, 2022, Tina Humphreys resigned or otherwise relinquished her position as the administrator for the facility at 309 Kirman Avenue in Reno, Nevada.

8. On or about July 12, 2022, Travis Humphreys assumed the role of the administrator for the facility at 309 Kirman Avenue in Reno, Nevada.

9. Respondent did not notify the Board that Travis Humphreys had assumed the role of Respondent's administrator, or that Tina Humphreys had ceased to be employed as the administrator for the facility at 309 Kirman Avenue in Reno, Nevada. As a consequence, the Board was unable to evaluate the qualifications of the new administrator.

10. Respondent did not notify the Board that Respondent had acquired the business assets and/or ownership interests formerly associated with the facility at 309 Kirman Avenue in Reno, Nevada.

11. On or about December 18, 2023, Respondent closed the facility at 309 Kirman Avenue in Reno, Nevada.

12. Between July 12, 2022, and December 18, 2022, Respondent conducted business as a medical products provider from the facility at 309 Kirman Avenue in Reno, Nevada. During this time frame, Respondent was not licensed by the Board to conduct business from the facility at 309 Kirman Avenue in Reno, Nevada.

13. Respondent continues to conduct business from a facility at 961 Matley Lane in Reno, Nevada.

14. Since 2010 or earlier, the facility at 961 Matley Lane in Reno, Nevada, has operated under license no. MP00721. Respondent also operates two or more Nevada-licensed facilities that are based in Utah.

APPLICABLE LAW

15. Any person who engages in business as a medical products provider must obtain a license from the Board. NRS 639.233; NAC 639.6942. "Medical products provider" means a person licensed pursuant to NAC 639.693 to 639.6958, inclusive, to sell, lease or otherwise provide medical products to a consumer in Nevada.

16. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. NAC 639.6935.

17. It is unlawful for any person to sell drugs or medical devices at wholesale or retail unless the person holds the appropriate certificate, license or permit issued by the Board. NRS 639.100(1)(a).

18. The owner of a medical products provider is responsible for the acts of his or her business administrator and employees. NAC 639.6941(2).

19. A medical products provider must employ an administrator, approved by the Board, who is competent to provide set up, instruction, repair and maintenance services for patients. NAC 639.694; NAC 639.6946(1).

20. A medical products provider must notify the Board within 3 business days after the administrator ceases to be employed in that capacity, and/or within 3 business days after a new administrator begins his or her employment. NRS 639.694(3).

21. A medical products provider may not operate for more than 10 business days without an administrator. NAC 639.694(4).

22. Upon a change in the controlling interest of a medical products provider, the medical products provider shall apply for a new license with the Board within 5 days after the completion of the transaction which changes the controlling interest. NAC 639.6947(1).

23. After a sale or change in the controlling interest of the business, the purchaser or acquiring party may not operate the business, except to service, maintain, repair or otherwise satisfy the outstanding obligations of the predecessor business, until the new owner is licensed by the Board. NAC 639.6947(3).

24. Licenses issued by the Board are not transferable. NAC 639.6942.

25. The Board may discipline a licensee or registrant for violating applicable statutes or regulations, NRS 639.210(12), or for engaging in unprofessional conduct, NRS 639.210(4). "Unprofessional conduct" includes performing one's duties as a licensee or registrant in a negligent manner, NAC 639.945(1)(i), or performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration, NAC 639.945(1)(k).

COUNT ONE

Failure to Notify the Board of Change of Administrator

26. As alleged above, Respondent failed to notify the Board when Tina Humphreys ceased to be employed as Respondent's administrator.

27. As noted above, Respondent has a legal duty to notify the Board when Tina Humphreys ceased to be employed as Respondent's administrator.

28. By failing to notify the Board that Tina Humphreys had ceased to be employed as Respondent's administrator, Respondent violated NAC 639.694(3) and/or performed its duties in a negligent manner.

29. Due to the acts and/or omissions detailed above, Respondent is guilty of conduct for which the Board may impose professional discipline. NRS 639.210(4), (12); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT TWO

Failure to Notify the Board of Change in Controlling Interest

30. As alleged above, Respondent failed to notify the Board of the sale and/or change in the controlling interest of the business licensed by the Board to sell medical products from a location at 309 Kirman Avenue in Reno, Nevada.

31. As noted above, Respondent had a legal duty as a licensed medical products provider to timely notify the Board of the sale and/or change in the controlling interest of said business.

32. By failing to notify the Board of the sale and/or change in the controlling interest of the business, Respondent violated NAC 639.6947(1) and/or performed its duties in a negligent manner.

33. Due to the acts and/or omissions detailed above, Respondent is guilty of conduct for which the Board may impose professional discipline. NRS 639.210(4), (12); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT THREE
Unlicensed Activity

34. As alleged above, between July 12, 2022, and December 18, 2022, Respondent conducted business as a medical products provider from a facility at 309 Kirman Avenue in Reno, Nevada.

35. Between July 12, 2022, and December 18, 2022, Respondent was not licensed by the Board to conduct business from the facility at 309 Kirman Avenue in Reno, Nevada.

36. By conducting business without a license, Respondent violated NRS 639.100 and/or engaged in unprofessional conduct.

37. Due to the acts and/or omissions detailed above, Respondent is guilty of conduct for which the Board may impose professional discipline. NRS 639.210(4), (12); NRS 639.255; NAC 639.945; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 20th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HANGER PROSTHETICS AND ORTHOTICS, License No. MP00721, as successor in interest to ABILITY PROSTHETICS AND ORTHOTICS OF NEVADA, LLC, License No. MP01037,** **Respondent.**	**Case No. 23-234-MP-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2CH day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HANGER PROSTHETICS AND ORTHOTICS, License No. MP00721, as successor in interest to ABILITY PROSTHETICS AND ORTHOTICS OF NEVADA, LLC, License No. MP01037,** **Respondent.**	**Case No. 25-234-MP-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR Ability Prosthetics and Orthotics of Nevada, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Hanger Prosthetics & Orthotics
961 Matley Ln #100
Reno, NV 89502

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondents.**	**Case Nos. 24-370-PH-N** **24-370-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (the "Board"), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has jurisdiction over Respondent PharMerica ("Respondent PharMerica"), the holder of Pharmacy License No. PH02018, because Respondent PharMerica is licensed by the Board to operate a pharmacy at 4750 Longley Lane in Reno, Nevada.

2. The Board has jurisdiction over Respondent Camilla Kim, RPh ("Respondent Kim"), the holder of Certificate of Registration No. 19388, because Respondent Kim is registered by the Board to engage in the practice of pharmacy in Nevada.

FACTUAL ALLEGATIONS

3. Respondent PharMerica operates a pharmacy in Reno, Nevada.

4. In March 2024, Respondent Kim was employed by Respondent PharMerica as a pharmacist.

5. In 2023 and 2024, Respondent PharMerica was under contract with MorningStar Senior Living of Sparks ("MorningStar"), an assisted living facility, to dispense prescription medication and provide medication management services to residents of the MorningStar facility.

6. Respondent PharMerica worked cooperatively with the nursing staff at MorningStar to store and deliver prescription medications for the residents of the MorningStar facility.

7. In 2023 and 2024, patient D.P., an 87-year-old female, resided at MorningStar, where she received medication and medication management services from Respondent PharMerica.

8. In 2023 and 2024, patient D.P. required levothyroxine for hypothyroidism.

9. Between March 2023 and March 2024, Respondent PharMerica dispensed levothyroxine to patient D.P. without interruption, according to the instructions of patient D.P.'s physician.

10. On March 6, 2024, patient D.P.'s physician issued her a new prescription for levothyroxine. The prescription directed Respondent PharMerica to dispense an initial 90-day supply of levothyroxine with two refills.

11. On its face, the above prescription sufficed to meet patient D.P.'s medical needs for 12 months.

12. Patient D.P.'s physician electronically transmitted the above prescription to Respondent PharMerica.

13. Respondent PharMerica assigned no. 343217 to the above prescription. Per standard operating procedure, PharMerica processed prescription no. 343217 at its facility in Kentucky.

14. At the facility in Kentucky, a pharmaceutical technician transferred the information from the electronic prescription to a computerized prescription management system.

15. When transferring the prescription information, the technician incorrectly entered code "X90D" related to the "duration" of medication treatment. This code suppressed the automatic refill

function on the system, thus instructing the system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

16. Since patient D.P.'s levothyroxine was considered a "maintenance" medication, there should not have been a duration code associated with prescription no 343217.

17. In March 2024, before dispensing any medication under prescription no. 343217, Respondent Kim verified the prescription at PharMerica's facility in Reno.

18. When verifying the above prescription, Respondent Kim failed to notice that the duration code X90D, as described above, was inconsistent with the number of refill authorizations on the prescription itself. As noted above, this code instructed the automated system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

19. In June of 2024, due to Respondent Kim's omission as described above, PharMerica failed to refill patient D.P.'s prescription for levothyroxine as directed by her physician.

20. Between June and September 2024, the nursing staff at MorningStar delivered no levothyroxine to patient D.P., and they made no inquiries of PharMerica concerning the abrupt cessation of patient D.P.'s medication treatment.

21. In August or September 2024, patient D.P.'s daughter observed that her mother's health had rapidly declined for no apparent reason. She alerted the nursing staff at MorningStar and/or patient D.P.'s physician.

22. In September 2024, Patient D.P. was admitted to the intensive care unit at Renown Hospital, where she was diagnosed with myxedema coma and cellulitis in her left leg. These medical conditions were caused by the cessation of medication treatment with levothyroxine.

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APPLICABLE LAW

23. The Board may discipline the holder of a license or registration issued by the Board if the holder engages in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Unprofessional conduct includes "failing strictly to follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling." NAC 639.945(1)(d).

25. Unprofessional conduct includes performing one's duties as the holder of a certificate of registration issued by the Board in an "incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

26. A pharmacist has a duty to supervise a pharmaceutical technician who performs one or more of the functions necessary to prepare a prescription. NAC 639.252. This includes the duty to verify the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2).

27. A pharmacist has a duty to maintain a record of each refill of a prescription. NAC 639.918.

28. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of its employees. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

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COUNT ONE
Unprofessional Conduct by a Pharmacist
(Respondent Kim)

29. As alleged above, Respondent Kim verified prescription no. 343217 for levothyroxine, including two refills. In verifying the prescription, Respondent Kim failed to notice that a pharmaceutical technician in Kentucky had incorrectly entered a duration code into PharMerica's prescription management system, thus causing the system to suppress the automatic refill function.

30. Respondent Kim had a duty to supervise the pharmaceutical technician in Kentucky who performed data entry tasks related to prescription no. 343217.

31. Respondent Kim had a duty to correct the data entry error described above.

32. Respondent Kim had a duty to strictly follow the instructions of patient D.P.'s physician as to the refilling of no. 343217.

33. Respondent Kim performed the above duties in an incompetent, unskillful or negligent manner.

34. Due to Respondent Kim's unprofessional conduct as described above, patient D.P. suffered harm.

35. For her unprofessional conduct as described above Respondent Kim is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

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COUNT TWO

Employer Liability for Unprofessional Conduct
(Respondent PharMerica)

36. Respondent Kim engaged in unprofessional conduct as described above.

37. As Respondent Kim's employer at the time, Respondent PharMerica is responsible for the unprofessional conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

38. For said unprofessional conduct, Respondent PharMerica is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Camilla Kim and the pharmacy license of Respondent PharMerica.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **Respondent.**	**Case No. 24-370-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **Respondent.**	**Case No. 24-370-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR PharMerica

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

PharMerica
4750 Longley Ln #204
Reno, NV 89502

Camilla Kim, RPh
[redacted]
Reno, NV [redacted]

PharMerica
c/o Camilla Kim, RPh
4750 Longley Ln #204
Reno, NV 89502

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondents.**	**Case Nos. 24-370-PH-N** **24-370-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (the "Board"), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has jurisdiction over Respondent PharMerica ("Respondent PharMerica"), the holder of Pharmacy License No. PH02018, because Respondent PharMerica is licensed by the Board to operate a pharmacy at 4750 Longley Lane in Reno, Nevada.

2. The Board has jurisdiction over Respondent Camilla Kim, RPh ("Respondent Kim"), the holder of Certificate of Registration No. 19388, because Respondent Kim is registered by the Board to engage in the practice of pharmacy in Nevada.

FACTUAL ALLEGATIONS

3. Respondent PharMerica operates a pharmacy in Reno, Nevada.

4. In March 2024, Respondent Kim was employed by Respondent PharMerica as a pharmacist.

5. In 2023 and 2024, Respondent PharMerica was under contract with MorningStar Senior Living of Sparks ("MorningStar"), an assisted living facility, to dispense prescription medication and provide medication management services to residents of the MorningStar facility.

6. Respondent PharMerica worked cooperatively with the nursing staff at MorningStar to store and deliver prescription medications for the residents of the MorningStar facility.

7. In 2023 and 2024, patient D.P., an 87-year-old female, resided at MorningStar, where she received medication and medication management services from Respondent PharMerica.

8. In 2023 and 2024, patient D.P. required levothyroxine for hypothyroidism.

9. Between March 2023 and March 2024, Respondent PharMerica dispensed levothyroxine to patient D.P. without interruption, according to the instructions of patient D.P.'s physician.

10. On March 6, 2024, patient D.P.'s physician issued her a new prescription for levothyroxine. The prescription directed Respondent PharMerica to dispense an initial 90-day supply of levothyroxine with two refills.

11. On its face, the above prescription sufficed to meet patient D.P.'s medical needs for 12 months.

12. Patient D.P.'s physician electronically transmitted the above prescription to Respondent PharMerica.

13. Respondent PharMerica assigned no. 343217 to the above prescription. Per standard operating procedure, PharMerica processed prescription no. 343217 at its facility in Kentucky.

14. At the facility in Kentucky, a pharmaceutical technician transferred the information from the electronic prescription to a computerized prescription management system.

15. When transferring the prescription information, the technician incorrectly entered code "X90D" related to the "duration" of medication treatment. This code suppressed the automatic refill

function on the system, thus instructing the system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

16. Since patient D.P.'s levothyroxine was considered a "maintenance" medication, there should not have been a duration code associated with prescription no 343217.

17. In March 2024, before dispensing any medication under prescription no. 343217, Respondent Kim verified the prescription at PharMerica's facility in Reno.

18. When verifying the above prescription, Respondent Kim failed to notice that the duration code X90D, as described above, was inconsistent with the number of refill authorizations on the prescription itself. As noted above, this code instructed the automated system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

19. In June of 2024, due to Respondent Kim's omission as described above, PharMerica failed to refill patient D.P.'s prescription for levothyroxine as directed by her physician.

20. Between June and September 2024, the nursing staff at MorningStar delivered no levothyroxine to patient D.P., and they made no inquiries of PharMerica concerning the abrupt cessation of patient D.P.'s medication treatment.

21. In August or September 2024, patient D.P.'s daughter observed that her mother's health had rapidly declined for no apparent reason. She alerted the nursing staff at MorningStar and/or patient D.P.'s physician.

22. In September 2024, Patient D.P. was admitted to the intensive care unit at Renown Hospital, where she was diagnosed with myxedema coma and cellulitis in her left leg. These medical conditions were caused by the cessation of medication treatment with levothyroxine.

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APPLICABLE LAW

23. The Board may discipline the holder of a license or registration issued by the Board if the holder engages in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Unprofessional conduct includes "failing strictly to follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling." NAC 639.945(1)(d).

25. Unprofessional conduct includes performing one's duties as the holder of a certificate of registration issued by the Board in an "incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

26. A pharmacist has a duty to supervise a pharmaceutical technician who performs one or more of the functions necessary to prepare a prescription. NAC 639.252. This includes the duty to verify the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2).

27. A pharmacist has a duty to maintain a record of each refill of a prescription. NAC 639.918.

28. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of its employees. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

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COUNT ONE
Unprofessional Conduct by a Pharmacist
(Respondent Kim)

29. As alleged above, Respondent Kim verified prescription no. 343217 for levothyroxine, including two refills. In verifying the prescription, Respondent Kim failed to notice that a pharmaceutical technician in Kentucky had incorrectly entered a duration code into PharMerica's prescription management system, thus causing the system to suppress the automatic refill function.

30. Respondent Kim had a duty to supervise the pharmaceutical technician in Kentucky who performed data entry tasks related to prescription no. 343217.

31. Respondent Kim had a duty to correct the data entry error described above.

32. Respondent Kim had a duty to strictly follow the instructions of patient D.P.'s physician as to the refilling of no. 343217.

33. Respondent Kim performed the above duties in an incompetent, unskillful or negligent manner.

34. Due to Respondent Kim's unprofessional conduct as described above, patient D.P. suffered harm.

35. For her unprofessional conduct as described above Respondent Kim is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

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COUNT TWO
Employer Liability for Unprofessional Conduct
(Respondent PharMerica)

36. Respondent Kim engaged in unprofessional conduct as described above.

37. As Respondent Kim's employer at the time, Respondent PharMerica is responsible for the unprofessional conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

38. For said unprofessional conduct, Respondent PharMerica is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Camilla Kim and the pharmacy license of Respondent PharMerica.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondent.**	**Case No. 24-370-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondent.**	**Case No. 24-370-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Camilla Kim, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

PharMerica
4750 Longley Ln #204
Reno, NV 89502

Camilla Kim, RPh
[redacted]
Reno, NV [redacted]

PharMerica
c/o Camilla Kim, RPh
4750 Longley Ln #204
Reno, NV 89502

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484, and** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos. 24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Sean Arora, M.D., ("Respondent Arora"), because Respondent Arora holds a certificate of registration issued by the Board authorizing him to prescribe controlled substances in Nevada. Respondent Arora holds certificate of registration no. CS31476, which was issued by the Board pursuant to NRS 453.226 and 453.231.

2. The Board has personal jurisdiction over Respondent Cassie Gifford, APRN, ("Respondent Gifford"), because Respondent Gifford holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent Gifford holds certificate of

registration no. PR18034, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.[1]

3. The Board has personal jurisdiction over Respondent Gabrielle McIntyre, APRN, ("Respondent McIntyre"), because Respondent McIntyre holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR17484, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.

4. The Board has personal jurisdiction over Respondent Allison Jaggard, APRN, ("Respondent Jaggard"), because Respondent Jaggard holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR171499, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations involving the purchase, receipt, storage, possession, prescribing and/or dispensing of dangerous drugs and controlled substances. As used herein, "dangerous drug" has the meaning ascribed to it in NRS 454.201, and "controlled substance" means a substance listed in NAC 453.510 to NAC 453.550, inclusive, or in 21 CFR Part 1308.

FACTUAL ALLEGATIONS

6. Respondent Arora is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. At all times alleged herein, Respondent Arora was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

7. Respondent Gifford is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent

1. Respondent Gifford formerly held certificate of registration no. CS34942, authorizing her to prescribe controlled substances. Certificate of registration no. CS34942 was not renewed when it came due for renewal on November 1, 2024.

Gifford was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

8. Respondent McIntyre is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

9. Respondent Jaggard is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

10. In 2024, Respondent Arora formed a partnership or other business relationship with We Treat, a medical consulting firm based in San Diego, California. We Treat provides consulting services and regulatory compliance advice to medical spas and wellness clinics.

11. We Treat provided consulting services and compliance advice to Youth, Inc. (Youth Inc.), the owner of a medical spa and wellness clinic located at 695 Sierra Rose Drive in Reno, Nevada.

12. We Treat developed a manual of policies, procedures and protocols for use by Youth Inc. Respondent Arora approved these policies, procedures and protocols for use by Youth Inc.

13. Between April 2024 and March 2025, Youth Inc. provided various anti-aging and wellness treatments for its patients. These included cosmetic treatments using botulinum toxin type A and dermal fillers, treatments for weight loss using compounded tirzepatide and semaglutide products, hormone replacement using injectable hormones, and treatment for erectile dysfunction using sildenafil and tadalafil.

14. Between April 2024 and March 2025, Youth Inc. did not lock or otherwise secure the dangerous drugs and/or controlled substances in its possession.

15. In early 2025, Youth Inc. was in possession of stock bottles containing sildenafil, tadalafil, and metformin hydrochloride, all dangerous drugs. Youth Inc.'s representatives claimed that

they were not planning to dispense these drugs until after they had secured a dispensing license issued by the Board.

16. We Treat arranged for Respondent Arora to serve as the "medical director" for Youth Inc., a role that Respondent Arora assumed sometime between April and August 2024.

17. Respondent Arora served as Youth Inc.'s medical director until early 2025.

18. During Respondent Arora's tenure as Youth Inc.'s medical director, Respondent Arora worked and resided in Seattle, Washington. Respondent Arora never visited Youth Inc.'s facility in Reno, Nevada.

19. Sometime between April 2024 and March 2025, Youth Inc. engaged the services of Respondent Gifford, Respondent McIntyre and Respondent Jaggard. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard rarely, if ever, visited Youth Inc.'s facility in Reno, Nevada.

20. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed a prospective patient's medical questionnaire prior to the prospective patient's initial treatment at Youth Inc. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed these medical questionnaires from a remote location and never saw or spoke to patients prior to their initial treatments at Youth Inc.

21. After reviewing medical questionnaires, and despite not ever seeing the patients in question, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the use or administration of dangerous drugs and/or controlled substances.

22. Sometime between April 2024 and March 2025, Youth Inc. employed Maddison Weiss-Frank, a registered nurse. Ms. Weiss-Frank was not an advanced practice registered nurse and was not a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

23. Ms. Weiss-Frank worked under the direction and supervision of Rachel Gonzalez, the co-owner and chief executive officer of Youth Inc. Ms. Gonzalez was not a "practitioner" as that term

is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125. On information and belief, Ms. Gonzalez has no formal medical training.

24. Because there was never a practitioner present at the location, Youth Inc.'s facility at 695 Sierra Rose Drive in Reno, Nevada, was not a location where a registered nurse could lawfully inject a neuromodulator pursuant to NRS 454.217.

25. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank treated patients using prescription drugs and/or controlled substances. Ms. Weiss-Frank did not act under the direction or supervision of a practitioner.

26. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances. Ms. Weiss-Frank did not work under the direction or supervision of a practitioner.

27. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

28. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

29. Consistent with the practice described above, Youth Inc. returned single-use vials to stock even after the vials were punctured and therefore rendered unusable for subsequent treatments.

30. As the medical director for Youth Inc., Respondent Arora periodically reviewed purchase invoices and signed for shipments of dangerous drugs and/or controlled substances.

31. As the medical director for Youth Inc., Respondent Arora periodically reviewed patient medical questionnaires and treatment records.

32. As the medical director for Youth Inc., Respondent Arora periodically reviewed Youth Inc.'s policies, procedures and protocols related to the procurement, storage, possession and administration of dangerous drugs and controlled substances.

33. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances without direction or supervision by a practitioner.

34. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank treated patients with prescription drugs and/or controlled substances despite not working under the supervision or direction of a practitioner.

35. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide .and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

36. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

37. As Youth Inc.'s medical director, Respondent Arora had a duty to understand Nevada law as it governs the receipt, possession, storage, and distribution of dangerous drugs and controlled substances.

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APPLICABLE LAW

38. It is unlawful for any person to engage in wholesale distribution, or permit to be distributed at wholesale, any drug or compound unless the person holds the appropriate certificate, license or permit issued by the Board. NRS 639.100(1).

39. To engage in wholesale distribution of any drug or compound in Nevada, a person must be licensed as a wholesaler or manufacturer, as applicable. NRS 639.100; NRS 639.233; NAC 639.593; NAC 639.6915.

40. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapters 453, 454, 639, or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12); NRS 453.236.

41. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 453.236.

42. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner, or if the practitioner assists or abets a person not licensed to practice pharmacy in Nevada. NAC 639.945(1)(i) and (j).

43. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner prescribes or orders a dangerous drug or controlled substance for a person with whom the practitioner does not have a bona fide therapeutic relationship. NAC 639.945(1)(n).

44. "'Practice of pharmacy' includes, but is not limited to, the . . . [p]erformance or supervision of activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug, including the receipt, handling and storage of prescriptions and other confidential information relating to patients." NRS 639.0124(1)(a).

45. It is unlawful to possess, store, or administer dangerous drugs, including botulinum toxin type A and injectable dermal fillers, except as authorized by NRS 454.213.

46. It is unlawful to possess, store, or administer controlled substances, including testosterone, except as provided by NRS 453.375.

47. "Administer" means the direct application of a [dangerous drug or controlled substance] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 453.021; NRS 454.191.

48. Pursuant to NRS 453.375, a registered nurse may not possess, store, or administer controlled substances except when working under the direction of a supervising practitioner.

49. Pursuant to NRS 454.213, a registered nurse may not possess, store, or administer dangerous drugs except at the direction of a supervising practitioner.

50. It is unlawful for a registered nurse to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

51. A person who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from stock for administering or dispensing to patients. NAC 639.050(2).

52. A practitioner is subject to discipline if the practitioner causes or allows a dangerous drug to be dispensed in a manner not authorized by NRS 454.215 and NRS 454.301. *See* NRS 639.100; NRS 639.210(12).

53. The term "dispense" includes the prescribing by a practitioner, administering, packaging, labeling, or compounding necessary to prepare a substance for delivery to a patient. NRS 639.0065; NRS 453.056.

54. It is unlawful to furnish drugs without a prescription. NRS 454.221.

55. "Furnish" means to supply by any means, by sale or otherwise. NRS 454.006.

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COUNT ONE
Permitting Unlicensed Wholesale Distribution
(Respondent Arora)

56. As alleged above, Respondent Arora served as the medical director for Youth Inc.

57. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

58. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage purchases from unlicensed distributors such as GLP-1 Sciences, LLC. Respondent failed to implement such policies, procedures and protocols.

59. Given the facts and circumstances alleged above, Respondent Arora permitted the unlicensed wholesale distribution of compounded drug products in violation of NRS 639.100(1).

60. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

61. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT TWO
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondent Arora)

62. As alleged above, Respondent Arora served as the medical director for Youth Inc.

63. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered, received, possessed, and/or stored dangerous drugs and/or controlled substances. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

64. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of

Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

65. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the above persons from ordering, receiving, possessing, storing and/or furnishing dangerous drugs and/or controlled substances. Respondent Arora failed to implement such policies, procedures and protocols.

66. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the unlicensed practice of pharmacy.

67. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

68. Respondent Arora's acts and/or omissions as alleged above amount to conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(i) and (j).

COUNT THREE
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondent Arora)

69. As alleged above, Respondent Arora served as the medical director for Youth Inc.

70. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

71. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the repeated or recurring use of punctured single-use vials. Respondent failed to implement such policies, procedures and protocols.

72. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the above violations of NAC 639.050(2).

73. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

74. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FOUR
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondents Gifford, McIntyre and Jaggard)

75. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

76. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of injectable drugs contained within single-use vials.

77. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard had a duty to ensure that Youth Inc. did not make repeated or recurring uses of punctured single-use vials.

78. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that Youth Inc. did not return single-use vials to stock after the vials were punctured.

79. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard assisted or abetted in the above violations of NAC 639.050(2).

80. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

81. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FIVE
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondents Gifford, McIntyre and Jaggard)

82. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

83. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

84. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that dangerous drugs and/or controlled substances were administered under the direction or supervision of a practitioner. Dangerous drugs and/or controlled substances were not administered under the direction or supervision of a practitioner.

85. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard assisted or abetted the unlicensed practice of pharmacy by Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank.

86. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

87. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT SIX
Failure to Establish a Bona Fide Therapeutic Relationship with Patients
(Respondents Gifford, McIntyre and Jaggard)

88. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

89. Respondent Gifford, Respondent McIntyre and Respondent Jaggard never saw or spoke with the above patients for whom they authorized treatments with dangerous drugs and/or controlled substances.

90. Having failed to see or speak with the above patients, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard failed to establish a bona fide therapeutic relationship with the above patients prior to authorizing their initial treatments with dangerous drugs and/or controlled substances.

91. Respondents' conduct as alleged above amounts to unprofessional conduct and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(n).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondent Sean Arora, Respondent Cassie Gifford, Respondent Gabrielle McIntyre, and Respondent Allison Jaggard.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **Respondent.**	**Case No. 24-509-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **Respondent.**	**Case No. 24-509-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Sean Arora, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sean Arora, MD
c/o Youth Inc
691 Sierra Rose Dr
Reno, NV 89511

Cassie Gifford, APRN
c/o Bionetics Health
5540 S Fort Apache Rd #120
Las Vegas, NV 89148

Gabrielle McIntyre, APRN
c/o Restore Hyper Wellness
1550 N Green Valley Pkwy., Ste 300
Henderson, NV 89074

Allison Jaggard, APRN
1708 Spring Green Blvd Ste 120-109
Katy, TX 77494

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
AUG 15 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos.** **24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENTS**

Respondents Sean Arora, M.D., Cassie Gifford, APRN, Gabrielle McIntyre, APRN, and Allison Jaggard, APRN, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-5

Paragraph 1: Dr. Arora acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation to the extent that the matter pertains to controlled substances as he holds a controlled substance registration issued by the Board.

Paragraph 2: Ms. Gifford acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 3: Ms. McIntyre acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 3 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 4: Ms. Jaggard acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 4 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 5: Respondents acknowledge that the Board has jurisdiction in the matter to the extent that the matter involves dangerous drugs and controlled substances. Dr. Arora acknowledges that the Board has jurisdiction over the allegations pertaining to his acts or omissions to the extent they concern controlled substances.

Factual Allegations: Paragraphs 6-37

Paragraph 6: Dr. Arora agrees with the factual allegations as set forth in Paragraph 6.

Paragraph 7: Ms. Gifford agrees with the factual allegations as set forth in Paragraph 7.

Paragraph 8: Ms. McIntyre agrees with the factual allegations as set forth in Paragraph 8.

Paragraph 9: Ms. Jaggard agrees with the factual allegations as set forth in Paragraph 9.

Paragraph 10: Dr. Arora agrees with the factual allegations set forth in Paragraph 10 only to the extent that he entered into an independent contractor agreement with We Treat, LLC in 2024.

Paragraph 11: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 11 as to the types of services which were provided to Youth Inc. However, to the best of Respondents' knowledge, Youth Inc. did receive services from

We Treat related to medical clearances for patients, policies and protocols and compliance information.

Paragraph 12: Dr. Arora agrees with the factual allegations set forth in Paragraph 12 only to the extent that he reviewed and approved policies and protocols directly related to the provision of certain medical services. Dr. Arora was not involved, nor did he review or approve, policies and procedures related to any other matters involving Youth, Inc.

Paragraph 13: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 13.

Paragraph 14: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 14.

Paragraph 15: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 15.

Paragraph 16: Dr. Arora acknowledges that as part of his duties for We Treat, he was assigned as medical director for Youth, Inc. in approximately April 2024. Dr. Arora's duties as medical director included the review and approval of protocols for certain medical treatments performed at Youth, Inc., responding to patient specific questions from the clinic, and authorization of the ordering of certain dangerous drugs, to be done in accordance with compliance policies prepared by We Treat.

Paragraph 17: Dr. Arora agrees with the factual allegations contained in Paragraph 17 to the extent that he provided services to We Treat until January 2025, services which included acting as medical director for Youth,. Inc., which were limited to the duties set forth in the response to Paragraph 16.

Paragraph 18: Dr. Arora acknowledges that he was based in Seattle, Washington and that his duties for Youth, Inc. did not require him to be physically at Youth, Inc.'s location.

Paragraph 19: Respondent's Gifford, McIntyre, and Jaggard deny the factual allegations set forth in Paragraph 19. None of the named Respondents were engaged by Youth, Inc. to provide any services. All three Respondents were employees/independent contractors of We Treat which provided medical clearance screening of patients for Youth, Inc. through Nevada licensed practitioners.

Paragraph 20: Respondents Gifford, McIntyre, and Jaggard acknowledge that they reviewed and medically cleared patients for treatments performed at Youth, Inc. pursuant to medical protocols reviewed and approved by Dr. Arora and performed these reviews in accordance with policies and protocols developed and approved by We Treat, not Dr. Arora.

Paragraph 21: Respondents Gifford, McIntyre and Jaggard acknowledge that they medically cleared patients, if appropriate, after the review of medical information and authorized treatments to be performed pursuant to protocols approved by Dr. Arora which included standing orders for administration of certain drugs or the issuance of prescriptions pursuant to those protocols. No approved protocols for treatments authorized the administration of controlled substances at Youth, Inc.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 22.

Paragraph 23: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 23.

Paragraph 24: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 24.

Paragraph 25: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 25.

Paragraph 26: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 26.

Paragraph 27: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 27.

Paragraph 28: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 28.

Paragraph 29: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 29.

Paragraph 30: Dr. Arora acknowledges that he would periodically review orders received for dangerous drugs and would sign, remotely for the same. Drugs were to be stored and accessed in accordance with policies and protocols developed by We Treat; Dr. Arora was not part of the development of those policies and procedures, nor was he asked to review them by We Treat. Dr. Arora denies that he ever signed off or approved of any shipments of controlled substances to Youth, Inc. and to his knowledge, no controlled substances were to be received or stored on-site at We Treat.

Paragraph 31: Dr. Arora denies the factual allegations contained in Paragraph 31, however he acknowledges that he would respond to patient specific questions posed to him and would review patient records at that time; however this occurred very rarely.

Paragraph 32: Dr. Arora denies the factual allegations contained in Paragraph 32. Dr. Arora was not responsible for the policies and procedures related to the procurement, storage, possession and/or administration of dangerous drugs or controlled substances other than approving

protocols directly related to the provision of medical services. We Treat's compliance department was solely responsible for the policies and protocols otherwise related to dangerous drugs and controlled substances.

Paragraph 33: Dr. Arora denies the allegations set forth in Paragraph 33.

Paragraph 34: Dr. Arora denies the allegations set forth in Paragraph 34.

Paragraph 35: Dr. Arora denies the allegations set forth in Paragraph 35.

Paragraph 36: Dr. Arora denies the allegations set forth in Paragraph 36.

Paragraph 37: Dr. Arora denies the allegations set forth in Paragraph 37 as he was not involved in, nor responsible for the receipt, possession storage, and distribution of dangerous drugs or controlled substances at Youth, Inc.

Applicable Law: Paragraphs 38-55

Paragraph 38-55: Respondents acknowledge that Paragraphs 38-55 accurately reflect the basic substance of the statutes and regulations cited therein.

Counts: Paragraphs 56-91

Count One (Paragraphs 56-61): Dr. Arora generally denies the allegations set forth in Count One in Paragraphs 56-61. Dr. Arora did not permit Youth, Inc. or any of its personnel to order any dangerous drugs from any manufacturer or supplier not licensed in Nevada. As discussed herein, Dr. Arora's duties for Youth, Inc. were limited to the review and authorization of protocols related to medical procedures. While Youth, Inc. was authorized to order supplies and dangerous drugs under Dr. Arora's credentials, this was to be done in accordance with policies and protocols developed and approved by We Treat's compliance department. To the best of Dr. Arora's knowledge, no client of We Treat was authorized to order or received dangerous drugs or other supplies from unlicensed suppliers/manufacturers.

Count Two (Paragraphs 62-68): Dr. Arora generally denies all allegations set forth in Count Two in Paragraphs 62-68. Further Dr. Arora asserts that a practice which orders, receives, and stores dangerous drugs is not engaging in the practice of pharmacy as alleged. If indeed this was accurate, every medical practice or facility that orders, receives and stores drugs for administration and/or dispensing, would be required to hold a pharmacy license with the Board; that is not currently a requirement and NRS 639.0124(1)(a) is inappropriately applied here.

Count Three (Paragraphs 69-74): Dr. Arora generally denies the allegations set forth in Count Three in Paragraphs 69-74. Again, as discussed herein, Dr. Arora's duties for Youth, Inc. were limited and did not include the development or approval of any protocols or procedures related to the procurement or storage of dangerous drugs. Dr. Arora's medical service protocols did not allow for the reuse of single use vials and any reuse of single use vials on the part of Youth, Inc. personnel would have been done without the knowledge of Dr. Arora and he did not aid or abet any violation of NAC 639.050(2).

Count Four (Paragraphs 75-81): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Four in Paragraphs 75-81. Respondents Gifford, McIntyre, and Jaggard, worked for We Treat, not Youth, Inc. Respondents' duties for Youth, Inc. were limited to conducting medical clearance reviews for patients and if cleared, the patient was authorized for treatment pursuant to approved medical protocols. None of the named respondents were responsible for supervising the staff of Youth, Inc. and would have had no knowledge of unauthorized reuse of single use vials by any personnel associated with Youth, Inc.

Count Five (Paragraphs 82-87): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Five in Paragraphs 75-81. The administration of dangerous drugs to patients is not the practice of pharmacy as defined by NRS 639.0124(1)(a) and

accordingly Respondents could not have aided or abetted in the violation of said statute. Again, as discussed above, should the Board take the position that the administration of a dangerous drug constitutes the practice of pharmacy, all practices and facilities at which any drug is administered would be required to hold a registration as a pharmacy with the Board which is not currently required.

Count Six (Paragraphs 88-91): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Six in Paragraphs 88-91.

NOTICE OF DEFENSE/MITIGATING INFORMATION

In regard to Respondent Arora, Dr. Arora stresses that his involvement with We Treat was limited as medical director. The term "medical director" is not defined under Nevada law and there is no legal precedent for what the duties of a medical director must consist of. Dr. Arora functioned as a medical director per the duties he had as a contractor for We Treat, LLC, which consisted solely of the review and authorization of protocols for medical services offered at practices contracted with We Treat and he was required to be available for consultations regarding specific patient questions as needed. The medical protocols authorized by Dr. Arora included standing orders for the administration of certain dangerous drugs and for the prescription of certain controlled substances. It should be noted that Dr. Arora never authorized the administration of controlled substances at Youth, Inc., or any other practice for which he provided services under We Treat and to his knowledge, no controlled substances were stored on-site at Youth, Inc.

We Treat's compliance department was responsible for the development and authorization of all other policies and protocols, including those related to the procurement, receipt, and storage of dangerous drugs. Dr. Arora was advised by We Treat that all policies and protocols were reviewed and vetted for compliance with the laws in each individual state in which We Treat had

clients. Dr. Arora had no reason to doubt the assurances made by We Treat that the policies and protocols for Youth, Inc. were in compliance with Nevada law.

In regard to Respondents Gifford, McIntyre, and Jaggard, all three were employees/contractors with We Treat during the times in question. Their duties were to provide medical clearance reviews for patients wishing to receive services at practices which were contracted with We Treat and if cleared, authorize treatment to be provide pursuant to previously approved medical protocols. Respondents had no duties related to the oversight or supervision of any practice served by We Treat. Respondents would be notified through a proprietary platform that a patient required a medical clearance evaluation at practices which received services from We Treat and would be given access to the patient records through the We Treat platform and would either clear the patient for treatment or deny treatment[1]. Each clinic had individual protocols which would be followed by Respondents. Respondents were informed by We Treat that policies related to requirements for providing medical clearance for patients was vetted by its compliance department and all protocols were in compliance with state laws; Respondents had no reason to question the representations of We Treat.

Respondent Gifford estimates that she performed very few medical clearance evaluations for Youth, Inc. through the We Treat platform. Respondent McIntyre estimates that she did approximately two medical clearance evaluations for Youth, Inc. Respondent Jaggard estimates that she did a maximum of ten to fifteen medical clearance evaluations for Youth, Inc.

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[1] We Treat practitioners only performed medical clearance evaluations for patients in states in which they were licensed.

All Respondents deny having violated NRS and/or NAC Chapters 453, 454, or 639. Further Respondents reserve all legal defenses available to them should this matter proceed to a hearing.

Respectfully submitted this 15th day of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484, and** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos. 24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Sean Arora, M.D., ("Respondent Arora"), because Respondent Arora holds a certificate of registration issued by the Board authorizing him to prescribe controlled substances in Nevada. Respondent Arora holds certificate of registration no. CS31476, which was issued by the Board pursuant to NRS 453.226 and 453.231.

2. The Board has personal jurisdiction over Respondent Cassie Gifford, APRN, ("Respondent Gifford"), because Respondent Gifford holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent Gifford holds certificate of

registration no. PR18034, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.[1]

3. The Board has personal jurisdiction over Respondent Gabrielle McIntyre, APRN, ("Respondent McIntyre"), because Respondent McIntyre holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR17484, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.

4. The Board has personal jurisdiction over Respondent Allison Jaggard, APRN, ("Respondent Jaggard"), because Respondent Jaggard holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR171499, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations involving the purchase, receipt, storage, possession, prescribing and/or dispensing of dangerous drugs and controlled substances. As used herein, "dangerous drug" has the meaning ascribed to it in NRS 454.201, and "controlled substance" means a substance listed in NAC 453.510 to NAC 453.550, inclusive, or in 21 CFR Part 1308.

FACTUAL ALLEGATIONS

6. Respondent Arora is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. At all times alleged herein, Respondent Arora was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

7. Respondent Gifford is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent

1. Respondent Gifford formerly held certificate of registration no. CS34942, authorizing her to prescribe controlled substances. Certificate of registration no. CS34942 was not renewed when it came due for renewal on November 1, 2024.

Gifford was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

8. Respondent McIntyre is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

9. Respondent Jaggard is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

10. In 2024, Respondent Arora formed a partnership or other business relationship with We Treat, a medical consulting firm based in San Diego, California. We Treat provides consulting services and regulatory compliance advice to medical spas and wellness clinics.

11. We Treat provided consulting services and compliance advice to Youth, Inc. (Youth Inc.), the owner of a medical spa and wellness clinic located at 695 Sierra Rose Drive in Reno, Nevada.

12. We Treat developed a manual of policies, procedures and protocols for use by Youth Inc. Respondent Arora approved these policies, procedures and protocols for use by Youth Inc.

13. Between April 2024 and March 2025, Youth Inc. provided various anti-aging and wellness treatments for its patients. These included cosmetic treatments using botulinum toxin type A and dermal fillers, treatments for weight loss using compounded tirzepatide and semaglutide products, hormone replacement using injectable hormones, and treatment for erectile dysfunction using sildenafil and tadalafil.

14. Between April 2024 and March 2025, Youth Inc. did not lock or otherwise secure the dangerous drugs and/or controlled substances in its possession.

15. In early 2025, Youth Inc. was in possession of stock bottles containing sildenafil, tadalafil, and metformin hydrochloride, all dangerous drugs. Youth Inc.'s representatives claimed that

they were not planning to dispense these drugs until after they had secured a dispensing license issued by the Board.

16. We Treat arranged for Respondent Arora to serve as the "medical director" for Youth Inc., a role that Respondent Arora assumed sometime between April and August 2024.

17. Respondent Arora served as Youth Inc.'s medical director until early 2025.

18. During Respondent Arora's tenure as Youth Inc.'s medical director, Respondent Arora worked and resided in Seattle, Washington. Respondent Arora never visited Youth Inc.'s facility in Reno, Nevada.

19. Sometime between April 2024 and March 2025, Youth Inc. engaged the services of Respondent Gifford, Respondent McIntyre and Respondent Jaggard. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard rarely, if ever, visited Youth Inc.'s facility in Reno, Nevada.

20. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed a prospective patient's medical questionnaire prior to the prospective patient's initial treatment at Youth Inc. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed these medical questionnaires from a remote location and never saw or spoke to patients prior to their initial treatments at Youth Inc.

21. After reviewing medical questionnaires, and despite not ever seeing the patients in question, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the use or administration of dangerous drugs and/or controlled substances.

22. Sometime between April 2024 and March 2025, Youth Inc. employed Maddison Weiss-Frank, a registered nurse. Ms. Weiss-Frank was not an advanced practice registered nurse and was not a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

23. Ms. Weiss-Frank worked under the direction and supervision of Rachel Gonzalez, the co-owner and chief executive officer of Youth Inc. Ms. Gonzalez was not a "practitioner" as that term

is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125. On information and belief, Ms. Gonzalez has no formal medical training.

24. Because there was never a practitioner present at the location, Youth Inc.'s facility at 695 Sierra Rose Drive in Reno, Nevada, was not a location where a registered nurse could lawfully inject a neuromodulator pursuant to NRS 454.217.

25. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank treated patients using prescription drugs and/or controlled substances. Ms. Weiss-Frank did not act under the direction or supervision of a practitioner.

26. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances. Ms. Weiss-Frank did not work under the direction or supervision of a practitioner.

27. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

28. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

29. Consistent with the practice described above, Youth Inc. returned single-use vials to stock even after the vials were punctured and therefore rendered unusable for subsequent treatments.

30. As the medical director for Youth Inc., Respondent Arora periodically reviewed purchase invoices and signed for shipments of dangerous drugs and/or controlled substances.

31. As the medical director for Youth Inc., Respondent Arora periodically reviewed patient medical questionnaires and treatment records.

32. As the medical director for Youth Inc., Respondent Arora periodically reviewed Youth Inc.'s policies, procedures and protocols related to the procurement, storage, possession and administration of dangerous drugs and controlled substances.

33. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances without direction or supervision by a practitioner.

34. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank treated patients with prescription drugs and/or controlled substances despite not working under the supervision or direction of a practitioner.

35. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

36. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

37. As Youth Inc.'s medical director, Respondent Arora had a duty to understand Nevada law as it governs the receipt, possession, storage, and distribution of dangerous drugs and controlled substances.

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APPLICABLE LAW

38. It is unlawful for any person to engage in wholesale distribution, or permit to be distributed at wholesale, any drug or compound unless the person holds the appropriate certificate, license or permit issued by the Board. NRS 639.100(1).

39. To engage in wholesale distribution of any drug or compound in Nevada, a person must be licensed as a wholesaler or manufacturer, as applicable. NRS 639.100; NRS 639.233; NAC 639.593; NAC 639.6915.

40. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapters 453, 454, 639, or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12); NRS 453.236.

41. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 453.236.

42. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner, or if the practitioner assists or abets a person not licensed to practice pharmacy in Nevada. NAC 639.945(1)(i) and (j).

43. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner prescribes or orders a dangerous drug or controlled substance for a person with whom the practitioner does not have a bona fide therapeutic relationship. NAC 639.945(1)(n).

44. "'Practice of pharmacy' includes, but is not limited to, the . . . [p]erformance or supervision of activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug, including the receipt, handling and storage of prescriptions and other confidential information relating to patients." NRS 639.0124(1)(a).

45. It is unlawful to possess, store, or administer dangerous drugs, including botulinum toxin type A and injectable dermal fillers, except as authorized by NRS 454.213.

46. It is unlawful to possess, store, or administer controlled substances, including testosterone, except as provided by NRS 453.375.

47. "Administer" means the direct application of a [dangerous drug or controlled substance] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 453.021; NRS 454.191.

48. Pursuant to NRS 453.375, a registered nurse may not possess, store, or administer controlled substances except when working under the direction of a supervising practitioner.

49. Pursuant to NRS 454.213, a registered nurse may not possess, store, or administer dangerous drugs except at the direction of a supervising practitioner.

50. It is unlawful for a registered nurse to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

51. A person who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from stock for administering or dispensing to patients. NAC 639.050(2).

52. A practitioner is subject to discipline if the practitioner causes or allows a dangerous drug to be dispensed in a manner not authorized by NRS 454.215 and NRS 454.301. *See* NRS 639.100; NRS 639.210(12).

53. The term "dispense" includes the prescribing by a practitioner, administering, packaging, labeling, or compounding necessary to prepare a substance for delivery to a patient. NRS 639.0065; NRS 453.056.

54. It is unlawful to furnish drugs without a prescription. NRS 454.221.

55. "Furnish" means to supply by any means, by sale or otherwise. NRS 454.006.

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COUNT ONE
Permitting Unlicensed Wholesale Distribution
(Respondent Arora)

56. As alleged above, Respondent Arora served as the medical director for Youth Inc.

57. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

58. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage purchases from unlicensed distributors such as GLP-1 Sciences, LLC. Respondent failed to implement such policies, procedures and protocols.

59. Given the facts and circumstances alleged above, Respondent Arora permitted the unlicensed wholesale distribution of compounded drug products in violation of NRS 639.100(1).

60. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

61. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT TWO
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondent Arora)

62. As alleged above, Respondent Arora served as the medical director for Youth Inc.

63. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered, received, possessed, and/or stored dangerous drugs and/or controlled substances. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

64. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of

Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

65. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the above persons from ordering, receiving, possessing, storing and/or furnishing dangerous drugs and/or controlled substances. Respondent Arora failed to implement such policies, procedures and protocols.

66. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the unlicensed practice of pharmacy.

67. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

68. Respondent Arora's acts and/or omissions as alleged above amount to conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(i) and (j).

COUNT THREE

Assisting or Abetting in Violations of NAC 639.050(2)
(Respondent Arora)

69. As alleged above, Respondent Arora served as the medical director for Youth Inc.

70. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

71. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the repeated or recurring use of punctured single-use vials. Respondent failed to implement such policies, procedures and protocols.

72. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the above violations of NAC 639.050(2).

73. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

74. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FOUR
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondents Gifford, McIntyre and Jaggard)

75. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

76. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of injectable drugs contained within single-use vials.

77. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard had a duty to ensure that Youth Inc. did not make repeated or recurring uses of punctured single-use vials.

78. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that Youth Inc. did not return single-use vials to stock after the vials were punctured.

79. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard assisted or abetted in the above violations of NAC 639.050(2).

80. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

81. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FIVE
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondents Gifford, McIntyre and Jaggard)

82. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

83. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

84. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that dangerous drugs and/or controlled substances were administered under the direction or supervision of a practitioner. Dangerous drugs and/or controlled substances were not administered under the direction or supervision of a practitioner.

85. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard assisted or abetted the unlicensed practice of pharmacy by Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank.

86. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

87. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT SIX
Failure to Establish a Bona Fide Therapeutic Relationship with Patients
(Respondents Gifford, McIntyre and Jaggard)

88. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

89. Respondent Gifford, Respondent McIntyre and Respondent Jaggard never saw or spoke with the above patients for whom they authorized treatments with dangerous drugs and/or controlled substances.

90. Having failed to see or speak with the above patients, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard failed to establish a bona fide therapeutic relationship with the above patients prior to authorizing their initial treatments with dangerous drugs and/or controlled substances.

91. Respondents' conduct as alleged above amounts to unprofessional conduct and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(n).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondent Sean Arora, Respondent Cassie Gifford, Respondent Gabrielle McIntyre, and Respondent Allison Jaggard.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **Respondent.**	**Case No. 24-509-PR-A-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **Respondent.**	**Case No. 24-509-PR-A-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Cassie Gifford, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sean Arora, MD
c/o Youth Inc
691 Sierra Rose Dr
Reno, NV 89511

Cassie Gifford, APRN
c/o Bionetics Health
5540 S Fort Apache Rd #120
Las Vegas, NV 89148

Gabrielle McIntyre, APRN
c/o Restore Hyper Wellness
1550 N Green Valley Pkwy., Ste 300
Henderson, NV 89074

Allison Jaggard, APRN
1708 Spring Green Blvd Ste 120-109
Katy, TX 77494

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
AUG 15 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos.** **24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENTS**

Respondents Sean Arora, M.D., Cassie Gifford, APRN, Gabrielle McIntyre, APRN, and Allison Jaggard, APRN, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-5

Paragraph 1: Dr. Arora acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation to the extent that the matter pertains to controlled substances as he holds a controlled substance registration issued by the Board.

Paragraph 2: Ms. Gifford acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 3: Ms. McIntyre acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 3 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 4: Ms. Jaggard acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 4 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 5: Respondents acknowledge that the Board has jurisdiction in the matter to the extent that the matter involves dangerous drugs and controlled substances. Dr. Arora acknowledges that the Board has jurisdiction over the allegations pertaining to his acts or omissions to the extent they concern controlled substances.

Factual Allegations: Paragraphs 6-37

Paragraph 6: Dr. Arora agrees with the factual allegations as set forth in Paragraph 6.

Paragraph 7: Ms. Gifford agrees with the factual allegations as set forth in Paragraph 7.

Paragraph 8: Ms. McIntyre agrees with the factual allegations as set forth in Paragraph 8.

Paragraph 9: Ms. Jaggard agrees with the factual allegations as set forth in Paragraph 9.

Paragraph 10: Dr. Arora agrees with the factual allegations set forth in Paragraph 10 only to the extent that he entered into an independent contractor agreement with We Treat, LLC in 2024.

Paragraph 11: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 11 as to the types of services which were provided to Youth Inc. However, to the best of Respondents' knowledge, Youth Inc. did receive services from

We Treat related to medical clearances for patients, policies and protocols and compliance information.

Paragraph 12: Dr. Arora agrees with the factual allegations set forth in Paragraph 12 only to the extent that he reviewed and approved policies and protocols directly related to the provision of certain medical services. Dr. Arora was not involved, nor did he review or approve, policies and procedures related to any other matters involving Youth, Inc.

Paragraph 13: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 13.

Paragraph 14: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 14.

Paragraph 15: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 15.

Paragraph 16: Dr. Arora acknowledges that as part of his duties for We Treat, he was assigned as medical director for Youth, Inc. in approximately April 2024. Dr. Arora's duties as medical director included the review and approval of protocols for certain medical treatments performed at Youth, Inc., responding to patient specific questions from the clinic, and authorization of the ordering of certain dangerous drugs, to be done in accordance with compliance policies prepared by We Treat.

Paragraph 17: Dr. Arora agrees with the factual allegations contained in Paragraph 17 to the extent that he provided services to We Treat until January 2025, services which included acting as medical director for Youth,. Inc., which were limited to the duties set forth in the response to Paragraph 16.

Paragraph 18: Dr. Arora acknowledges that he was based in Seattle, Washington and that his duties for Youth, Inc. did not require him to be physically at Youth, Inc.'s location.

Paragraph 19: Respondent's Gifford, McIntyre, and Jaggard deny the factual allegations set forth in Paragraph 19. None of the named Respondents were engaged by Youth, Inc. to provide any services. All three Respondents were employees/independent contractors of We Treat which provided medical clearance screening of patients for Youth, Inc. through Nevada licensed practitioners.

Paragraph 20: Respondents Gifford, McIntyre, and Jaggard acknowledge that they reviewed and medically cleared patients for treatments performed at Youth, Inc. pursuant to medical protocols reviewed and approved by Dr. Arora and performed these reviews in accordance with policies and protocols developed and approved by We Treat, not Dr. Arora.

Paragraph 21: Respondents Gifford, McIntyre and Jaggard acknowledge that they medically cleared patients, if appropriate, after the review of medical information and authorized treatments to be performed pursuant to protocols approved by Dr. Arora which included standing orders for administration of certain drugs or the issuance of prescriptions pursuant to those protocols. No approved protocols for treatments authorized the administration of controlled substances at Youth, Inc.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 22.

Paragraph 23: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 23.

Paragraph 24: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 24.

Paragraph 25: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 25.

Paragraph 26: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 26.

Paragraph 27: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 27.

Paragraph 28: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 28.

Paragraph 29: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 29.

Paragraph 30: Dr. Arora acknowledges that he would periodically review orders received for dangerous drugs and would sign, remotely for the same. Drugs were to be stored and accessed in accordance with policies and protocols developed by We Treat; Dr. Arora was not part of the development of those policies and procedures, nor was he asked to review them by We Treat. Dr. Arora denies that he ever signed off or approved of any shipments of controlled substances to Youth, Inc. and to his knowledge, no controlled substances were to be received or stored on-site at We Treat.

Paragraph 31: Dr. Arora denies the factual allegations contained in Paragraph 31, however he acknowledges that he would respond to patient specific questions posed to him and would review patient records at that time; however this occurred very rarely.

Paragraph 32: Dr. Arora denies the factual allegations contained in Paragraph 32. Dr. Arora was not responsible for the policies and procedures related to the procurement, storage, possession and/or administration of dangerous drugs or controlled substances other than approving

protocols directly related to the provision of medical services. We Treat's compliance department was solely responsible for the policies and protocols otherwise related to dangerous drugs and controlled substances.

Paragraph 33: Dr. Arora denies the allegations set forth in Paragraph 33.

Paragraph 34: Dr. Arora denies the allegations set forth in Paragraph 34.

Paragraph 35: Dr. Arora denies the allegations set forth in Paragraph 35.

Paragraph 36: Dr. Arora denies the allegations set forth in Paragraph 36.

Paragraph 37: Dr. Arora denies the allegations set forth in Paragraph 37 as he was not involved in, nor responsible for the receipt, possession storage, and distribution of dangerous drugs or controlled substances at Youth, Inc.

Applicable Law: Paragraphs 38-55

Paragraph 38-55: Respondents acknowledge that Paragraphs 38-55 accurately reflect the basic substance of the statutes and regulations cited therein.

Counts: Paragraphs 56-91

Count One (Paragraphs 56-61): Dr. Arora generally denies the allegations set forth in Count One in Paragraphs 56-61. Dr. Arora did not permit Youth, Inc. or any of its personnel to order any dangerous drugs from any manufacturer or supplier not licensed in Nevada. As discussed herein, Dr. Arora's duties for Youth, Inc. were limited to the review and authorization of protocols related to medical procedures. While Youth, Inc. was authorized to order supplies and dangerous drugs under Dr. Arora's credentials, this was to be done in accordance with policies and protocols developed and approved by We Treat's compliance department. To the best of Dr. Arora's knowledge, no client of We Treat was authorized to order or received dangerous drugs or other supplies from unlicensed suppliers/manufacturers.

Count Two (Paragraphs 62-68): Dr. Arora generally denies all allegations set forth in Count Two in Paragraphs 62-68. Further Dr. Arora asserts that a practice which orders, receives, and stores dangerous drugs is not engaging in the practice of pharmacy as alleged. If indeed this was accurate, every medical practice or facility that orders, receives and stores drugs for administration and/or dispensing, would be required to hold a pharmacy license with the Board; that is not currently a requirement and NRS 639.0124(1)(a) is inappropriately applied here.

Count Three (Paragraphs 69-74): Dr. Arora generally denies the allegations set forth in Count Three in Paragraphs 69-74. Again, as discussed herein, Dr. Arora's duties for Youth, Inc. were limited and did not include the development or approval of any protocols or procedures related to the procurement or storage of dangerous drugs. Dr. Arora's medical service protocols did not allow for the reuse of single use vials and any reuse of single use vials on the part of Youth, Inc. personnel would have been done without the knowledge of Dr. Arora and he did not aid or abet any violation of NAC 639.050(2).

Count Four (Paragraphs 75-81): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Four in Paragraphs 75-81. Respondents Gifford, McIntyre, and Jaggard, worked for We Treat, not Youth, Inc. Respondents' duties for Youth, Inc. were limited to conducting medical clearance reviews for patients and if cleared, the patient was authorized for treatment pursuant to approved medical protocols. None of the named respondents were responsible for supervising the staff of Youth, Inc. and would have had no knowledge of unauthorized reuse of single use vials by any personnel associated with Youth, Inc.

Count Five (Paragraphs 82-87): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Five in Paragraphs 75-81. The administration of dangerous drugs to patients is not the practice of pharmacy as defined by NRS 639.0124(1)(a) and

accordingly Respondents could not have aided or abetted in the violation of said statute. Again, as discussed above, should the Board take the position that the administration of a dangerous drug constitutes the practice of pharmacy, all practices and facilities at which any drug is administered would be required to hold a registration as a pharmacy with the Board which is not currently required.

Count Six (Paragraphs 88-91): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Six in Paragraphs 88-91.

NOTICE OF DEFENSE/MITIGATING INFORMATION

In regard to Respondent Arora, Dr. Arora stresses that his involvement with We Treat was limited as medical director. The term "medical director" is not defined under Nevada law and there is no legal precedent for what the duties of a medical director must consist of. Dr. Arora functioned as a medical director per the duties he had as a contractor for We Treat, LLC, which consisted solely of the review and authorization of protocols for medical services offered at practices contracted with We Treat and he was required to be available for consultations regarding specific patient questions as needed. The medical protocols authorized by Dr. Arora included standing orders for the administration of certain dangerous drugs and for the prescription of certain controlled substances. It should be noted that Dr. Arora never authorized the administration of controlled substances at Youth, Inc., or any other practice for which he provided services under We Treat and to his knowledge, no controlled substances were stored on-site at Youth, Inc.

We Treat's compliance department was responsible for the development and authorization of all other policies and protocols, including those related to the procurement, receipt, and storage of dangerous drugs. Dr. Arora was advised by We Treat that all policies and protocols were reviewed and vetted for compliance with the laws in each individual state in which We Treat had

clients. Dr. Arora had no reason to doubt the assurances made by We Treat that the policies and protocols for Youth, Inc. were in compliance with Nevada law.

In regard to Respondents Gifford, McIntyre, and Jaggard, all three were employees/contractors with We Treat during the times in question. Their duties were to provide medical clearance reviews for patients wishing to receive services at practices which were contracted with We Treat and if cleared, authorize treatment to be provide pursuant to previously approved medical protocols. Respondents had no duties related to the oversight or supervision of any practice served by We Treat. Respondents would be notified through a proprietary platform that a patient required a medical clearance evaluation at practices which received services from We Treat and would be given access to the patient records through the We Treat platform and would either clear the patient for treatment or deny treatment[1]. Each clinic had individual protocols which would be followed by Respondents. Respondents were informed by We Treat that policies related to requirements for providing medical clearance for patients was vetted by its compliance department and all protocols were in compliance with state laws; Respondents had no reason to question the representations of We Treat.

Respondent Gifford estimates that she performed very few medical clearance evaluations for Youth, Inc. through the We Treat platform. Respondent McIntyre estimates that she did approximately two medical clearance evaluations for Youth, Inc. Respondent Jaggard estimates that she did a maximum of ten to fifteen medical clearance evaluations for Youth, Inc.

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[1] We Treat practitioners only performed medical clearance evaluations for patients in states in which they were licensed.

All Respondents deny having violated NRS and/or NAC Chapters 453, 454, or 639. Further Respondents reserve all legal defenses available to them should this matter proceed to a hearing.

Respectfully submitted this 15th day of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484, and** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos. 24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Sean Arora, M.D., ("Respondent Arora"), because Respondent Arora holds a certificate of registration issued by the Board authorizing him to prescribe controlled substances in Nevada. Respondent Arora holds certificate of registration no. CS31476, which was issued by the Board pursuant to NRS 453.226 and 453.231.

2. The Board has personal jurisdiction over Respondent Cassie Gifford, APRN, ("Respondent Gifford"), because Respondent Gifford holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent Gifford holds certificate of

registration no. PR18034, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.[1]

3. The Board has personal jurisdiction over Respondent Gabrielle McIntyre, APRN, ("Respondent McIntyre"), because Respondent McIntyre holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR17484, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.

4. The Board has personal jurisdiction over Respondent Allison Jaggard, APRN, ("Respondent Jaggard"), because Respondent Jaggard holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR171499, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations involving the purchase, receipt, storage, possession, prescribing and/or dispensing of dangerous drugs and controlled substances. As used herein, "dangerous drug" has the meaning ascribed to it in NRS 454.201, and "controlled substance" means a substance listed in NAC 453.510 to NAC 453.550, inclusive, or in 21 CFR Part 1308.

FACTUAL ALLEGATIONS

6. Respondent Arora is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. At all times alleged herein, Respondent Arora was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

7. Respondent Gifford is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent

1. Respondent Gifford formerly held certificate of registration no. CS34942, authorizing her to prescribe controlled substances. Certificate of registration no. CS34942 was not renewed when it came due for renewal on November 1, 2024.

Gifford was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

8. Respondent McIntyre is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

9. Respondent Jaggard is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

10. In 2024, Respondent Arora formed a partnership or other business relationship with We Treat, a medical consulting firm based in San Diego, California. We Treat provides consulting services and regulatory compliance advice to medical spas and wellness clinics.

11. We Treat provided consulting services and compliance advice to Youth, Inc. (Youth Inc.), the owner of a medical spa and wellness clinic located at 695 Sierra Rose Drive in Reno, Nevada.

12. We Treat developed a manual of policies, procedures and protocols for use by Youth Inc. Respondent Arora approved these policies, procedures and protocols for use by Youth Inc.

13. Between April 2024 and March 2025, Youth Inc. provided various anti-aging and wellness treatments for its patients. These included cosmetic treatments using botulinum toxin type A and dermal fillers, treatments for weight loss using compounded tirzepatide and semaglutide products, hormone replacement using injectable hormones, and treatment for erectile dysfunction using sildenafil and tadalafil.

14. Between April 2024 and March 2025, Youth Inc. did not lock or otherwise secure the dangerous drugs and/or controlled substances in its possession.

15. In early 2025, Youth Inc. was in possession of stock bottles containing sildenafil, tadalafil, and metformin hydrochloride, all dangerous drugs. Youth Inc.'s representatives claimed that

they were not planning to dispense these drugs until after they had secured a dispensing license issued by the Board.

16. We Treat arranged for Respondent Arora to serve as the "medical director" for Youth Inc., a role that Respondent Arora assumed sometime between April and August 2024.

17. Respondent Arora served as Youth Inc.'s medical director until early 2025.

18. During Respondent Arora's tenure as Youth Inc.'s medical director, Respondent Arora worked and resided in Seattle, Washington. Respondent Arora never visited Youth Inc.'s facility in Reno, Nevada.

19. Sometime between April 2024 and March 2025, Youth Inc. engaged the services of Respondent Gifford, Respondent McIntyre and Respondent Jaggard. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard rarely, if ever, visited Youth Inc.'s facility in Reno, Nevada.

20. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed a prospective patient's medical questionnaire prior to the prospective patient's initial treatment at Youth Inc. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed these medical questionnaires from a remote location and never saw or spoke to patients prior to their initial treatments at Youth Inc.

21. After reviewing medical questionnaires, and despite not ever seeing the patients in question, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the use or administration of dangerous drugs and/or controlled substances.

22. Sometime between April 2024 and March 2025, Youth Inc. employed Maddison Weiss-Frank, a registered nurse. Ms. Weiss-Frank was not an advanced practice registered nurse and was not a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

23. Ms. Weiss-Frank worked under the direction and supervision of Rachel Gonzalez, the co-owner and chief executive officer of Youth Inc. Ms. Gonzalez was not a "practitioner" as that term

is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125. On information and belief, Ms. Gonzalez has no formal medical training.

24. Because there was never a practitioner present at the location, Youth Inc.'s facility at 695 Sierra Rose Drive in Reno, Nevada, was not a location where a registered nurse could lawfully inject a neuromodulator pursuant to NRS 454.217.

25. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank treated patients using prescription drugs and/or controlled substances. Ms. Weiss-Frank did not act under the direction or supervision of a practitioner.

26. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances. Ms. Weiss-Frank did not work under the direction or supervision of a practitioner.

27. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

28. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

29. Consistent with the practice described above, Youth Inc. returned single-use vials to stock even after the vials were punctured and therefore rendered unusable for subsequent treatments.

30. As the medical director for Youth Inc., Respondent Arora periodically reviewed purchase invoices and signed for shipments of dangerous drugs and/or controlled substances.

31. As the medical director for Youth Inc., Respondent Arora periodically reviewed patient medical questionnaires and treatment records.

32. As the medical director for Youth Inc., Respondent Arora periodically reviewed Youth Inc.'s policies, procedures and protocols related to the procurement, storage, possession and administration of dangerous drugs and controlled substances.

33. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances without direction or supervision by a practitioner.

34. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank treated patients with prescription drugs and/or controlled substances despite not working under the supervision or direction of a practitioner.

35. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

36. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

37. As Youth Inc.'s medical director, Respondent Arora had a duty to understand Nevada law as it governs the receipt, possession, storage, and distribution of dangerous drugs and controlled substances.

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APPLICABLE LAW

38. It is unlawful for any person to engage in wholesale distribution, or permit to be distributed at wholesale, any drug or compound unless the person holds the appropriate certificate, license or permit issued by the Board. NRS 639.100(1).

39. To engage in wholesale distribution of any drug or compound in Nevada, a person must be licensed as a wholesaler or manufacturer, as applicable. NRS 639.100; NRS 639.233; NAC 639.593; NAC 639.6915.

40. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapters 453, 454, 639, or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12); NRS 453.236.

41. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 453.236.

42. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner, or if the practitioner assists or abets a person not licensed to practice pharmacy in Nevada. NAC 639.945(1)(i) and (j).

43. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner prescribes or orders a dangerous drug or controlled substance for a person with whom the practitioner does not have a bona fide therapeutic relationship. NAC 639.945(1)(n).

44. "'Practice of pharmacy' includes, but is not limited to, the . . . [p]erformance or supervision of activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug, including the receipt, handling and storage of prescriptions and other confidential information relating to patients." NRS 639.0124(1)(a).

45. It is unlawful to possess, store, or administer dangerous drugs, including botulinum toxin type A and injectable dermal fillers, except as authorized by NRS 454.213.

46. It is unlawful to possess, store, or administer controlled substances, including testosterone, except as provided by NRS 453.375.

47. "Administer" means the direct application of a [dangerous drug or controlled substance] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 453.021; NRS 454.191.

48. Pursuant to NRS 453.375, a registered nurse may not possess, store, or administer controlled substances except when working under the direction of a supervising practitioner.

49. Pursuant to NRS 454.213, a registered nurse may not possess, store, or administer dangerous drugs except at the direction of a supervising practitioner.

50. It is unlawful for a registered nurse to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

51. A person who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from stock for administering or dispensing to patients. NAC 639.050(2).

52. A practitioner is subject to discipline if the practitioner causes or allows a dangerous drug to be dispensed in a manner not authorized by NRS 454.215 and NRS 454.301. *See* NRS 639.100; NRS 639.210(12).

53. The term "dispense" includes the prescribing by a practitioner, administering, packaging, labeling, or compounding necessary to prepare a substance for delivery to a patient. NRS 639.0065; NRS 453.056.

54. It is unlawful to furnish drugs without a prescription. NRS 454.221.

55. "Furnish" means to supply by any means, by sale or otherwise. NRS 454.006.

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COUNT ONE
Permitting Unlicensed Wholesale Distribution
(Respondent Arora)

56. As alleged above, Respondent Arora served as the medical director for Youth Inc.

57. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

58. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage purchases from unlicensed distributors such as GLP-1 Sciences, LLC. Respondent failed to implement such policies, procedures and protocols.

59. Given the facts and circumstances alleged above, Respondent Arora permitted the unlicensed wholesale distribution of compounded drug products in violation of NRS 639.100(1).

60. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

61. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT TWO
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondent Arora)

62. As alleged above, Respondent Arora served as the medical director for Youth Inc.

63. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered, received, possessed, and/or stored dangerous drugs and/or controlled substances. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

64. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of

Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

65. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the above persons from ordering, receiving, possessing, storing and/or furnishing dangerous drugs and/or controlled substances. Respondent Arora failed to implement such policies, procedures and protocols.

66. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the unlicensed practice of pharmacy.

67. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

68. Respondent Arora's acts and/or omissions as alleged above amount to conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(i) and (j).

COUNT THREE
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondent Arora)

69. As alleged above, Respondent Arora served as the medical director for Youth Inc.

70. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

71. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the repeated or recurring use of punctured single-use vials. Respondent failed to implement such policies, procedures and protocols.

72. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the above violations of NAC 639.050(2).

73. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

74. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FOUR
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondents Gifford, McIntyre and Jaggard)

75. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

76. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of injectable drugs contained within single-use vials.

77. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard had a duty to ensure that Youth Inc. did not make repeated or recurring uses of punctured single-use vials.

78. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that Youth Inc. did not return single-use vials to stock after the vials were punctured.

79. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard assisted or abetted in the above violations of NAC 639.050(2).

80. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

81. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FIVE
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondents Gifford, McIntyre and Jaggard)

82. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

83. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

84. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that dangerous drugs and/or controlled substances were administered under the direction or supervision of a practitioner. Dangerous drugs and/or controlled substances were not administered under the direction or supervision of a practitioner.

85. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard assisted or abetted the unlicensed practice of pharmacy by Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank.

86. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

87. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT SIX
Failure to Establish a Bona Fide Therapeutic Relationship with Patients
(Respondents Gifford, McIntyre and Jaggard)

88. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

89. Respondent Gifford, Respondent McIntyre and Respondent Jaggard never saw or spoke with the above patients for whom they authorized treatments with dangerous drugs and/or controlled substances.

90. Having failed to see or speak with the above patients, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard failed to establish a bona fide therapeutic relationship with the above patients prior to authorizing their initial treatments with dangerous drugs and/or controlled substances.

91. Respondents' conduct as alleged above amounts to unprofessional conduct and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(n).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondent Sean Arora, Respondent Cassie Gifford, Respondent Gabrielle McIntyre, and Respondent Allison Jaggard.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **Respondent.**	**Case No. 24-509-PR-B-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **Respondent.**	**Case No. 24-509-PR-B-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Gabrielle McIntyre, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sean Arora, MD
c/o Youth Inc
691 Sierra Rose Dr
Reno, NV 89511

Cassie Gifford, APRN
c/o Bionetics Health
5540 S Fort Apache Rd #120
Las Vegas, NV 89148

Gabrielle McIntyre, APRN
c/o Restore Hyper Wellness
1550 N Green Valley Pkwy., Ste 300
Henderson, NV 89074

Allison Jaggard, APRN
1708 Spring Green Blvd Ste 120-109
Katy, TX 77494

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
AUG 15 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos.** **24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENTS**

Respondents Sean Arora, M.D., Cassie Gifford, APRN, Gabrielle McIntyre, APRN, and Allison Jaggard, APRN, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-5

Paragraph 1: Dr. Arora acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation to the extent that the matter pertains to controlled substances as he holds a controlled substance registration issued by the Board.

Paragraph 2: Ms. Gifford acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 3: Ms. McIntyre acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 3 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 4: Ms. Jaggard acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 4 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 5: Respondents acknowledge that the Board has jurisdiction in the matter to the extent that the matter involves dangerous drugs and controlled substances. Dr. Arora acknowledges that the Board has jurisdiction over the allegations pertaining to his acts or omissions to the extent they concern controlled substances.

Factual Allegations: Paragraphs 6-37

Paragraph 6: Dr. Arora agrees with the factual allegations as set forth in Paragraph 6.

Paragraph 7: Ms. Gifford agrees with the factual allegations as set forth in Paragraph 7.

Paragraph 8: Ms. McIntyre agrees with the factual allegations as set forth in Paragraph 8.

Paragraph 9: Ms. Jaggard agrees with the factual allegations as set forth in Paragraph 9.

Paragraph 10: Dr. Arora agrees with the factual allegations set forth in Paragraph 10 only to the extent that he entered into an independent contractor agreement with We Treat, LLC in 2024.

Paragraph 11: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 11 as to the types of services which were provided to Youth Inc. However, to the best of Respondents' knowledge, Youth Inc. did receive services from

We Treat related to medical clearances for patients, policies and protocols and compliance information.

Paragraph 12: Dr. Arora agrees with the factual allegations set forth in Paragraph 12 only to the extent that he reviewed and approved policies and protocols directly related to the provision of certain medical services. Dr. Arora was not involved, nor did he review or approve, policies and procedures related to any other matters involving Youth, Inc.

Paragraph 13: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 13.

Paragraph 14: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 14.

Paragraph 15: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 15.

Paragraph 16: Dr. Arora acknowledges that as part of his duties for We Treat, he was assigned as medical director for Youth, Inc. in approximately April 2024. Dr. Arora's duties as medical director included the review and approval of protocols for certain medical treatments performed at Youth, Inc., responding to patient specific questions from the clinic, and authorization of the ordering of certain dangerous drugs, to be done in accordance with compliance policies prepared by We Treat.

Paragraph 17: Dr. Arora agrees with the factual allegations contained in Paragraph 17 to the extent that he provided services to We Treat until January 2025, services which included acting as medical director for Youth,. Inc., which were limited to the duties set forth in the response to Paragraph 16.

Paragraph 18: Dr. Arora acknowledges that he was based in Seattle, Washington and that his duties for Youth, Inc. did not require him to be physically at Youth, Inc.'s location.

Paragraph 19: Respondent's Gifford, McIntyre, and Jaggard deny the factual allegations set forth in Paragraph 19. None of the named Respondents were engaged by Youth, Inc. to provide any services. All three Respondents were employees/independent contractors of We Treat which provided medical clearance screening of patients for Youth, Inc. through Nevada licensed practitioners.

Paragraph 20: Respondents Gifford, McIntyre, and Jaggard acknowledge that they reviewed and medically cleared patients for treatments performed at Youth, Inc. pursuant to medical protocols reviewed and approved by Dr. Arora and performed these reviews in accordance with policies and protocols developed and approved by We Treat, not Dr. Arora.

Paragraph 21: Respondents Gifford, McIntyre and Jaggard acknowledge that they medically cleared patients, if appropriate, after the review of medical information and authorized treatments to be performed pursuant to protocols approved by Dr. Arora which included standing orders for administration of certain drugs or the issuance of prescriptions pursuant to those protocols. No approved protocols for treatments authorized the administration of controlled substances at Youth, Inc.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 22.

Paragraph 23: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 23.

Paragraph 24: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 24.

Paragraph 25: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 25.

Paragraph 26: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 26.

Paragraph 27: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 27.

Paragraph 28: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 28.

Paragraph 29: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 29.

Paragraph 30: Dr. Arora acknowledges that he would periodically review orders received for dangerous drugs and would sign, remotely for the same. Drugs were to be stored and accessed in accordance with policies and protocols developed by We Treat; Dr. Arora was not part of the development of those policies and procedures, nor was he asked to review them by We Treat. Dr. Arora denies that he ever signed off or approved of any shipments of controlled substances to Youth, Inc. and to his knowledge, no controlled substances were to be received or stored on-site at We Treat.

Paragraph 31: Dr. Arora denies the factual allegations contained in Paragraph 31, however he acknowledges that he would respond to patient specific questions posed to him and would review patient records at that time; however this occurred very rarely.

Paragraph 32: Dr. Arora denies the factual allegations contained in Paragraph 32. Dr. Arora was not responsible for the policies and procedures related to the procurement, storage, possession and/or administration of dangerous drugs or controlled substances other than approving

protocols directly related to the provision of medical services. We Treat's compliance department was solely responsible for the policies and protocols otherwise related to dangerous drugs and controlled substances.

Paragraph 33: Dr. Arora denies the allegations set forth in Paragraph 33.

Paragraph 34: Dr. Arora denies the allegations set forth in Paragraph 34.

Paragraph 35: Dr. Arora denies the allegations set forth in Paragraph 35.

Paragraph 36: Dr. Arora denies the allegations set forth in Paragraph 36.

Paragraph 37: Dr. Arora denies the allegations set forth in Paragraph 37 as he was not involved in, nor responsible for the receipt, possession storage, and distribution of dangerous drugs or controlled substances at Youth, Inc.

Applicable Law: Paragraphs 38-55

Paragraph 38-55: Respondents acknowledge that Paragraphs 38-55 accurately reflect the basic substance of the statutes and regulations cited therein.

Counts: Paragraphs 56-91

Count One (Paragraphs 56-61): Dr. Arora generally denies the allegations set forth in Count One in Paragraphs 56-61. Dr. Arora did not permit Youth, Inc. or any of its personnel to order any dangerous drugs from any manufacturer or supplier not licensed in Nevada. As discussed herein, Dr. Arora's duties for Youth, Inc. were limited to the review and authorization of protocols related to medical procedures. While Youth, Inc. was authorized to order supplies and dangerous drugs under Dr. Arora's credentials, this was to be done in accordance with policies and protocols developed and approved by We Treat's compliance department. To the best of Dr. Arora's knowledge, no client of We Treat was authorized to order or received dangerous drugs or other supplies from unlicensed suppliers/manufacturers.

Count Two (Paragraphs 62-68): Dr. Arora generally denies all allegations set forth in Count Two in Paragraphs 62-68. Further Dr. Arora asserts that a practice which orders, receives, and stores dangerous drugs is not engaging in the practice of pharmacy as alleged. If indeed this was accurate, every medical practice or facility that orders, receives and stores drugs for administration and/or dispensing, would be required to hold a pharmacy license with the Board; that is not currently a requirement and NRS 639.0124(1)(a) is inappropriately applied here.

Count Three (Paragraphs 69-74): Dr. Arora generally denies the allegations set forth in Count Three in Paragraphs 69-74. Again, as discussed herein, Dr. Arora's duties for Youth, Inc. were limited and did not include the development or approval of any protocols or procedures related to the procurement or storage of dangerous drugs. Dr. Arora's medical service protocols did not allow for the reuse of single use vials and any reuse of single use vials on the part of Youth, Inc. personnel would have been done without the knowledge of Dr. Arora and he did not aid or abet any violation of NAC 639.050(2).

Count Four (Paragraphs 75-81): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Four in Paragraphs 75-81. Respondents Gifford, McIntyre, and Jaggard, worked for We Treat, not Youth, Inc. Respondents' duties for Youth, Inc. were limited to conducting medical clearance reviews for patients and if cleared, the patient was authorized for treatment pursuant to approved medical protocols. None of the named respondents were responsible for supervising the staff of Youth, Inc. and would have had no knowledge of unauthorized reuse of single use vials by any personnel associated with Youth, Inc.

Count Five (Paragraphs 82-87): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Five in Paragraphs 75-81. The administration of dangerous drugs to patients is not the practice of pharmacy as defined by NRS 639.0124(1)(a) and

accordingly Respondents could not have aided or abetted in the violation of said statute. Again, as discussed above, should the Board take the position that the administration of a dangerous drug constitutes the practice of pharmacy, all practices and facilities at which any drug is administered would be required to hold a registration as a pharmacy with the Board which is not currently required.

Count Six (Paragraphs 88-91): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Six in Paragraphs 88-91.

NOTICE OF DEFENSE/MITIGATING INFORMATION

In regard to Respondent Arora, Dr. Arora stresses that his involvement with We Treat was limited as medical director. The term "medical director" is not defined under Nevada law and there is no legal precedent for what the duties of a medical director must consist of. Dr. Arora functioned as a medical director per the duties he had as a contractor for We Treat, LLC, which consisted solely of the review and authorization of protocols for medical services offered at practices contracted with We Treat and he was required to be available for consultations regarding specific patient questions as needed. The medical protocols authorized by Dr. Arora included standing orders for the administration of certain dangerous drugs and for the prescription of certain controlled substances. It should be noted that Dr. Arora never authorized the administration of controlled substances at Youth, Inc., or any other practice for which he provided services under We Treat and to his knowledge, no controlled substances were stored on-site at Youth, Inc.

We Treat's compliance department was responsible for the development and authorization of all other policies and protocols, including those related to the procurement, receipt, and storage of dangerous drugs. Dr. Arora was advised by We Treat that all policies and protocols were reviewed and vetted for compliance with the laws in each individual state in which We Treat had

clients. Dr. Arora had no reason to doubt the assurances made by We Treat that the policies and protocols for Youth, Inc. were in compliance with Nevada law.

In regard to Respondents Gifford, McIntyre, and Jaggard, all three were employees/contractors with We Treat during the times in question. Their duties were to provide medical clearance reviews for patients wishing to receive services at practices which were contracted with We Treat and if cleared, authorize treatment to be provide pursuant to previously approved medical protocols. Respondents had no duties related to the oversight or supervision of any practice served by We Treat. Respondents would be notified through a proprietary platform that a patient required a medical clearance evaluation at practices which received services from We Treat and would be given access to the patient records through the We Treat platform and would either clear the patient for treatment or deny treatment[1]. Each clinic had individual protocols which would be followed by Respondents. Respondents were informed by We Treat that policies related to requirements for providing medical clearance for patients was vetted by its compliance department and all protocols were in compliance with state laws; Respondents had no reason to question the representations of We Treat.

Respondent Gifford estimates that she performed very few medical clearance evaluations for Youth, Inc. through the We Treat platform. Respondent McIntyre estimates that she did approximately two medical clearance evaluations for Youth, Inc. Respondent Jaggard estimates that she did a maximum of ten to fifteen medical clearance evaluations for Youth, Inc.

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[1] We Treat practitioners only performed medical clearance evaluations for patients in states in which they were licensed.

All Respondents deny having violated NRS and/or NAC Chapters 453, 454, or 639. Further Respondents reserve all legal defenses available to them should this matter proceed to a hearing.

Respectfully submitted this 15th day of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484, and** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos. 24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Sean Arora, M.D., ("Respondent Arora"), because Respondent Arora holds a certificate of registration issued by the Board authorizing him to prescribe controlled substances in Nevada. Respondent Arora holds certificate of registration no. CS31476, which was issued by the Board pursuant to NRS 453.226 and 453.231.

2. The Board has personal jurisdiction over Respondent Cassie Gifford, APRN, ("Respondent Gifford"), because Respondent Gifford holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent Gifford holds certificate of

registration no. PR18034, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.[1]

3. The Board has personal jurisdiction over Respondent Gabrielle McIntyre, APRN, ("Respondent McIntyre"), because Respondent McIntyre holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR17484, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.

4. The Board has personal jurisdiction over Respondent Allison Jaggard, APRN, ("Respondent Jaggard"), because Respondent Jaggard holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR171499, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations involving the purchase, receipt, storage, possession, prescribing and/or dispensing of dangerous drugs and controlled substances. As used herein, "dangerous drug" has the meaning ascribed to it in NRS 454.201, and "controlled substance" means a substance listed in NAC 453.510 to NAC 453.550, inclusive, or in 21 CFR Part 1308.

FACTUAL ALLEGATIONS

6. Respondent Arora is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. At all times alleged herein, Respondent Arora was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

7. Respondent Gifford is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent

1. Respondent Gifford formerly held certificate of registration no. CS34942, authorizing her to prescribe controlled substances. Certificate of registration no. CS34942 was not renewed when it came due for renewal on November 1, 2024.

Gifford was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

8. Respondent McIntyre is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

9. Respondent Jaggard is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

10. In 2024, Respondent Arora formed a partnership or other business relationship with We Treat, a medical consulting firm based in San Diego, California. We Treat provides consulting services and regulatory compliance advice to medical spas and wellness clinics.

11. We Treat provided consulting services and compliance advice to Youth, Inc. (Youth Inc.), the owner of a medical spa and wellness clinic located at 695 Sierra Rose Drive in Reno, Nevada.

12. We Treat developed a manual of policies, procedures and protocols for use by Youth Inc. Respondent Arora approved these policies, procedures and protocols for use by Youth Inc.

13. Between April 2024 and March 2025, Youth Inc. provided various anti-aging and wellness treatments for its patients. These included cosmetic treatments using botulinum toxin type A and dermal fillers, treatments for weight loss using compounded tirzepatide and semaglutide products, hormone replacement using injectable hormones, and treatment for erectile dysfunction using sildenafil and tadalafil.

14. Between April 2024 and March 2025, Youth Inc. did not lock or otherwise secure the dangerous drugs and/or controlled substances in its possession.

15. In early 2025, Youth Inc. was in possession of stock bottles containing sildenafil, tadalafil, and metformin hydrochloride, all dangerous drugs. Youth Inc.'s representatives claimed that

they were not planning to dispense these drugs until after they had secured a dispensing license issued by the Board.

16. We Treat arranged for Respondent Arora to serve as the "medical director" for Youth Inc., a role that Respondent Arora assumed sometime between April and August 2024.

17. Respondent Arora served as Youth Inc.'s medical director until early 2025.

18. During Respondent Arora's tenure as Youth Inc.'s medical director, Respondent Arora worked and resided in Seattle, Washington. Respondent Arora never visited Youth Inc.'s facility in Reno, Nevada.

19. Sometime between April 2024 and March 2025, Youth Inc. engaged the services of Respondent Gifford, Respondent McIntyre and Respondent Jaggard. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard rarely, if ever, visited Youth Inc.'s facility in Reno, Nevada.

20. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed a prospective patient's medical questionnaire prior to the prospective patient's initial treatment at Youth Inc. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed these medical questionnaires from a remote location and never saw or spoke to patients prior to their initial treatments at Youth Inc.

21. After reviewing medical questionnaires, and despite not ever seeing the patients in question, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the use or administration of dangerous drugs and/or controlled substances.

22. Sometime between April 2024 and March 2025, Youth Inc. employed Maddison Weiss-Frank, a registered nurse. Ms. Weiss-Frank was not an advanced practice registered nurse and was not a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

23. Ms. Weiss-Frank worked under the direction and supervision of Rachel Gonzalez, the co-owner and chief executive officer of Youth Inc. Ms. Gonzalez was not a "practitioner" as that term

is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125. On information and belief, Ms. Gonzalez has no formal medical training.

24. Because there was never a practitioner present at the location, Youth Inc.'s facility at 695 Sierra Rose Drive in Reno, Nevada, was not a location where a registered nurse could lawfully inject a neuromodulator pursuant to NRS 454.217.

25. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank treated patients using prescription drugs and/or controlled substances. Ms. Weiss-Frank did not act under the direction or supervision of a practitioner.

26. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances. Ms. Weiss-Frank did not work under the direction or supervision of a practitioner.

27. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

28. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

29. Consistent with the practice described above, Youth Inc. returned single-use vials to stock even after the vials were punctured and therefore rendered unusable for subsequent treatments.

30. As the medical director for Youth Inc., Respondent Arora periodically reviewed purchase invoices and signed for shipments of dangerous drugs and/or controlled substances.

31. As the medical director for Youth Inc., Respondent Arora periodically reviewed patient medical questionnaires and treatment records.

32. As the medical director for Youth Inc., Respondent Arora periodically reviewed Youth Inc.'s policies, procedures and protocols related to the procurement, storage, possession and administration of dangerous drugs and controlled substances.

33. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances without direction or supervision by a practitioner.

34. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank treated patients with prescription drugs and/or controlled substances despite not working under the supervision or direction of a practitioner.

35. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

36. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

37. As Youth Inc.'s medical director, Respondent Arora had a duty to understand Nevada law as it governs the receipt, possession, storage, and distribution of dangerous drugs and controlled substances.

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APPLICABLE LAW

38. It is unlawful for any person to engage in wholesale distribution, or permit to be distributed at wholesale, any drug or compound unless the person holds the appropriate certificate, license or permit issued by the Board. NRS 639.100(1).

39. To engage in wholesale distribution of any drug or compound in Nevada, a person must be licensed as a wholesaler or manufacturer, as applicable. NRS 639.100; NRS 639.233; NAC 639.593; NAC 639.6915.

40. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapters 453, 454, 639, or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12); NRS 453.236.

41. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 453.236.

42. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner, or if the practitioner assists or abets a person not licensed to practice pharmacy in Nevada. NAC 639.945(1)(i) and (j).

43. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner prescribes or orders a dangerous drug or controlled substance for a person with whom the practitioner does not have a bona fide therapeutic relationship. NAC 639.945(1)(n).

44. "'Practice of pharmacy' includes, but is not limited to, the . . . [p]erformance or supervision of activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug, including the receipt, handling and storage of prescriptions and other confidential information relating to patients." NRS 639.0124(1)(a).

45. It is unlawful to possess, store, or administer dangerous drugs, including botulinum toxin type A and injectable dermal fillers, except as authorized by NRS 454.213.

46. It is unlawful to possess, store, or administer controlled substances, including testosterone, except as provided by NRS 453.375.

47. "Administer" means the direct application of a [dangerous drug or controlled substance] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 453.021; NRS 454.191.

48. Pursuant to NRS 453.375, a registered nurse may not possess, store, or administer controlled substances except when working under the direction of a supervising practitioner.

49. Pursuant to NRS 454.213, a registered nurse may not possess, store, or administer dangerous drugs except at the direction of a supervising practitioner.

50. It is unlawful for a registered nurse to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

51. A person who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from stock for administering or dispensing to patients. NAC 639.050(2).

52. A practitioner is subject to discipline if the practitioner causes or allows a dangerous drug to be dispensed in a manner not authorized by NRS 454.215 and NRS 454.301. *See* NRS 639.100; NRS 639.210(12).

53. The term "dispense" includes the prescribing by a practitioner, administering, packaging, labeling, or compounding necessary to prepare a substance for delivery to a patient. NRS 639.0065; NRS 453.056.

54. It is unlawful to furnish drugs without a prescription. NRS 454.221.

55. "Furnish" means to supply by any means, by sale or otherwise. NRS 454.006.

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COUNT ONE
Permitting Unlicensed Wholesale Distribution
(Respondent Arora)

56. As alleged above, Respondent Arora served as the medical director for Youth Inc.

57. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

58. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage purchases from unlicensed distributors such as GLP-1 Sciences, LLC. Respondent failed to implement such policies, procedures and protocols.

59. Given the facts and circumstances alleged above, Respondent Arora permitted the unlicensed wholesale distribution of compounded drug products in violation of NRS 639.100(1).

60. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

61. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT TWO
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondent Arora)

62. As alleged above, Respondent Arora served as the medical director for Youth Inc.

63. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered, received, possessed, and/or stored dangerous drugs and/or controlled substances. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

64. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of

Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

65. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the above persons from ordering, receiving, possessing, storing and/or furnishing dangerous drugs and/or controlled substances. Respondent Arora failed to implement such policies, procedures and protocols.

66. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the unlicensed practice of pharmacy.

67. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

68. Respondent Arora's acts and/or omissions as alleged above amount to conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(i) and (j).

COUNT THREE
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondent Arora)

69. As alleged above, Respondent Arora served as the medical director for Youth Inc.

70. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

71. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the repeated or recurring use of punctured single-use vials. Respondent failed to implement such policies, procedures and protocols.

72. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the above violations of NAC 639.050(2).

73. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

74. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FOUR
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondents Gifford, McIntyre and Jaggard)

75. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

76. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of injectable drugs contained within single-use vials.

77. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard had a duty to ensure that Youth Inc. did not make repeated or recurring uses of punctured single-use vials.

78. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that Youth Inc. did not return single-use vials to stock after the vials were punctured.

79. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard assisted or abetted in the above violations of NAC 639.050(2).

80. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

81. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FIVE
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondents Gifford, McIntyre and Jaggard)

82. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

83. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

84. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that dangerous drugs and/or controlled substances were administered under the direction or supervision of a practitioner. Dangerous drugs and/or controlled substances were not administered under the direction or supervision of a practitioner.

85. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard assisted or abetted the unlicensed practice of pharmacy by Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank.

86. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

87. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT SIX
Failure to Establish a Bona Fide Therapeutic Relationship with Patients
(Respondents Gifford, McIntyre and Jaggard)

88. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

89. Respondent Gifford, Respondent McIntyre and Respondent Jaggard never saw or spoke with the above patients for whom they authorized treatments with dangerous drugs and/or controlled substances.

90. Having failed to see or speak with the above patients, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard failed to establish a bona fide therapeutic relationship with the above patients prior to authorizing their initial treatments with dangerous drugs and/or controlled substances.

91. Respondents' conduct as alleged above amounts to unprofessional conduct and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(n).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondent Sean Arora, Respondent Cassie Gifford, Respondent Gabrielle McIntyre, and Respondent Allison Jaggard.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondent.**	**Case No. 24-509-PR-C-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondent.**	**Case No. 24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Allison Jaggard, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sean Arora, MD
c/o Youth Inc
691 Sierra Rose Dr
Reno, NV 89511

Cassie Gifford, APRN
c/o Bionetics Health
5540 S Fort Apache Rd #120
Las Vegas, NV 89148

Gabrielle McIntyre, APRN
c/o Restore Hyper Wellness
1550 N Green Valley Pkwy., Ste 300
Henderson, NV 89074

Allison Jaggard, APRN
1708 Spring Green Blvd Ste 120-109
Katy, TX 77494

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
AUG 15 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos.** **24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENTS**

Respondents Sean Arora, M.D., Cassie Gifford, APRN, Gabrielle McIntyre, APRN, and Allison Jaggard, APRN, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-5

Paragraph 1: Dr. Arora acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation to the extent that the matter pertains to controlled substances as he holds a controlled substance registration issued by the Board.

Paragraph 2: Ms. Gifford acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 3: Ms. McIntyre acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 3 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 4: Ms. Jaggard acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 4 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 5: Respondents acknowledge that the Board has jurisdiction in the matter to the extent that the matter involves dangerous drugs and controlled substances. Dr. Arora acknowledges that the Board has jurisdiction over the allegations pertaining to his acts or omissions to the extent they concern controlled substances.

Factual Allegations: Paragraphs 6-37

Paragraph 6: Dr. Arora agrees with the factual allegations as set forth in Paragraph 6.

Paragraph 7: Ms. Gifford agrees with the factual allegations as set forth in Paragraph 7.

Paragraph 8: Ms. McIntyre agrees with the factual allegations as set forth in Paragraph 8.

Paragraph 9: Ms. Jaggard agrees with the factual allegations as set forth in Paragraph 9.

Paragraph 10: Dr. Arora agrees with the factual allegations set forth in Paragraph 10 only to the extent that he entered into an independent contractor agreement with We Treat, LLC in 2024.

Paragraph 11: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 11 as to the types of services which were provided to Youth Inc. However, to the best of Respondents' knowledge, Youth Inc. did receive services from

We Treat related to medical clearances for patients, policies and protocols and compliance information.

Paragraph 12: Dr. Arora agrees with the factual allegations set forth in Paragraph 12 only to the extent that he reviewed and approved policies and protocols directly related to the provision of certain medical services. Dr. Arora was not involved, nor did he review or approve, policies and procedures related to any other matters involving Youth, Inc.

Paragraph 13: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 13.

Paragraph 14: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 14.

Paragraph 15: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 15.

Paragraph 16: Dr. Arora acknowledges that as part of his duties for We Treat, he was assigned as medical director for Youth, Inc. in approximately April 2024. Dr. Arora's duties as medical director included the review and approval of protocols for certain medical treatments performed at Youth, Inc., responding to patient specific questions from the clinic, and authorization of the ordering of certain dangerous drugs, to be done in accordance with compliance policies prepared by We Treat.

Paragraph 17: Dr. Arora agrees with the factual allegations contained in Paragraph 17 to the extent that he provided services to We Treat until January 2025, services which included acting as medical director for Youth,. Inc., which were limited to the duties set forth in the response to Paragraph 16.

Paragraph 18: Dr. Arora acknowledges that he was based in Seattle, Washington and that his duties for Youth, Inc. did not require him to be physically at Youth, Inc.'s location.

Paragraph 19: Respondent's Gifford, McIntyre, and Jaggard deny the factual allegations set forth in Paragraph 19. None of the named Respondents were engaged by Youth, Inc. to provide any services. All three Respondents were employees/independent contractors of We Treat which provided medical clearance screening of patients for Youth, Inc. through Nevada licensed practitioners.

Paragraph 20: Respondents Gifford, McIntyre, and Jaggard acknowledge that they reviewed and medically cleared patients for treatments performed at Youth, Inc. pursuant to medical protocols reviewed and approved by Dr. Arora and performed these reviews in accordance with policies and protocols developed and approved by We Treat, not Dr. Arora.

Paragraph 21: Respondents Gifford, McIntyre and Jaggard acknowledge that they medically cleared patients, if appropriate, after the review of medical information and authorized treatments to be performed pursuant to protocols approved by Dr. Arora which included standing orders for administration of certain drugs or the issuance of prescriptions pursuant to those protocols. No approved protocols for treatments authorized the administration of controlled substances at Youth, Inc.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 22.

Paragraph 23: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 23.

Paragraph 24: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 24.

Paragraph 25: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 25.

Paragraph 26: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 26.

Paragraph 27: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 27.

Paragraph 28: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 28.

Paragraph 29: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 29.

Paragraph 30: Dr. Arora acknowledges that he would periodically review orders received for dangerous drugs and would sign, remotely for the same. Drugs were to be stored and accessed in accordance with policies and protocols developed by We Treat; Dr. Arora was not part of the development of those policies and procedures, nor was he asked to review them by We Treat. Dr. Arora denies that he ever signed off or approved of any shipments of controlled substances to Youth, Inc. and to his knowledge, no controlled substances were to be received or stored on-site at We Treat.

Paragraph 31: Dr. Arora denies the factual allegations contained in Paragraph 31, however he acknowledges that he would respond to patient specific questions posed to him and would review patient records at that time; however this occurred very rarely.

Paragraph 32: Dr. Arora denies the factual allegations contained in Paragraph 32. Dr. Arora was not responsible for the policies and procedures related to the procurement, storage, possession and/or administration of dangerous drugs or controlled substances other than approving

protocols directly related to the provision of medical services. We Treat's compliance department was solely responsible for the policies and protocols otherwise related to dangerous drugs and controlled substances.

Paragraph 33: Dr. Arora denies the allegations set forth in Paragraph 33.

Paragraph 34: Dr. Arora denies the allegations set forth in Paragraph 34.

Paragraph 35: Dr. Arora denies the allegations set forth in Paragraph 35.

Paragraph 36: Dr. Arora denies the allegations set forth in Paragraph 36.

Paragraph 37: Dr. Arora denies the allegations set forth in Paragraph 37 as he was not involved in, nor responsible for the receipt, possession storage, and distribution of dangerous drugs or controlled substances at Youth, Inc.

Applicable Law: Paragraphs 38-55

Paragraph 38-55: Respondents acknowledge that Paragraphs 38-55 accurately reflect the basic substance of the statutes and regulations cited therein.

Counts: Paragraphs 56-91

Count One (Paragraphs 56-61): Dr. Arora generally denies the allegations set forth in Count One in Paragraphs 56-61. Dr. Arora did not permit Youth, Inc. or any of its personnel to order any dangerous drugs from any manufacturer or supplier not licensed in Nevada. As discussed herein, Dr. Arora's duties for Youth, Inc. were limited to the review and authorization of protocols related to medical procedures. While Youth, Inc. was authorized to order supplies and dangerous drugs under Dr. Arora's credentials, this was to be done in accordance with policies and protocols developed and approved by We Treat's compliance department. To the best of Dr. Arora's knowledge, no client of We Treat was authorized to order or received dangerous drugs or other supplies from unlicensed suppliers/manufacturers.

Count Two (Paragraphs 62-68): Dr. Arora generally denies all allegations set forth in Count Two in Paragraphs 62-68. Further Dr. Arora asserts that a practice which orders, receives, and stores dangerous drugs is not engaging in the practice of pharmacy as alleged. If indeed this was accurate, every medical practice or facility that orders, receives and stores drugs for administration and/or dispensing, would be required to hold a pharmacy license with the Board; that is not currently a requirement and NRS 639.0124(1)(a) is inappropriately applied here.

Count Three (Paragraphs 69-74): Dr. Arora generally denies the allegations set forth in Count Three in Paragraphs 69-74. Again, as discussed herein, Dr. Arora's duties for Youth, Inc. were limited and did not include the development or approval of any protocols or procedures related to the procurement or storage of dangerous drugs. Dr. Arora's medical service protocols did not allow for the reuse of single use vials and any reuse of single use vials on the part of Youth, Inc. personnel would have been done without the knowledge of Dr. Arora and he did not aid or abet any violation of NAC 639.050(2).

Count Four (Paragraphs 75-81): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Four in Paragraphs 75-81. Respondents Gifford, McIntyre, and Jaggard, worked for We Treat, not Youth, Inc. Respondents' duties for Youth, Inc. were limited to conducting medical clearance reviews for patients and if cleared, the patient was authorized for treatment pursuant to approved medical protocols. None of the named respondents were responsible for supervising the staff of Youth, Inc. and would have had no knowledge of unauthorized reuse of single use vials by any personnel associated with Youth, Inc.

Count Five (Paragraphs 82-87): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Five in Paragraphs 75-81. The administration of dangerous drugs to patients is not the practice of pharmacy as defined by NRS 639.0124(1)(a) and

accordingly Respondents could not have aided or abetted in the violation of said statute. Again, as discussed above, should the Board take the position that the administration of a dangerous drug constitutes the practice of pharmacy, all practices and facilities at which any drug is administered would be required to hold a registration as a pharmacy with the Board which is not currently required.

Count Six (Paragraphs 88-91): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Six in Paragraphs 88-91.

NOTICE OF DEFENSE/MITIGATING INFORMATION

In regard to Respondent Arora, Dr. Arora stresses that his involvement with We Treat was limited as medical director. The term "medical director" is not defined under Nevada law and there is no legal precedent for what the duties of a medical director must consist of. Dr. Arora functioned as a medical director per the duties he had as a contractor for We Treat, LLC, which consisted solely of the review and authorization of protocols for medical services offered at practices contracted with We Treat and he was required to be available for consultations regarding specific patient questions as needed. The medical protocols authorized by Dr. Arora included standing orders for the administration of certain dangerous drugs and for the prescription of certain controlled substances. It should be noted that Dr. Arora never authorized the administration of controlled substances at Youth, Inc., or any other practice for which he provided services under We Treat and to his knowledge, no controlled substances were stored on-site at Youth, Inc.

We Treat's compliance department was responsible for the development and authorization of all other policies and protocols, including those related to the procurement, receipt, and storage of dangerous drugs. Dr. Arora was advised by We Treat that all policies and protocols were reviewed and vetted for compliance with the laws in each individual state in which We Treat had

clients. Dr. Arora had no reason to doubt the assurances made by We Treat that the policies and protocols for Youth, Inc. were in compliance with Nevada law.

In regard to Respondents Gifford, McIntyre, and Jaggard, all three were employees/contractors with We Treat during the times in question. Their duties were to provide medical clearance reviews for patients wishing to receive services at practices which were contracted with We Treat and if cleared, authorize treatment to be provide pursuant to previously approved medical protocols. Respondents had no duties related to the oversight or supervision of any practice served by We Treat. Respondents would be notified through a proprietary platform that a patient required a medical clearance evaluation at practices which received services from We Treat and would be given access to the patient records through the We Treat platform and would either clear the patient for treatment or deny treatment[1]. Each clinic had individual protocols which would be followed by Respondents. Respondents were informed by We Treat that policies related to requirements for providing medical clearance for patients was vetted by its compliance department and all protocols were in compliance with state laws; Respondents had no reason to question the representations of We Treat.

Respondent Gifford estimates that she performed very few medical clearance evaluations for Youth, Inc. through the We Treat platform. Respondent McIntyre estimates that she did approximately two medical clearance evaluations for Youth, Inc. Respondent Jaggard estimates that she did a maximum of ten to fifteen medical clearance evaluations for Youth, Inc.

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[1] We Treat practitioners only performed medical clearance evaluations for patients in states in which they were licensed.

All Respondents deny having violated NRS and/or NAC Chapters 453, 454, or 639. Further Respondents reserve all legal defenses available to them should this matter proceed to a hearing.

Respectfully submitted this 15th day of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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FILED
JUN - 9 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **QUI THAI, MD,** **Certificate of Registration No. CS13843,** **Respondent.**	**Case No. 22-476-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Qui Thai, MD ("Respondent") held a registration issued by the Board, Certificate of Registration No. CS13843.

FACTUAL ALLEGATIONS

2. Respondent is licensed by the Nevada State Board of Medical Examiners to practice medicine. At the time of the violations alleged herein, Respondent was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

3. Since September 25, 2016, through present, Respondent has held a certificate of registration issued by the Board pursuant to NRS 453.226. This certificate of registration authorized Respondent to prescribe controlled substances. Respondent's current certificate of registration was renewed November 1, 2024, and is set to expire October 31, 2026.

4. On February 21, 2017, Respondent established an account with Nevada's Prescription Monitoring Program (PMP). The account provided Respondent with individual access

to the PMP database, a confidential source of information concerning all prescriptions written in Nevada for controlled substances.

5. According to the Board's records, between February 21, 2017, through the present, Respondent never accessed the PMP database to review his own prescribing activity. Also, according to the Board's records, between February 21, 2017, and November 15, 2022, Respondent never accessed the PMP database to evaluate the prescription histories of the patients for whom he prescribed controlled substances.

6. Between February 21, 2017, and March 20, 2025, Respondent wrote 14,051 prescriptions for controlled substances, including refills for 1,295 unique patients. Of those, between February 21, 2017, and November 15, 2022, Respondent wrote prescriptions for controlled substances for 1,075 unique patients.

APPLICABLE LAW

7. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. NRS 453.056.

8. Every practitioner who intends to prescribe controlled substances in Nevada must first apply for and obtain a certificate of registration from the Board. NRS 453.226(1); NRS 453.231(3). The practitioner must renew the certificate of registration on a biennial basis. *Id.* A practitioner who fails to register or renew may be subject to criminal and/or civil penalties for prescribing controlled substances without a certificate of registration. NRS 453.232; NRS 453.553; NRS 453.5531.

9. When a practitioner first obtains a certificate of registration to prescribe controlled substances, the practitioner must enroll in the PMP and complete a course of instruction concerning the use of the PMP database. NRS 453.164(5) & (6); NAC 453.065.

10. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the

controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

11. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

12. The Board may revoke or suspend the registration of any practitioner who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

13. The Board may revoke or suspend the existing registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

14. A practitioner's conduct is deemed unprofessional and/or contrary to the public interest if the practitioner performs his or her duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

15. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon the practitioner. The fine may not exceed $10,000 for each offense. NRS 639.255(1)(f) and (3).

COUNT ONE

Noncompliance with Prescription Monitoring Program

16. As alleged above, between February 21, 2017, and November 15, 2022, Respondent failed to query the PMP database regarding his patients' histories of using controlled substances. The PMP database compiles a controlled substance utilization report for any practitioner who makes such a query. The controlled substance utilization report provides the

practitioner with evidence as to whether a patient is doctor-shopping and/or abusing controlled substances.

17. As alleged above, between February 21, 2017, through the present, Respondent failed to query the PMP database regarding his own prescriber activity. The PMP database compiles a report of prescribing activity for any practitioner who makes such a query. This allows the practitioner to evaluate whether anyone has fraudulently used the practitioner's credentials to prescribe controlled substances.

18. As alleged above, between February 21, 2017, and March 20, 2025, Respondent wrote 14,051 prescriptions for controlled substances, including refills, for 1,295 unique patients. Of those, between February 21, 2017, and November 15, 2022, Respondent wrote prescriptions for controlled substances for 1,075 unique patients.

19. By failing to query the PMP database to review his patients' utilization report prior to issuing a prescription for a controlled substance, and by failing to review his own prescriber activity on a semi-annual basis, Respondent violated NRS 453.164(7) and NRS 639.23507. These are violations of state law and acts that render Respondent's Nevada controlled substance registration inconsistent with the public interest. Therefore, the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 639.255(3), NRS 453.236(1)(d) and (e), and NRS 453.241(1).

COUNT TWO

Unprofessional Conduct by a Practitioner

20. As alleged above, between February 21, 2017, and November 15, 2022, Respondent failed to query the PMP database regarding his patients' histories of using controlled substances.

21. As alleged above, between February 21, 2017, through the present, Respondent failed to query the PMP database regarding his own prescriber activity.

22. As alleged above, between February 21, 2017, and March 20, 2025, Respondent wrote 14,051 prescriptions for controlled substances, including refills, for 1,295 unique patients.

23. As alleged above, between February 21, 2017, and November 15, 2022, Respondent wrote prescriptions for controlled substances for 1,075 unique patients.

24. By failing to query the PMP database to review his patients' utilization report prior to issuing a prescription for a controlled substance, and by failing to review his own prescriber activity on a semi-annual basis, Respondent performed his duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner.

25. As alleged above, Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4); NAC 639.945(1)(i).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Qui Thai.

DATED this 9th day of June 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **QUI THAI, MD,** **Certificate of Registration No. CS13843,** **Respondent.**	**Case No. 22-476-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, July 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of June 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **QUI THAI, MD,** **Certificate of Registration No. CS13843,** **Respondent.**	**Case No. 22-476-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

QUI THAI, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 18th day of June 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Qui Thai, MD
[redacted]
Las Vegas, NV [redacted]

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

FILED
JUL 21 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** v. **QUI THAI, MD,** **Certificate of Registration No. CS13843,** **Respondent.**	**Case No. 22-476-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

None.

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I admit that between February 21, 2017, and November 15, 2022, I had unintentionally failed to query the PMP database regarding my patients' histories of using controlled substances, and that between February 21, 2017, through 2024 I unintentionally failed to query the PMP database regarding my own prescriber activity, both due to my misunderstanding of the PMP laws.

However, I deny that I failed to query the PMP database regarding "refills" because it is my custom and practice to never prescribe refills for narcotics. I also deny that I failed to query my own prescriber activity in 2025, because I recently did so in 2025, prior to receiving the Notice of Intended Action and Accusation. I also deny that my failure to comply with the PMP laws constituted unprofessional conduct for the reasons set forth below. In response to the allegations against me, I offer the following assertions for the Board's consideration:

At the outset I express my sincere apology to the Board that I misunderstood Nevada's statutory requirements to query the PMP database. I agree that my practice was in violation of NRS 639.23507 and NRS 453.164(7) due to my unfamiliarity with the Nevada PMP statutes.

I am a primary care physician board certified in Internal Medicine, and my practice also involves treatment of elderly patients at areas skilled nursing facilities who often require a greater frequency of controlled substances prescriptions than the average patient population. My practice has always been centered on a very strong physician-patient relationship, in which I spend time with each patient to carefully assess them for "red flags" that may indicate substance use disorder and/or diversion of controlled substances. This is why I do not prescribe refills for narcotics – I want to personally evaluate each patient prior to prescribing narcotics. I have implemented urine drug screens, referrals to pain management specialists or orthopedists, and have terminated the physician-patient relationship when indicated. I am proud that during my entire career, (including the subject time period of 2017 to present), none of my patients have experienced any adverse outcomes due to my prescriptions of controlled substances. Similarly, to my knowledge, none of my patients have experienced any criminal investigation or prosecution for controlled substances diversion. I believe this track record is the result of my careful clinical screening of each patient prior to any prescription of a controlled substance, in combination with the strong physician patient relationship I have created with each patient.

I also treat each patient as an individual, and do not practice any regimented "one size fits all" practice for medication selection or dosing. My customary practice to "start low, and go slow," often by prescribing opioids at the lowest dose and lowest frequency – such as only on an "as needed basis" for breakthrough pain in combination with NSAIDs, instead of on a daily scheduled basis. The PMP reports in Attachment E of the Board's investigative file produced to me evidence this, because the daily dose MME for those patients ranged between

7.5 and 45 MME, with an average of only 34.5 MME.[1] Further, the PMP reports in the investigative file also include "NARX scores" created by Bamboo Health. Mindful that NARX scores cannot be viewed in isolation for clinical decision making, the Board may note that most of my patients' NARX narcotics scores were below 200, representing the range of 75% of all prescriptions. None of these patients had a NARX narcotics score or overdose risk score above 300. Further, none of the sample reports evidence any instances of my patients obtaining duplicative pain medication prescriptions from other providers.

After referring my patients to specialists, I later learned that other than increasing the dosage and/or frequency of controlled substance prescriptions, their treatment plans often remain the same as mine. Again, this information is provided to the Board as evidence of my very careful and very conservative practices in prescribing controlled substances.

Unfortunately, like many other practitioners, I have not kept pace with developments in the Nevada laws applicable to prescribing controlled substances because my focus has always been the subject of medicine and not law. I have practiced internal medicine for decades and maintained my customary prescribing practices while unintentionally misunderstanding the laws enacted regarding the PMP. My prescribing practices during the subject time-period were analogous to driving a car safely along a road, but inadvertently missing a change in speed sign indicating a slower speed is required. I simply did not fully understand the sign advising when PMP queries were required, I again apologize to the Board, and stress that I would have changed my practices sooner if I had fully understood the sign. Yet despite my misunderstanding the sign, I continued to drive very safely based on decades of cautious and conservative prescribing practices, and no adverse patient events have occurred.

I would also point out that the frequency of my PMP queries has increased over the past two years, and prior to the filing of the Notice of Intended Action and Accusation. In other

[1] *See* Patient ML 45 MME at page 31; Patient KC 45 MME at page 36; Patient JW 7.5 MME at page 41; Patient AL 30 MME at page 31; and Patient HW 45 MME at page 54.

words, I have taken affirmative steps to bring myself into compliance with the PMP laws prior to the Board of Pharmacy alerting me of its concerns.

I do not consider my lack of familiarity with the Nevada statutes referenced in the Notice of Intended Action and Accusation to be a rare occurrence, because it is my understanding that many other practitioners are also unfamiliar with their obligations to query the PMP. It has been reported that across the nation a large percentage of practitioners do not always query the PMP even when state laws require that they do so:

> In many jurisdictions, health care providers are not aware that a PMP exists where they practice, or similarly, some are aware of PMPs but do not know how to make use of the data in their practice. For example, **in a recent study of physicians in jurisdictions with PMPs from across the United States, approximately 72% of providers knew that a PMP was present in their jurisdiction, but only 53% reported actually using one of the programs**.
> …
> We completed a systematic review to, first, determine what proportion of health care providers access and use PMP data in their practice in jurisdictions where a PMP is available, and second, identify common barriers to accessing PMP data that have been identified by health care providers. …
> …
>
> **Prevalence of PMP Data Use**
>
> Among the 46 included studies (131,587 participants) reporting data use, the most common outcome reported was the proportion of prescribers or dispensers who have "ever" used PMP data. This outcome was reported in 26 studies representing 30 unique prescriber/dispenser groups (107,998 participants), with proportions of "ever use" of PMP data ranging from 0.08 to 1.00 (Figure 2) [23–25, 27, 28, 39–591. **Overall, the pooled proportion of health care providers who have ever used PMP data was 0.57** (95% CI: 0.48–0.66). Among the health care providers included in these studies, physicians and pharmacists were the two specific groups studied most often, in fourteen and seven studies, respectively. The pooled proportions of **physicians (0.63**; 95% CI: 0.43–0.81) and pharmacists (0.57; 95% CI: 0.41–0.73) ever using PMP data did not differ significantly. There were no observable differences in data use by year of study publication. …
> …
> Across these 11 studies, there was a low percentage of health care providers who always used PMP data when making prescribing or dispensing decisions, **ranging from 0% to 68%** (mean [SD1: 18.7% [18.4%1).

Robinson, A. et al., *Health Care Provider Utilization of Prescription Monitoring Programs: A Systematic Review and Meta-Analysis,* 22(7) Pain Medicine 1570-15982 (2021) (emphasis added and in original), attached as Exhibit A.

The laws of the State of Kentucky are similar to the State of Nevada, requiring PMP query with each controlled substance prescription under penalty of discipline. Yet it has been reported that after Kentucky law mandated PMP query, approximately half of primary care physicians still did not check the PMP:

> The [PMP] law requires all providers licensed to prescribe controlled substances to register with the state's PDMP, the Kentucky All Schedule Prescription Electronic Reporting system (KASPER). Providers are also required, with limited exceptions, to query KASPER for a report before prescribing to new patients and to query every three months for continuing patients. Failure to comply can result in disciplinary action, including emergency suspension or restriction of the provider's license.
> …
> Exhibit 3 also reports the share of prescriptions queried in the pre- and postmandate periods for each characteristic, as well as raw and regression-adjusted differences. Among provider specialties, **the share of prescriptions queried increased most among primary care physicians** (48 percentage points, **to 56 percent**)… Shares of prescriptions queried were low in both the pre and post periods for low-volume prescribers; those who prescribed to fewer than five patients per month only queried for 2 percent of prescriptions before the mandate and **20 percent after.**
> …
> By the late post period there were continued reductions in opioid prescribing, particularly among high-risk patients. The reduction in prescribing to the high-risk category was driven almost entirely by providers who queried at least half the time. These reductions suggest that many formerly high-risk patients transitioned to "chronic" status or stopped taking opioids altogether by the late post period (see the transition matrix in appendix exhibit S8). **However, the high-risk patient group continued to receive about the same number of prescriptions from providers who queried less than half the time.** …
> …
> Our analysis of administrative data does not reveal why providers did not query all required prescriptions.

Carey, C. et al., *Provider Compliance With Kentucky's Prescription Drug Monitoring Program's Mandate to Query Patient Opioid History* 40(3) Health Affairs 461-464 (2021) (emphasis added), enclosed as Exhibit B.

Similarly, in the State of Minnesota all controlled substance prescribers are required to make accounts and search the PDMP before writing most controlled substance prescriptions, yet has been reported that "many did not:"

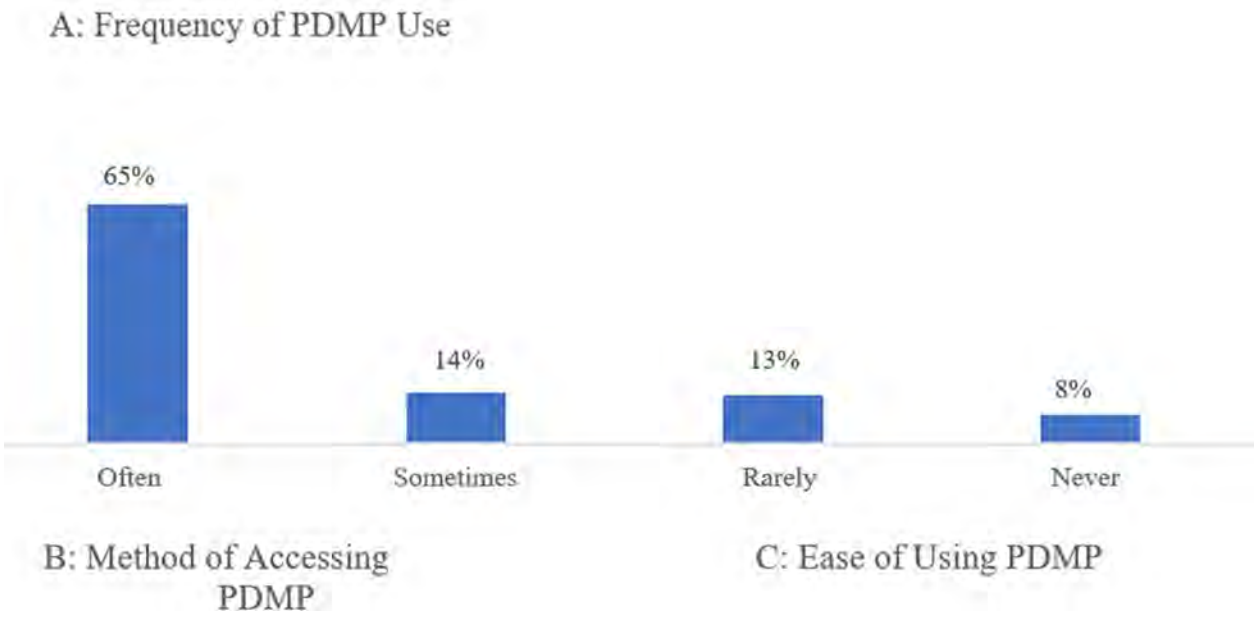
> We obtained data on the universe of Minnesota controlled substance prescribing, PDMP searches, and PDMP accounts from the Minnesota Prescription Monitoring Program. We then analyzed PDMP search and account-holding by prescriber characteristics for the 180-day period starting February 1, 2023. …
> …

> There were 16 378 clinicians who prescribed opioids (Table 1). A slim majority were physicians and one-third were nurse practitioners or physician assistants. The average prescriber supplied 747 days of opioids to 31.9 distinct patients. **While most opioid prescribers engaged with the PDMP, many did not: 4 in 10 did not search the PDMP during this period and 2 in 10 did not hold an account. … 32.2% of opioid fills and 11.1% of opioid days came from clinicians who never searched the PDMP.**
>
> **…**
>
> Most clinicians are aware of the risks of opioid prescribing and prescribe opioids safely. Still, we found that a group of clinicians continues to prescribe opioids without using the tools available and required to ensure safe prescribing. **The overrepresentation of low-volume prescribers in this group may reflect a lack of information about state mandates.**

Sacarny, A., *Prescription Drug Monitoring Program Use By Opioid Prescribers: A Cross-Sectional Study* 1(6) Health Affairs Scholar 1-3 (2023) (emphasis added), enclosed as Exhibit C.

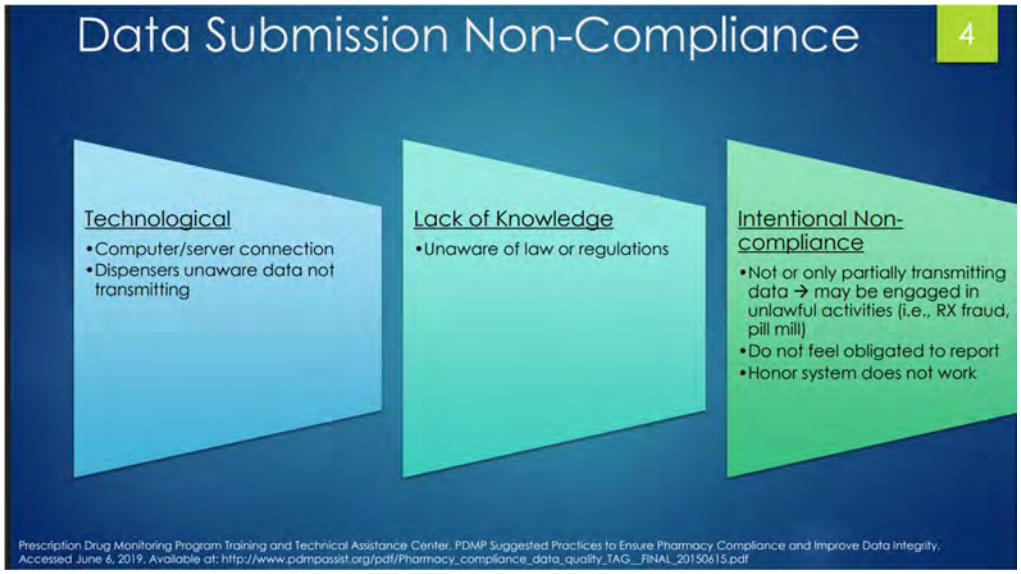
A study of PMP compliance by medical specialty in the State of Washington, which studied 17,390 providers who prescribed opioids to Medicaid beneficiaries, found that overall 50% had not registered with the PMP, 27% registered with but had no recorded use of the PMP, and 23% used the PMP. Focusing on General Medicine practitioners, it found only 31.1% queried its PMP, however 31% were registered but had never used the PMP, and 37.9% were not even registered with the PMP- the latter two values combined totaling 68.9%. Sun, B. et al., *Variations in Prescription Drug Monitoring Program Use by Prescriber Specialty* 94 J. Subst. Abuse Treat. 35-40 at Table 1 (2018), enclosed as Exhibit D.

A study based on a nationwide survey of 1,524 office-based physicians, (the majority of which were primary care practitioners), concluded **less than two-thirds of office-based physicians in the USA reported frequent use of their state PDMP**:



Richwine, C., et al., *National Estimates and Physician-Reported Impacts of Prescription Drug Monitoring Program Use* 38(4) J. Gen. Intern. Med. 881 and Fig. 1 (Published online October 13, 2022) enclosed as Exhibit E.

Based on the reports above, between one third and two thirds of all prescribers are not frequently querying their PMP in various states. The most likely reason for this is that they, like me, had a lack of understanding of the mandates of state law. I would add that a lack of knowledge of PMP laws has not been confined to prescribers, but was also found in a 2019 study to have been the cause of a 24% error rate by dispensing pharmacists in Nevada:



Zarley, D., *PMP Data Quality and Pharmacy Compliance* at 4, 18 (June 27, 2019)(accessed June 26, 2024 at: https://www.pdmpassist.org/Content/Documents/pdf/27B2_Zarley.pdf), enclosed as Exhibit F.

To my knowledge, the PMP compliance rate for Nevada prescribers has not been published or otherwise been made publicly available. Nevertheless, a review of settlements posted on the Board of Pharmacy meeting agendas confirms I am not alone in my lack of understanding of the PMP statutes or compliance with same. During legislative meetings discussing Assembly Bill 474 in the 2017 legislative session a committee noted that despite the establishment of the PMP in 1997 and the state's initiation of mandatory review in 2015, in 2015 almost one in five (19%) of Nevada prescribers had not yet established a PMP account, and in 2017 some prescribers had still not even signed up for the PMP:

> While the State Board of Pharmacy has seen a sharp increase in the number of prescribers enrolled in the system since the passage of Senate Bill 459 of the 78th Session—from 16 percent of prescribers enrolled to 81 percent of prescribers enrolled—there are still prescribers of controlled substances who have not signed up for the system.

Minutes of the Senate Committee on Health and Human Services, Seventy-Ninth Session at 5 (May 17, 2017) enclosed as Exhibit G (accessed June 26, 2024 at: https://www.leg.state.nv.us/Session/79th2017/Minutes/Senate/HHS/Final/1185.pdf).

This likely led to the use of funding between 2015 – 2019 from the SAPG Block Grant: Funding Opportunity 003 to: "Target efforts to encourage the use of Prescription Drug Monitoring System by prescribers." *Nevada Opioid Crisis Needs Assessment: Division of Public and Behavioral Health Opioid State Targeted Response to the Opioid Crisis Grant Program* at 35 (December, 2018), enclosed as Exhibit H.

At the time AB 474 was passed in 2016 to strengthen the PMP laws, it was reported that the purpose of the law was to protect patients, and not to discipline physicians:

> The Board of Medical Examiners, which licenses the bulk of the state's doctors, said they use the reports to remind doctors to check that their patients aren't suffering from an addiction. **It would be inappropriate to use them to initiate an investigation, Cousineau said.**

> "I've talked to many doctors over the years and they've implored me, they don't want constraints, whether through statute or regulation, that limits their subjective ability to treat patients," Cousineau said.

Damon, A. et al., *Over-Prescribing Doctors Can Escape Scrutiny in Nevada* Reno Gazette Journal (May 14, 2016), enclosed as Exhibit I.

I understand that "ignorance of the law is not an excuse." I offer the above information to the Board not as an excuse, but instead as a reasonable explanation for my lack of fully understanding and complying with the Nevada PMP laws.

Respectfully however, given the reported lack of prescriber familiarity with PMP laws in Nevada and other states evidenced above, I do not consider my noncompliance to have constituted "unprofessional conduct by a practitioner" under NRS 639.210(4) or NAC 639.945(1)(i). With regard to allopathic physicians (M.D.s) in Nevada, the legislature has defined unprofessional conduct as follows:

> **NAC 630.230 Prohibited professional conduct. (NRS 630.130, 630.275)**
>
> 1. A person who is licensed as a physician or physician assistant shall not:
> (a) Falsify records of health care;
> (b) Falsify the medical records of a hospital so as to indicate his or her presence at a time when he or she was not in attendance or falsify those records to indicate that procedures were performed by him or her which were in fact not performed by him or her;
> (c) Render professional services to a patient while the physician or physician assistant is under the influence of alcohol or any controlled substance or is in any impaired mental or physical condition;
> (d) Acquire any controlled substances from any pharmacy or other source by misrepresentation, fraud, deception or subterfuge;
> (e) Prescribe anabolic steroids for any person to increase muscle mass for competitive or athletic purposes;
> (f) Make an unreasonable additional charge for tests in a laboratory, radiological services or other services for testing which are ordered by the physician or physician assistant and performed outside his or her own office;
> (g) Allow any person to act as a medical assistant in the treatment of a patient of the physician or physician assistant, unless the medical assistant has sufficient training to provide the assistance;
> (h) Fail to provide adequate supervision of a medical assistant who is employed or supervised by the physician or physician assistant, including, without limitation, supervision provided in the manner described in NAC 630.810 or 630.820;

(i) If the person is a physician, fail to provide adequate supervision of a physician assistant or an advanced practice registered nurse;

(j) Fail to honor the advance directive of a patient without informing the patient or the surrogate or guardian of the patient, and without documenting in the patient's records the reasons for failing to honor the advance directive of the patient contained therein;

(k) Engage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the policies set forth in the *Guidelines for the Chronic Use of Opioid Analgesics* adopted by reference in NAC 630.187; or

(l) Administer or use, or allow any person under his or her supervision, direction or control to administer or use, a single-use medical device:

(1) For more than one procedure;

(2) For more than one patient; or

(3) In a manner inconsistent with the manufacturer's instructions or directions included on or with the single-use medical device.

The definition above did not include a physician's inadvertent failure to query the PMP. Instead, it considers much more egregious conduct to constitute prohibited professional conduct, typically with an intentional malicious motivation.

With regard to doctors of osteopathic medicine (D.O.s) in Nevada, the legislature has defined unprofessional conduct, in pertinent part, as follows:

NRS 633.131 - "Unprofessional conduct" defined.

1. "Unprofessional conduct" includes:

(a) Knowingly or willfully making a false or fraudulent statement or submitting a forged or false document in applying for a license to practice osteopathic medicine, to practice as a physician assistant or to practice as an anesthesiologist assistant, or in applying for the renewal of a license to practice osteopathic medicine, to practice as a physician assistant or to practice as an anesthesiologist assistant.

(b) Failure of a person who is licensed to practice osteopathic medicine to identify himself or herself professionally by using the term D.O., osteopathic physician, doctor of osteopathy or a similar term.

(c) Directly or indirectly giving to or receiving from any person, corporation or other business organization any fee, commission, rebate or other form of compensation for sending, referring or otherwise inducing a person to communicate with an osteopathic physician in his or her professional capacity or for any professional services not actually and personally rendered, except as otherwise provided in subsection 2.

(d) Employing, directly or indirectly, any suspended or unlicensed person in the practice of osteopathic medicine or in practice as a physician assistant or anesthesiologist assistant, or the aiding or abetting of any unlicensed person to

practice osteopathic medicine or to practice as a physician assistant or anesthesiologist assistant.
(e) Advertising the practice of osteopathic medicine in a manner which does not conform to the guidelines established by regulations of the Board.
(f) Engaging in any:
(1) Professional conduct which is intended to deceive or which the Board by regulation has determined is unethical; or
(2) Medical practice harmful to the public or any conduct detrimental to the public health, safety or morals which does not constitute gross or repeated malpractice or professional incompetence.
(g) Administering, dispensing or prescribing any controlled substance or any dangerous drug as defined in chapter 454 of NRS, otherwise than in the course of legitimate professional practice or as authorized by law.
(h) An alcohol or other substance use disorder.
(i) Performing, assisting in or advising an unlawful abortion or the injection of any liquid silicone substance into the human body, other than the use of silicone oil to repair a retinal detachment.
(j) Knowingly or willfully disclosing a communication privileged pursuant to a statute or court order.
(k) **Knowingly or willfully disobeying regulations** of the State Board of Health, the State Board of Pharmacy or the State Board of Osteopathic Medicine.
(l) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any prohibition made in this chapter.
(m) Failure of a licensee to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient.
(n) Making alterations to the medical records of a patient that the licensee knows to be false.
(o) Making or filing a report which the licensee knows to be false.
(p) Failure of a licensee to file a record or report as required by law, or knowingly or willfully obstructing or inducing any person to obstruct such filing.
(q) Failure of a licensee to make medical records of a patient available for inspection and copying as provided by NRS 629.061, if the licensee is the custodian of health care records with respect to those records.
(r) Providing false, misleading or deceptive information to the Board in connection with an investigation conducted by the Board.

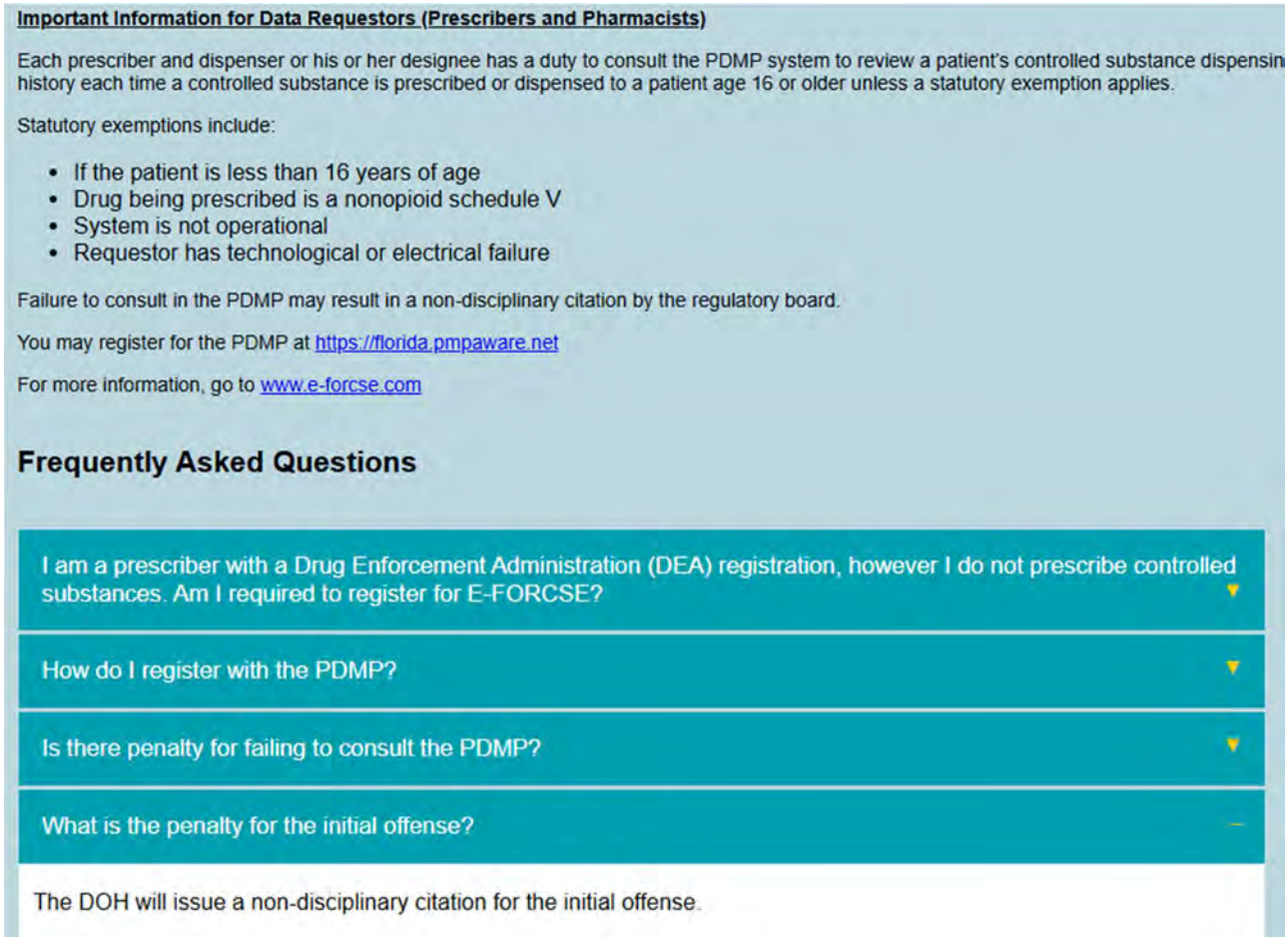
(Emphasis added.)

The statute above only considers a willful and knowing violation of regulations of the State Board of Pharmacy to constitute professional conduct, and an inadvertent failure to query the PMP due to misunderstanding the law was not included in the definition. Again, I admit that I unknowingly violated NRS 639.23507 and NRS 453.164(7) due to my unfamiliarity with the Nevada statutes, but I stress that my violation was not a willful or knowing violation. Further,

as previously stated, prior to my receipt of the notice of accusation I had already increased my compliance with the PMP laws as I became more familiar with them, evidencing that I did not willfully or knowingly intend to continue the inadvertent violation.

My concern is that a finding of "professional misconduct" against me could be misinterpreted by the medical community and public and jeopardize my ability to continue primary care services to my patients.

Other states including Florida, (which has also imposed mandatory consultation of its PMP), do not impose a disciplinary sanction as a penalty for the initial offense of failure to consult its PMP. Instead, for an initial offense a non-disciplinary citation is given:



Important Information for Data Requestors (Prescribers and Pharmacists)

Each prescriber and dispenser or his or her designee has a duty to consult the PDMP system to review a patient's controlled substance dispensin history each time a controlled substance is prescribed or dispensed to a patient age 16 or older unless a statutory exemption applies.

Statutory exemptions include:

- If the patient is less than 16 years of age
- Drug being prescribed is a nonopioid schedule V
- System is not operational
- Requestor has technological or electrical failure

Failure to consult in the PDMP may result in a non-disciplinary citation by the regulatory board.

You may register for the PDMP at https://florida.pmpaware.net

For more information, go to www.e-forcse.com

Frequently Asked Questions

I am a prescriber with a Drug Enforcement Administration (DEA) registration, however I do not prescribe controlled substances. Am I required to register for E-FORCSE?

How do I register with the PDMP?

Is there penalty for failing to consult the PDMP?

What is the penalty for the initial offense?

The DOH will issue a non-disciplinary citation for the initial offense.

Florida Prescription Drug Monitoring Program (2025)(accessed July 2, 2025 at: https://flhealthsource.gov/FloridaTakeControl/pdmp/), attached Exhibit J.

Nevada is in a healthcare crisis, and is in dire need of its primary care physicians:

> With a population of over 3 million people and with one of the biggest entertainment capitals in the world, Las Vegas, the state of Nevada still faces a healthcare crisis. Out of the 50 states in America, **Nevada is currently ranked forty-eighth for the number of primary care doctors available for 100,000 Nevadans** and ranked forty-ninth for the number of general surgeons available for 100,000 Nevadans. …
>
> Current research has shown that there is a higher probability of a healthy community when there are more primary care physicians available for the general population. Concurrently, an increase in the number of primary care physicians has also been shown to lower the frequency of patients presenting to the emergency department or hospital. One study assessed the association between the severity of cardiovascular disease and access to primary care. It concluded that the readmission rate for cardiovascular patients was 33.3% for those who had challenges receiving preventative care, which is significantly higher than the 17.9% readmission rate for patients who had access to primary care. **For patients in Nevada, many may wait up to or even longer than one month just to see their primary care physicians.**

Do K, Do J, Kawana E, et al. *Nevada's Healthcare Crisis: A Severe Shortage of Physicians and Residency Positions* Cureus 15(7): e41700. DOI 10.7759/cureus.41700 (July 11, 2023) (emphasis added), attached as Exhibit K.

In my opinion, Count Two – Unprofessional Conduct by a Practitioner should not have been charged against me, given that Count One already pled Noncompliance with Prescription Monitoring Program.[2] By pleading two counts against me for the same violation, it appears as though the Board is seeking to discipline me twice for the same offense. Respectfully, such an aggressive approach is unwarranted where, as here, I did not willfully violate the PMP laws, none of my patients were harmed, and I was trying to do better before receiving the accusation.

In closing, I wish to stress to the Board that I always concern myself with the best interests of my patients. I acknowledge that Nevada's PMP laws exist for the protection of my patients, and I wish that I had fully understood these laws sooner. I am open to the suggestion of additional education to further my knowledge of PMP requirements to optimize my

[2] Neither NRS 453.164(7) nor NRS 639.23507 state that a failure to query the PMP subjects a prescriber to discipline, evidencing the legislature's intention for board to impose a non-disciplinary citation for violation. Nevertheless, for purposes of reporting potential discipline against me, Count One would likely cause me fewer challenges to my practice of medicine.

compliance moving forward. I thank the Board for its time and consideration of the above, and I will strictly adhere to all requirements that may be imposed on me due to my past unintentional noncompliance.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 14th day of July, 2025.

QUI THAI, MD

EXHIBIT A

EXHIBIT A

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Review Article

Health Care Provider Utilization of Prescription Monitoring Programs: A Systematic Review and Meta-Analysis

Alysia Robinson, MSc,* Maria N. Wilson, MSc,* Jill A. Hayden, PhD,* Emily Rhodes, MSc,* Samuel Campbell, MD,† Peter MacDougall, MD,†,‡ and Mark Asbridge, PhD*,†

*Department of Community Health and Epidemiology, Dalhousie University, Halifax, Nova Scotia, Canada; †Department of Emergency Medicine, Dalhousie University, Halifax, Nova Scotia, Canada; and ‡Department of Anesthesiology, Pain Management and Peri-Operative Medicine, Dalhousie University, Halifax, Nova Scotia, Canada

Correspondence to: Mark Asbridge, PhD, Centre for Clinical Research, 5790 University Ave Rm. 407, Halifax, NS B3H 1V7, Canada. Tel: (1) 902-494-3761; E-mail: mark.asbridge@dal.ca

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Abstract

Objective. To synthesize the literature on the proportion of health care providers who access and use prescription monitoring program data in their practice, as well as associated barriers to the use of such data. **Design**. We performed a systematic review using a standard systematic review method with meta-analysis and qualitative meta-summary. We included full-published peer-reviewed reports of study data, as well as theses and dissertations. **Methods**. We identified relevant quantitative and qualitative studies. We synthesized outcomes related to prescription monitoring program data use (i.e., ever used, frequency of use). We pooled the proportion of health care providers who had ever used prescription monitoring program data by using random effects models, and we used meta-summary methodology to identify prescription monitoring program use barriers. **Results**. Fifty-three studies were included in our review, all from the United States. Of these, 46 reported on prescription monitoring program use and 32 reported on barriers. The pooled proportion of health care providers who had ever used prescription monitoring program data was 0.57 (95% confidence interval: 0.48–0.66). Common barriers to prescription monitoring program data use included time constraints and administrative burdens, low perceived value of prescription monitoring program data, and problems with prescription monitoring program system usability. **Conclusions**. Our study found that health care providers underutilize prescription monitoring program data and that many barriers exist to prescription monitoring program data use.

Key words: Prescription Monitoring Programs; Prescription Drug Monitoring Programs; Opioids; Utilization; Systematic Review

Introduction

North America and Western Europe are amid an opioid crisis. In the United States, opioids were found to account for two thirds of all drug overdose deaths, and in Canada, the rate of opioid-related deaths was found to be 7.8 per 100,000 [1, 2]. In Europe, the role of opioids in mortality is also apparent, with opioids being found in 81% of all fatal overdoses [3].

Although considerable attention has been directed to the use of illicit opioids, the crisis is strongly linked to the emergence of prescription opioids as the primary treatment modality to address acute and chronic pain over the past few decades [4–8]. As many patients with pain turned to opioids for treatment, prescription opioids, such as morphine, hydromorphone, and oxycodone, were revealed to have a high risk for abuse and potential for dependence, which has been since reflected in their classification as Schedule II controlled substances [9]. Many strategies developed to combat this crisis have, therefore, also targeted prescription opioids, with a goal

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to promote appropriate use of these medications while reducing dependence and potential for harm.

One such strategy is the implementation of prescription monitoring programs (PMPs). PMPs house prescribing and dispensing data for controlled substances from health care providers such as physicians and pharmacists. Opioids are among these controlled substances, making PMPs an important source of a patient's history of controlled substance use, but more specifically, opioid history. In most jurisdictions, PMPs can be used by health care providers when making prescribing or dispensing decisions, ensuring opioids are prescribed in appropriate quantities and when necessary, following best-practice guidelines [10] and reducing the number of individuals at risk of subsequent dependence and harm [11, 12]. PMPs also aim to regulate opioid exposure in the community by monitoring patient behaviors, such as use of multiple providers, and other potential flags for diversion of supply or misuse. Finally, PMPs monitor health care provider prescribing practices and habits and may use this information to inform and educate providers on appropriate prescribing practices [13, 14]. Variations of PMPs have been implemented in 49 states, the District of Columbia, and two territories across the United States and in nine provinces and territories across Canada [15–17]. Few distinct PMPs exist in Europe, as many jurisdictions instead integrate the functions of PMPs into their broader drug distribution systems [18].

The evidence on whether PMPs are effective in reducing inappropriate prescribing is mixed [19–21]. This may be explained by the varying use of PMPs, where there is often suboptimal use of PMP data by health care providers to inform their prescribing and dispensing decisions [22]. In many jurisdictions, health care providers are not aware that a PMP exists where they practice, or similarly, some are aware of PMPs but do not know how to make use of the data in their practice. For example, in a recent study of physicians in jurisdictions with PMPs from across the United States, approximately 72% of providers knew that a PMP was present in their jurisdiction, but only 53% reported actually using one of the programs [23]. It is important to understand the extent to which these programs are being used, and in the case that they are not being frequently used, it is also important to understand why. Health care professionals often identify the presence of too many barriers as a reason why they may not use PMPs [23–25]. Identifying and acknowledging potential barriers to PMP use is an essential first step to optimize utilization [16, 24, 26–28].

We completed a systematic review to, first, determine what proportion of health care providers access and use PMP data in their practice in jurisdictions where a PMP is available, and second, identify common barriers to accessing PMP data that have been identified by health care providers.

Methods

We used a standard systematic review approach [29], following a predefined protocol, and structured the report according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [30]. This research received ethics approval from the research ethics board at Dalhousie University.

Data Sources and Search Strategy

To retrieve all relevant publications, we developed our search strategy in consultation with a medical librarian and applied this strategy to a range of data sources (see Supplementary Appendix A for the Ovid MEDLINE search strategy). Our search had no restrictions on language, country, or study design and included both quantitative and qualitative findings to provide evidence about factors associated with PMP use; we searched up until January 22, 2018. Only fully published peer-reviewed reports of study data were included, except for theses or dissertations. We searched five electronic databases (Medline, Embase, CINAHL, PsychInfo, and Web of Science), as well as dissertation and theses databases. Additionally, we manually searched the reference lists of all included studies and identified relevant reviews. EndNote X8.1 was used to de-duplicate and manage citations [31]. All identified studies were imported to Covidence, a Web-based software developed by Cochrane to facilitate the systematic review process [32].

Study Selection

All titles and abstracts were screened independently for eligibility by two of four investigators (AR, MW, ER, MA) and were pushed forward to full-text review if consensus was achieved on relevance. Two of the four reviewers (same as above) also independently screened full-text articles to determine eligibility for data extraction. Rates of discordance between reviewers for the title/abstract and full-text review were 8.9% and 9.7%, respectively. At all stages, any discrepancies in eligibility between reviewers were discussed to reach consensus. If no consensus could be reached, a third investigator reviewed and assessed the eligibility. Studies were included for full review if they met the following criteria: 1) The publication was a primary research study in full text (i.e., not a systematic review, editorial, abstract, or commentary), 2) the jurisdiction being studied had an operational PMP (not pending or forthcoming), 3) the study had a measure of PMP use (with a denominator for the measure) and/or had identified barriers to PMP use, and 4) the study population consisted of health care providers. Multiple publications presenting data on the same group of respondents are identified as linked in Supplementary Appendix B. Overlapping outcomes from these publications were included only so as to not overweight the findings.

Data Extraction and Quality Assessment

We used a pre-tested data extraction form developed in Covidence to extract relevant study details (authors, year, jurisdiction, study design, sample size, response rate), population characteristics (provider or dispenser type), data sources (focus group, survey, administrative), information on data use, and any barriers identified (including whether these barriers were identified by <50%, ≥50%, or an unknown percentage of the study population) for included studies. Two reviewers completed the data extraction for each study independently, and discrepancies were discussed. When consensus could not be reached by the two initial reviewers, the assessment of a third reviewer was sought. The quality of studies was assessed with the Appraisal tool for Cross-Sectional Studies (AXIS) critical appraisal tool for quantitative studies [33] and the Critical Appraisal Skills Programme (CASP) tool for qualitative studies [34].

Data Analysis

Prevalence of PMP data use was expressed as the proportion of respondents reporting having ever used or always using PMP data. We used Stata version 15 (the metaprop command) to combine proportions of ever using PMP data under a random effects model due to the heterogeneity between studies, using the Freeman-Tukey Double Transformation to stabilize variances. We present the proportion of providers using PMP as a range and a pooled estimate with 95% confidence interval (CI). We also examined rates of PMP data use by provider type. Finally, we present data on the proportion of providers who reported "always using PMP data while prescribing" in our meta-summary. Always using PMP data was presented as mean and standard deviation. Other measures of frequency of use were not pooled due to significant heterogeneity.

Barriers associated with using PMP data were synthesized with qualitative meta-summary methods [35]. Barriers (and the percentage of respondents reporting them) were first extracted at the study level in the context of each individual study and were then coded, compared, and combined by theme through the use of data maps. For syntheses and ease of interpretation, we categorized barriers, as mentioned above, into: those reported by <50% of the study sample (defined as a less common barrier), those reported by ≥50% of the study population (defined as a more common barrier), and those reported by an unknown percentage (i.e., those identified in a qualitative meta-summary, labeled as a general barrier) of the study population.

Results

Searches

Using the search strategy outlined above, we initially identified 1,490 unique records (Figure 1) and reviewed 192 of these publications in full text. In total, we identified 53 studies (56 publications) that met the inclusion for our review, of which 46 reported on PMP data use and 32 identified barriers to PMP data use (Supplementary Appendix B) [36–38].

Study Characteristics

All included studies were conducted in the United States and covered a range of health care professionals: prescriber populations, including physicians (23 studies), dentists (1 study), nurse practitioners (5 studies); administrative populations (i.e., PMP and health care administrators; 3 studies); and pharmacists (13 studies). Many studies identified the health care professionals included in their study broadly, using terms such as *providers* (7 studies), *clinicians* (2 studies), or *prescribers* (7 studies), and 13 studies looked at more than one specific group of health care professionals. Study participation/response rates varied greatly between studies, from 4% to 100%. Specific characteristics of the PMPs and their implementation were not well described in the studies and were therefore not included in our analysis. However, to add context when discussing specific studies, up-to-date information on the current status of PMPs in different jurisdictions within the United States was collected from "PDMP Assist" and is presented in Supplementary Appendix C.

Methodological Quality

The included studies were of variable methodological quality (Supplementary Appendix D). The highest area of concern for study quality among quantitative studies was poor response rates, which were reported to be as low as 4%. Other areas of concern across studies included whether the data were adequately described, replicability of methods, the use of validated instruments to collect observations, justification of the sample size, and the selection of a representative sample, particularly given the use of convenience sampling approaches in many studies (Table 1).

We identified three main areas of concern for qualitative study results: the appropriateness of the recruitment strategy, whether the relationship between researcher and participants was addressed, and the rigor of data analysis (Table 1). In all, qualitative studies were good with respect to their comprehensive assessment of barriers to PMP. Of the 13, six studies used some sort of framework, approach, or method from the literature to describe barriers, and the rest either thematically coded barriers (four studies) or had predefined groupings for barriers based on the structure of questions (three studies).

Prevalence of PMP Data Use

Among the 46 included studies (131,587 participants) reporting data use, the most common outcome reported was the proportion of prescribers or dispensers who have

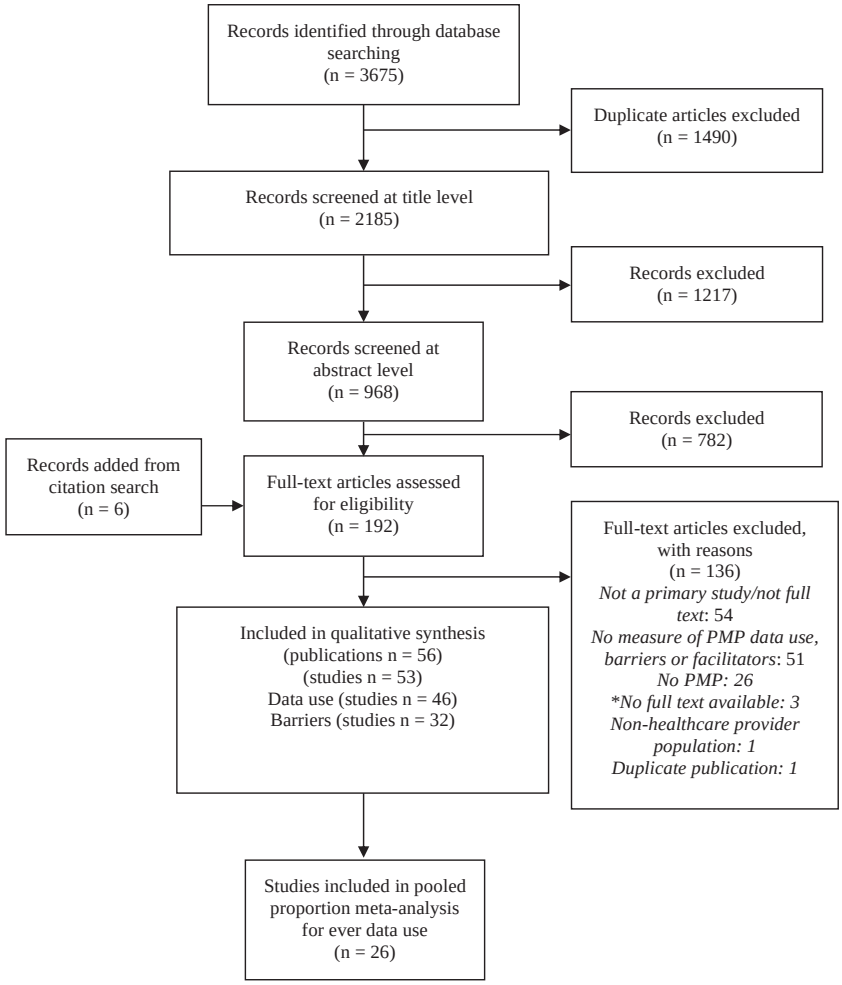


Figure 1. PRISMA diagram for study screening and inclusion process. ES = effect size.

*Reasons for full texts being unavailable to authors: embargoed (1); not yet digitized and informed it would take at least a month (1); not enough information available for authors or library services to find it (1).

"ever" used PMP data. This outcome was reported in 26 studies representing 30 unique prescriber/dispenser groups (107,998 participants), with proportions of "ever use" of PMP data ranging from 0.08 to 1.00 (Figure 2) [23–25, 27, 28, 39–59]. Overall, the pooled proportion of health care providers who have ever used PMP data was 0.57 (95% CI: 0.48–0.66). Among the health care providers included in these studies, physicians and pharmacists were the two specific groups studied most often, in fourteen and seven studies, respectively. The pooled proportions of physicians (0.63; 95% CI: 0.43–0.81) and pharmacists (0.57; 95% CI: 0.41–0.73) ever using PMP data did not differ significantly. There were no observable differences in data use by year of study publication (Supplementary Appendix E).

Another 24 studies (108,327 participants) reported on other measures of frequency of PMP data use [22, 23, 27, 28, 39, 41, 43, 46, 47, 50, 56, 57, 60–71]. Frequency of use was defined either within a specified time frame (i.e., past week, past month, over study period) or in specific scenarios (i.e., when prescribing to a new patient or to high-risk patients). A common measure of frequency of use was the proportion of health care professionals who "always" checked or used PMP data when making a prescribing or dispensing decision, which was reported by 11 studies (4,919 participants) [23, 24, 43, 46, 52, 56, 60, 61, 65, 67, 71].

Across these 11 studies, there was a low percentage of health care providers who always used PMP data when making prescribing or dispensing decisions, ranging from 0% to 68% (mean [SD]: 18.7% [18.4%]). Three studies reported a percentage of health care providers who always used PMP data that was markedly higher than the mean: Blum (2016), Fleming (2014), and Chaudhary (2017) [56, 60, 61].

Barriers to PMP Data Utilization

From the 32 studies (11,266 participants) that discussed barriers to PMP data use, we identified 18 groups of barriers (Table 2) [23–25, 27, 28, 41–47, 49, 50, 54–56, 58, 59, 64, 66, 67, 71–80].

Table 1. Summary of critical appraisal of studies with quantitative data using AXIS and CASP tool

	Total studies yes, n*	Total studies yes, %
AXIS Item		
1. Were the aims/objectives of the study clear?	41	93.2%
2. Was the study design appropriate for the stated aim(s)?	41	93.2%
3. Was the sample size justified?	8	18.2%
4. Was the target/reference population clearly defined? (Is it clear whom the research was about?)	43	97.7%
5. Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	36	81.8%
6. Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	26	59.1%
7. Were measures undertaken to address and categorize nonresponders?	6	15.4%
8. Were the risk factor and outcome variables measured appropriate to the aims of the study?	41	93.2%
9. Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialed, piloted, or published previously?	30	68.2%
10. Is it clear what was used to determine statistical significance and/or precision estimates? (e.g., *P* values, CIs)	28	80.0%
11. Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	30	68.2%
12. Were the basic data adequately described?	28	63.6%
13. Does the response rate raise concerns about nonresponse bias?†	33	86.8%
14. If appropriate, was information about nonresponders described?	5	13.2%
15. Were the results internally consistent?	35	79.5%
16. Were the results for the analyses described in the methods presented?	38	86.4%
17. Were the authors' discussions and conclusions justified by the results?	39	88.6%
18. Were the limitations of the study discussed?	42	95.5%
19. Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?†	0	0.0%
20. Was ethics approval or consent of participants attained?	42	95.5%
CASP Item	**Total studies yes, n**	**Total studies yes, %**
1. Was there a clear statement of the aims of the research?	14	100.0%
2. Is a qualitative methodology appropriate?	14	100.0%
3. Was the research design appropriate to address the aims of the research?	12	85.7%
4. Was the recruitment strategy appropriate to the aims of the research?	9	64.3%
5. Were the data collected in a way that addressed the research issue?	14	100.0%
6. Has the relationship between researcher and participants been adequately considered?	8	57.1%
7. Have ethics issues been taken into consideration?	13	92.9%
8. Was the data analysis sufficiently rigorous?	10	71.4%
9. Is there a clear statement of findings?	14	100.0%
10. How valuable is the research?‡	12	85.7%

*Because of certain questions being inapplicable for some studies, N is not always 44: Question 7, N = 39; Question 10, N = 35; Question 13, N = 38; and Question 14, N = 38.

†Higher rate of responding *yes* can be interpreted as of concern.

‡*Yes* answer indicates that value was demonstrated.

Time constraints were the most commonly identified barrier. Time constraints were identified as a less common barrier in eight studies [24, 27, 41, 45, 54–56, 67], a more common barrier in five studies [23, 43, 46, 47, 74], and a general barrier in another five studies [50, 64, 71, 78, 80]. This was represented by reports from health care providers that the process of obtaining information from the PMP to advise prescribing or dispensing situations, specifically in the processes of logging in or retrieving information, was too time consuming.

Issues with system slowness were identified as a less common barrier in five studies [24, 27, 41, 44, 55], a more common barrier in three studies [44, 74, 79], and a general barrier in seven studies [50, 64, 71, 72, 76, 78, 80]. Specific issues included lag times in system updates, as well as infrequent updates, the "timing out" of data access requests, and the lack of timely receipt of information from the system (including inability to query in real time). These issues impact the utility of PMPs for health care providers in a prescribing or dispensing situation.

Related to system issues are issues with usability and a lack of training or guidance in using the PMP. Issues with usability were identified as a less common barrier in ten studies [23, 28, 41, 43, 45, 47, 55, 56, 67, 75], a more common barrier in two studies [54, 74], and a general barrier in seven studies [49, 64, 72, 73, 77, 78, 80]. The issue of a lack of training or guidance in using the PMP was identified as a less common barrier in one study [79], a more common barrier in one study [74], and a general barrier in three studies [42, 64, 71]. Usability issues, including difficulty accessing or navigating the PMP and interpreting the data, could promote a lack of confidence

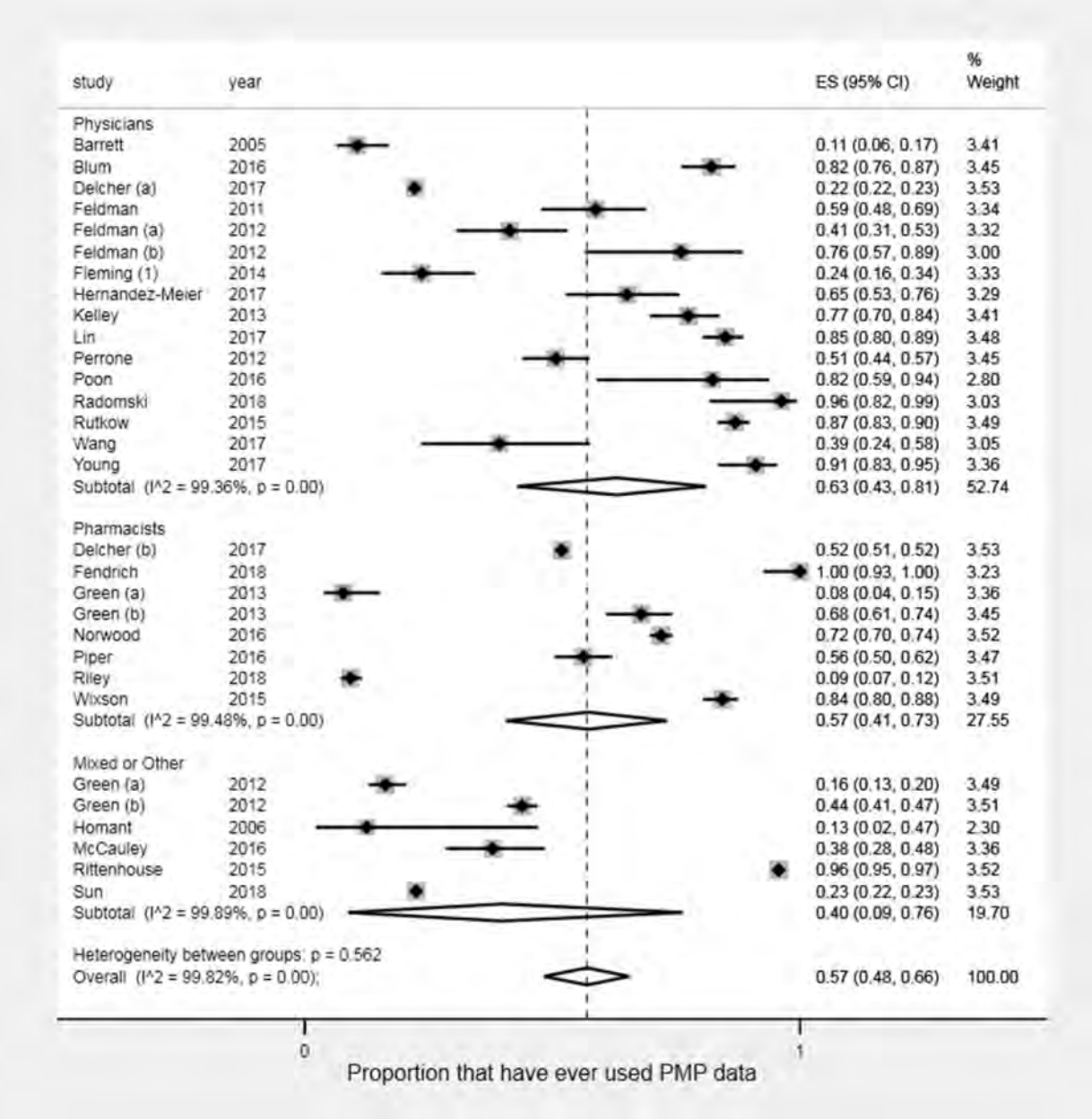


Figure 2. Results of pooled proportion meta-analysis of ever PMP data use by physicians, pharmacists, and mixed or other populations.*

*Feldman (a) represents the subgroup of residents, whereas Feldman (b) represents the subgroup of attending physicians. Green (a) represents pharmacists in Rhode Island, and Green (b) represents pharmacists in Connecticut.

in using the PMP that may prompt health care providers to identify the need for better training or guidance.

Not seeing the value in PMP data was identified as a less common barrier in ten studies [23, 28, 41, 44, 45, 47, 55, 56, 58, 79] and a general barrier in four studies (it was not identified in any study as a more common barrier) [42, 71, 72, 74]. Most often, this was reported as providers feeling that the use of PMPs would not impact their clinical practice. Other reports included not wanting to use PMP data or feeling that they could rely on their instincts in prescribing or dispensing situations.

Along with this, health care professionals expressed that PMPs inhibited their ability to prescribe, impairing their autonomy and raising concerns about patient privacy. This was identified as a less common barrier in six studies [43, 46, 55, 56, 58, 66] and a general barrier in two studies (it was not identified in any study as a more common barrier) [64, 72]. This is linked to a concern that PMPs may result in patients being under-treated (one less common and one general) [56, 72].

Health care providers were also concerned about patient satisfaction ratings and patient flow. This was identified as a less common barrier in two studies [43, 79]

Table 2. Reporting barriers to PMP use identified from included studies

	Study IDs and Frequency of Barrier Reporting			
Barrier Group	Minor (Reported by <50% of Study Sample)	Major (Reported by ≥50% of Study Sample)	General (No Frequency Reported)	Examples of Barrier Group
Not seeing value in PMP data	Rutkow 2015 (23), Perrone 2012 (47), McCauley 2016 (45), Lin 2017 (44), Feldman 2012 (58), Barrett 2005 (45), Hernandez-Meier 2017 (41), Blum 2016 (56), Green 2012 (28), Ulbrich 2010 (79)	NA	Warren 2016 (71), Carnes 2017 (72), Homant 2006 (42), Deyo 2015 (74)	Feel it would not impact or change clinical practice, did not want to use PMP, feel they can rely on their own instinct.
Availability of technology	Perrone 2012 (47), Hernandez-Meier 2017 (41), Green 2012 (28), Green 2013 (27), Wixson 2015 (25)	Ulbrich 2010 (79)	Pugliese 2018 (77), Hildebran 2014 (64)	Limited access to phone, internet, or computers at work, not having access to PMP during all hours of the dazy.
Usability issues	Rutkow 2015 (23), Blum 2016 (56), Perrone 2012 (47), McAllister 2015 (67), Fazio 2017 (75), Hernandez-Meier 2017 (41), Green 2012 (28), McCauley 2016 (45), Kelley 2013 (43), Barrett 2005 (55)	Deyo 2015 (74), Wang 2017 (54)	Pugliese 2018 (77), Poon 2016 (49), Worley 2015 (80), Click 2017 (73) , Carnes 2017 (72), Smith 2015 (78), Hildebran 2014 (64)	Difficulty interpreting PMP data, difficulty accessing and navigating the PMP, format of information is not easy to use, lack of confidence in performing PMP tasks.
Time constraints to using PMP data	McCauley 2016 (45), McAllister 2015 (67), Hernandez-Meier 2017 (41), Blum 2016 (56), Green 2013 (27), Young 2017 (24), Wang 2017 (54), Barrett 2005 (55)	Rutkow 2015 (23), Perrone 2012 (47), Norwood 2016 (46), Kelley 2013 (43), Deyo 2015 (74)	Radomski 2018 (50), Hildebran 2014 (64), Worley 2015 (80), Warren 2016 (71), Smith 2015 (78)	Time consuming to log in, to retrieve information, increase in burden or workload.
Lack of awareness of PMP	Perrone 2012 (47), Feldman 2011 (59), Ulbrich 2010 (79), Lin 2017 (44)	McCauley 2016 (45), Green 2012 (28), Green 2013 (27)	NA	Unaware of PMP or availability of PMP data among non-users.
System slowness	Young 2017 (24), Barrett 2005 (55), Green 2013 (27), Lin 2017* (44), Hernandez-Meier 2017 (41)	Ulbrich 2010 (79), Lin 2017* (44), Deyo 2015 (74)	Radomski 2018 (50), Carnes 2017 (72), Naiman 2013 (76), Hildebran 2014 (64), Worley 2015 (80), Warren 2016 (71), Smith 2015 (78)	Delay in receiving requested reports, lag time in system updates from when a prescription is dispensed to when it shows up in the PMP, delays in reporting to the system, inability to directly query the system in real time, requests not processing or timing out, system slowness.
Concerns with privacy, monitoring, and autonomy	LeMire 2012 (66), Kelley 2013 (43), Blum 2016 (56), Feldman 2012 (58), Barrett 2005 (55), Norwood 2016 (46)	NA	Hildebran 2014 (64), Carnes 2017 (72)	Concerns with patient privacy, feel they are being policed, feel they are being inhibited in prescribing, fear of legal ramifications.
Lack of training/education or policies/guidelines	Ulbrich 2010 (79)	Deyo 2015 (74)	Hildebran 2014 (64), Homant 2006 (42), Warren 2016 (71)	Lack of training on how to use PMP or interpret findings, no guidance on how to integrate PMP into workflow, lack of knowledge on PMP policies or laws.
Inability to delegate access	Green 2012 (28), Green 2013 (27), Deyo 2015 (74)	NA	Carnes 2017 (72), Smith 2015 (78), Click 2017 (73)	Lack of staff available to access the system, inability of residents to query the system, unable to share account or delegate access.

(continued)

	Study IDs and Frequency of Barrier Reporting			
Barrier Group	Minor (Reported by <50% of Study Sample)	Major (Reported by ≥50% of Study Sample)	General (No Frequency Reported)	Examples of Barrier Group
Lack of integration and data sharing (between systems and jurisdictions)	Blum 2016 (56), Deyo 2015 (74)	NA	Radomski 2018 (50), Naiman 2013 (76), Worley 2015 (80), Carnes 2017 (72), Click 2017 (73)	No interstate data sharing, no integration with electronic health/medical record, inability to search outside of one's jurisdiction.
Patient satisfaction concerns	Kelley 2013 (43), Ulbrich 2010 (79)	NA	Hildebran 2014 (64), Smith 2015 (78)	Worried about patient satisfaction rating (which may impact salary), concern with confronting patients, detracting from patient flow.
PMP does not meet provider data needs	Blum 2016 (56), Barrett 2005 (55)	NA	Radomski 2018, (50) Carnes 2017 (72), Homant 2006 (42)	Does not cover certain populations such as Veteran's Affairs or homeless, does not monitor drugs of interest, inability to access information on ones own prescribing history.
Problems with log-in credentials	Perrone 2012 (47), Hernandez-Meier 2017 (41), Blum 2016 (56), Young 2017 (24)	NA	Poon 2016 (49), Naiman 2013 (76), Hildebran 2014 (64), Click 2017 (73)	Difficulty remembering login credentials, frequent password changes required.
Problems with registration process	Perrone 2012 (47), Norwood 2016 (46), McAllister 2015 (67), Lin 2017 (44), Hernandez-Meier 2017 (41), Green 2012, Blum 2016 (56), Green 2013 (27)	Ulbrich 2010 (79)	Hildebran 2014 (64), Smith 2015 (78)	Too time consuming to register, do not know how to register, having to register on each new computer.
No incentive to use PMP	Perrone 2012 (47)	NA	Hildebran 2014 (64), Smith 2015 (78)	No reimbursement for task or incentive (financial or otherwise) to use PMP data.
Data not reliable	Lin 2017* (44), Blum 2016 (44)	Lin 2017 * (44)	Hildebran 2014 (64), Click 2017 (73)	Patient reports filed under more than one ID, missing data, inaccurate data or errors in the system, not all clinicians use the system so patient history may not be comprehensive..
Lack of support from administration	Green 2012 (28), Green 2013 (27), Kelley 2013 (43)	NA	NA	PMP not required or promoted by administration, or PMP use is discouraged by administration.
Potential for undertreatment	Blum 2016 (56)	NA	Carnes 2017 (72)	Restrictions in providing opioids to patients who patients feel really need them (i.e. cancer, palliative care, surgery, etc.).

*Identifies studies that have reported barriers within the barrier group for more than one category of frequency of reporting.

and a general barrier in two studies (it was not identified in any study as a more common barrier) [64, 78].

Less frequently acknowledged barriers included the lack of incentives to use the PMP (one less common [47] and two general [64, 78]), the perception that the data collected for PMPs were not reliable (two less common [44, 56], one more common [44], and two general [64, 73]), and a lack of support from PMP administrators (three less common) [27, 28, 43]. Others included an inability to delegate access to staff (three less common [27, 28, 74] and three general [72, 73, 78]), a feeling that the PMP did not provide the type of data a health care provider needed to make dispensing decisions (two less common [55, 56] and three general [42, 50, 72]), and a lack of integration and data sharing across PMP systems in different jurisdictions (two more common [56, 74] and five general [50, 72, 73, 76, 80]). Further barriers related to usability included the availability of the technology required to use the PMP (five less common [25, 27, 28, 41, 47], one more common [79], and two general [64, 77]) and problems with log-in credentials (four more common [24, 41, 47, 56] and four general [49, 64, 73, 76]). Finally, there was an identified lack

of awareness of the PMP system (four more common [44, 47, 59, 79] and three less common [27, 28, 45]), as well as problems in registering for the PMP (eight more common [27, 28, 41, 44, 46, 47, 56, 67], one less common [79], and two general [64, 78]).

Discussion

This systematic review identified a significant body of literature on PMP data use and barriers, with 46 identified studies examining PMP data use and 32 identified studies looking at barriers to PMP data use.

Only half of health care providers have ever used PMP data, and on average only about 20% check the system with each prescribing or dispensing decision. Some studies lacked detail that would allow us to distinguish whether "always use" was measured only within the context that the PMP should be used, or simply for every visit. Therefore, we are unable to distinguish "always use" from "always use in the appropriate scenario," where the appropriate scenario is use of the PMP in cases in which opioids or other controlled substances are being prescribed or filled. The wide range in health care professionals who had ever used a PMP could be influenced by the unique characteristics of the PMP itself (i.e., mandatory PMP use or training) or the study design.

We were unable to study the unique characteristics of the PMPs because of the insufficiency of information on the PMP itself in the studies; however, we were able to summarize information from "PDMP Assist" (Supplementary Appendix C) to add context and hypothesize about our results below. One characteristic we discuss below is mandatory use. There are many complex factors of mandatory PMP use, particularly with regard to the degree to which mandatory use is expected (i.e., only for certain substances, or certain providers, or under suspicious circumstances) and how it would be enforced. As such, we were unable to fully explore the impact of mandatory PMP use laws/declarations on actual PMP use by health care providers, nor have we included this information in Supplementary Appendix C (characteristics of PMPs). However, some information on mandatory use can be obtained from the "PDMP Assist" website [81]. How information on use was gathered would also affect reported estimates, including whether data was collected from surveys or in a cohort study, while the response rate and those who agree to participate may capture different levels of PMP users. The year of the study did not seem to have an impact on use as per our sensitivity analysis. This may be due to the different timelines for PMP implementation and uptake in each jurisdiction.

When comparing the characteristics of PMPs (see Supplementary Appendix C) in studies in the top 15% of PMP ever use [23, 24, 39, 50, 52] against those in the bottom 15% of PMP ever use [27, 28, 42, 51, 55], the only difference of note is the inclusion of mandatory training. None of the jurisdictions in the studies in the bottom 15% of PMP ever use currently have mandatory training, whereas jurisdictions in three of the five studies in the top 15% of PMP ever use currently have mandatory training, which suggests that it may play a role in facilitating greater PMP use. We also compared whether either solicited, or solicited and unsolicited, reports to prescribers and dispensers had any impact on ever use of PMPs. We determined whether reports were solicited, or solicited and unsolicited, by the jurisdiction in which the study took place, using information in Supplementary Appendix C, for those studies that reported ever use and were conducted in just one jurisdiction (19 out of the 26 studies reporting ever use). For reports to prescribers, there were only slight differences in the percentage of ever use according to whether reports were solicited or solicited and unsolicited (59% vs. 52%, respectively). However, for reports to dispensers, there was a greater difference in the percentage of ever use depending on whether reports were solicited or solicited and unsolicited (53% vs. 69%, respectively); however, the latter figure is based on only four studies.

Three studies reported notably higher frequencies of health care providers always using PMP data. Features of these studies that may have accounted for those high frequencies are mandatory use [82], timeliness of data availability [83], law enforcement connection [84], and provider groups [85]. Mandating the use of PMPs may generate greater use, though it does not generate perfect compliance [56]. Targeting the timeliness and ease of accessing data might increase PMP use by addressing numerous identified barriers (Table 2) [61]. More immediate data availability, as well as law enforcement involvement, may stress the importance of checking PMP data. Finally, though many health care professional groups were assessed, a study of nurse practitioners showed higher levels of always using the PMP [60]. Specific provider groups might be more engaged with using the PMP, and understanding why that is the case could be important in developing interventions to increase PMP data use overall.

Barriers that contribute to the low overall utilization of PMPs are important targets for policy and system planning. Many of the barriers identified by health care providers were strongly interrelated and point largely to system-level changes. The largest of these were related to time and usability. To increase use, PMP administrators must look at ways to simplify and speed up the process of accessing PMP data, to increase confidence and ease of using the system among health care providers. Because health care providers already have such a brief time to interact with patients, any improvements to system speed and usability may alleviate the burden of limited time. An intervention to improve PMP literacy may further support this aim and may reassure health care providers by helping them understand the information that the PMP provides, why it is necessary for public health

safety, and how patient privacy/confidentiality is protected.

Although these are not the only barriers identified, finding resolutions to these common perceived barriers might be expected to facilitate an increase in PMP data use. Health care professionals have themselves stated that the removal of barriers would increase their day-to-day use of their PMP [24]. Administrators and policy makers have incentive and justification, and now information, to allocate resources toward removing barriers to PMP use.

Better-controlled prescribing (including the use of PMP data) may help to reduce harms directly, through controlling inappropriate prescribing, and indirectly, by reducing the number of problem users. Our finding that PMP data use is low and that many barriers exist to using PMP data demonstrates that this tool is not being used to its fullest potential and could potentially have a larger positive impact on the opioid crisis in reducing misuse and potential harms.

The data collected on PMP data use may be biased in several ways and should be interpreted with caution. The main concerns identified in our critical appraisal of the literature included sampling methods, low response rates, and whether nonresponders may have been systematically different from responders in terms of the outcome of interest. This low response rate and lack of information on nonresponders is problematic, as it not possible to assess whether responders and nonresponders were systematically different from one another. It is likely that those who responded were more actively engaged in the use of PMPs and hold stronger opinions about PMPs. This could have caused an overestimation of the proportion of health care providers who use PMPs and could have inflated the reporting of barriers. Furthermore, there is the potential for biases to emerge in self-reported studies, including social desirability and recall bias. This should not detract from the large number of studies that were identified and pooled for this analysis, which is a study strength.

It is also important to note that we were unable to distinguish between "PMP use" and "appropriate use of a PMP" because of the lack of detail in the included studies. This is a limitation, as we know all use is not created equal. Nevertheless, through this review, we were still able to synthesize information on patterns of use, which has been a gap in the literature.

Another important consideration is that all studies included in this review are from the United States. Although the identified barriers in U.S. studies may be applicable to similar PMP systems in Canada, they may not be applicable to more integrated prescription systems, as are found in many parts of Europe. As such, primary studies are required in both Europe and Canada, as they are both embedded in different health care systems. Additionally, whether or not a jurisdiction has mandatory PMP checking is likely an important characteristic of the PMP that may have contributed to the varying rates of use reported above. Lastly, it should be acknowledged that the mere existence of a PMP may produce a benefit, regardless of its barriers or usage, as it serves as a reminder to prescribe opioids with careful consideration.

The findings from this review may have implications for other studies and reviews examining aspects of PMP utilization or effectiveness, as we know there are barriers that would directly impact use and indirectly impact effectiveness. Two recent systematic reviews of the impact of PMP status on prescribing and overdose outcomes found unclear and mixed results [86, 87]. In both cases, the barriers and low usage levels of PMPs identified in our review may help explain the uncertainty in relationships between PMPs and outcomes. In terms of future studies, we note that among the studies in this review, PMPs (their implementation and features) were not well described. Rather than assessing simply the presence or absence of a PMP, future research should assess the impact of different features or different modes of implementation of PMPs on use and effectiveness.

Conclusion

This review has described the current use of PMP data among health care providers and has highlighted several key barriers experienced by health care providers in their daily use of PMP data. PMPs remain a vital tool to help combat the potential harms associated with prescription opioid misuse. Although these tools are present in most jurisdictions in North America, PMPs remain sorely underutilized, and many barriers to use have been identified. For PMPs to reach their fullest potential for health care providers, patients, and the public, these barriers must be removed or reduced. This review represents a first step in cataloging PMP use barriers for PMP administrators so that meaningful changes can be implemented.

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Supplementary Data

Supplementary Data may be found online at http://painmedicine.oxfordjournals.org.

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EXHIBIT B

EXHIBIT B

By Colleen M. Carey, Giacomo Meille, and Thomas C. Buchmueller

Provider Compliance With Kentucky's Prescription Drug Monitoring Program's Mandate To Query Patient Opioid History

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ABSTRACT **Forty states mandate that providers query their patients' prescription histories in the state's prescription drug monitoring program (PDMP) before prescribing controlled substances. However, little is known about providers' use of PDMPs, either with or without a mandate. We measured the share of opioid prescriptions with PDMP queries in Kentucky from 2010 to 2018, before and after the implementation of the first comprehensive PDMP mandate in the US. Providers queried the PDMP for 12 percent of opioid prescriptions before the mandate; after the mandate, they queried for 56 percent of prescriptions. The share of prescriptions queried was lowest for patients without recent opioid use (3 percent before the mandate, 25 percent after) and highest for pain management specialists (31 percent before, 72 percent after). Over time, high-compliance providers reduced prescribing to the riskiest patients, whereas low-compliance providers continued to prescribe to them. Although the share of prescriptions queried greatly increased after the mandate, compliance remained incomplete, including for patients with high-risk patterns of opioid use.**

Colleen M. Carey is an assistant professor in the Department of Policy Analysis and Management at Cornell University, in Ithaca, New York.

Giacomo Meille is a PhD student in the Stephen M. Ross School of Business, University of Michigan, in Ann Arbor, Michigan.

Thomas C. Buchmueller (tbuch@umich.edu) is the Waldo O. Hildebrand Professor of Risk Management and Insurance at the Stephen M. Ross School of Business, University of Michigan.

Prescription drug monitoring programs (PDMPs)—databases that track all controlled substance prescription fills and supply providers with patients' prescription histories—represent one of the most significant policy responses to the opioid epidemic. Every state but one has established a PDMP, and in recent years many have enacted legislation to make their programs more effective.[1] Early PDMPs did not require providers to have an account or to access the database before prescribing. Under these conditions, provider engagement was limited,[2–4] which may be why early studies found no effect of PDMPs on opioid prescribing.[5–8]

By 2019 forty states had laws requiring prescribers to query their PDMP before prescribing opioids and other controlled substances.[9] Kentucky established the first such comprehensive law, effective July 20, 2012. The law requires all providers licensed to prescribe controlled substances to register with the state's PDMP, the Kentucky All Schedule Prescription Electronic Reporting system (KASPER). Providers are also required, with limited exceptions, to query KASPER for a report before prescribing to new patients and to query every three months for continuing patients. Failure to comply can result in disciplinary action, including emergency suspension or restriction of the provider's license.

Research suggests that PDMP mandates significantly reduce opioid prescriptions, particularly those written for patients whose prescription histories are suggestive of "doctor shopping," as well as overdose deaths from prescription opioids.[10–18] Research on the Kentucky mandate in particular has found reductions in opioid supply and risky patterns of use.[14,15,18,19]

In this article we use a unique prescription-

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level data set from KASPER to measure the share of opioid prescriptions with an associated query both before and after Kentucky's mandate. To our knowledge, this study is the first to offer direct evidence on compliance with a PDMP mandate. Direct observation of PDMP queries revealed how the probability of querying prescriptions varied with patient and provider characteristics. In addition, direct measures of querying compliance can inform the policy evaluation of PDMP mandates by measuring the extent to which a mandate changes providers' engagement with the PDMP.

Study Data And Methods

DATA SOURCES AND STUDY POPULATION We obtained KASPER data for 2010–18 via a data use agreement. The data track Schedule II–V outpatient controlled substance prescriptions filled in Kentucky as well as all queries of KASPER patient histories made by providers. The University of Michigan Institutional Review Board approved the study.

The 2012 law pertains only to providers' use of KASPER reports, not the reporting of prescriptions to the monitoring system, which is performed by pharmacies. Comparisons with federal data sources suggest that KASPER captures roughly 95 percent of all opioids distributed in Kentucky.[15] For all analyses we limited the sample to prescriptions written by Kentucky medical providers and filled by Kentucky patients. We excluded dentists because the dental licensing board did not finalize its regulations until 2015.

Each KASPER prescription record contains the following fields: fill date; National Drug Code; number of units; days supplied; patient ZIP code; and encrypted identifiers for patient, prescriber, and pharmacy. Starting in April 2014 KASPER also required dispensers to report the type of payment used to purchase a prescription. We converted each prescription to its morphine-equivalent dosage.[20,21] We further limited the sample to opioids covered by the mandate: Schedule II opioids and Schedule III drugs containing hydrocodone.

KASPER supplied data on queries aggregated to the provider-patient-month level. It also reported provider type or specialty for all registered providers. Providers who never registered prescribed 6 percent of opioids, and we imputed their specialty as described in the online appendix.[22]

MEASURING THE SHARE OF PRESCRIPTIONS QUERIED We defined a binary "querying" measure that operationalizes the requirements that went into effect in 2012. For Schedule II or hydrocodone-containing Schedule III outpatient prescriptions, providers were required to conduct a query initially for all new patients and at least once every three months for continuing patients. Thus, we considered a prescription "queried" if the provider queried the patient in the month the prescription was filled or one of the previous four months.[23]

The mandate exempts prescriptions related to cancer, hospice, or end-of-life treatment, as well as prescriptions of fourteen days or less associated with surgery or trauma. We assumed that all patients who ever got a PDMP-covered prescription from a hematologist, oncologist, or hospice/palliative care physician were patients with cancer or end-of-life patients and that all of their prescriptions were exempt. We also assumed that prescriptions from surgical or emergency specialists for fourteen days or fewer were exempt. See the appendix for details on exempt prescriptions.[22]

The Kentucky mandate allowed providers to designate nonprescribing employees to access the system via delegate accounts. KASPER data capture all such queries, and we assigned them to the delegating provider. Providers were also in compliance with the mandate if another provider, such as a partner in their practice, conducted a query on their behalf. In the appendix we describe a procedure for measuring potential "unofficial delegates" and show that accommodating them had little effect on our qualitative results.[22] Our main analysis did not account for unofficial delegates.

Patients were divided into three mutually exclusive categories on the basis of their number of opioid prescriptions in the previous six months (across all opioids, not just those subject to mandatory querying), as well as the number of prescribers and Kentucky pharmacies from which they obtained opioids. We classified patients as opioid naïve if they did not fill any opioid prescriptions in the previous six months. Chronic patients received one or more opioid prescriptions, written by four or fewer prescribers and filled at four or fewer Kentucky pharmacies in the previous six months. Because receiving prescriptions from multiple providers is suggestive of "doctor shopping,"[6,13,24] we classified patients as high risk if they filled prescriptions from five or more prescribers or Kentucky pharmacies over the previous six months.

Providers were categorized according to medical specialty and the average number of patients to whom they wrote opioid prescriptions each month. Patients were characterized by use category, sex, and age. We characterized prescriptions by primary ingredient, daily morphine-equivalent dosage, and payment source. We collected county characteristics from other

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The increase in the share of prescriptions queried coincided with a large decrease in opioid prescriptions.

sources: the percentage of the county population that is urban (2010 census), the county's monthly unemployment rate (Bureau of Labor Statistics), and opioid-related mortality in the prior twelve months (National Vital Statistics System).

Our analysis focused on nonexempt opioid prescriptions covered by the mandate. Our analytical sample included 24,702,052 prescriptions written by 19,110 unique providers to 1,857,982 unique patients.[25]

ANALYSIS We plotted trends in the share of prescriptions queried before and after the July 2012 law across provider and patient characteristics. We also computed the share of prescriptions queried in the pre and post periods and the difference for a larger set of provider, patient, prescription, and county characteristics. We estimated a prescription-level logistic regression predicting querying using provider, patient, prescription, and county characteristics interacted with an indicator for the post period. For each characteristic in the logistic regression, we obtained the predictive margin in the pre and post periods and computed the difference.

We also examined how prescribing was distributed across providers of various querying rates. To do so, we classified each provider into one of four categories by their querying rate: providers who queried fewer than 5 percent of prescriptions, those who queried 5–49 percent, those who queried 50–74 percent, and those who queried 75 percent or more. We formed these categories for three distinct periods: the pre period (July 2010–June 2012), the early post period (July 2012–December 2015), and the late post period (2016–18). For each period we calculated the share of prescriptions written by providers at each level of querying for patients of each use category.

LIMITATIONS Our data had several limitations. We were not able to directly observe exemptions from the mandate, and we may have underestimated queries by not counting those made by an "unofficial delegate," such as the coworker of the prescriber. In appendix exhibit S5 we present results using a broader definition of exemptions and including queries from potential unofficial delegates.[22] Our qualitative results were not sensitive to these changes.

The legislation establishing the mandate also introduced new regulations on pain clinics. The law limits ownership of clinics to physicians and requires an on-site physician with appropriate board certification at least 50 percent of the time. It was not possible to disentangle the impacts of the new pain clinic regulations from the mandatory query mandate. However, the pain clinic regulations did not impose query requirements on pain clinics beyond those imposed on all Kentucky providers. In addition, it is evident from our exhibits that the change in querying occurred exactly at the time of the mandate's imposition. Although KASPER officials report the closure of twenty-four pain clinics after the implementation of the new regulations, these closures occurred gradually over the following three years.[15]

Study Results

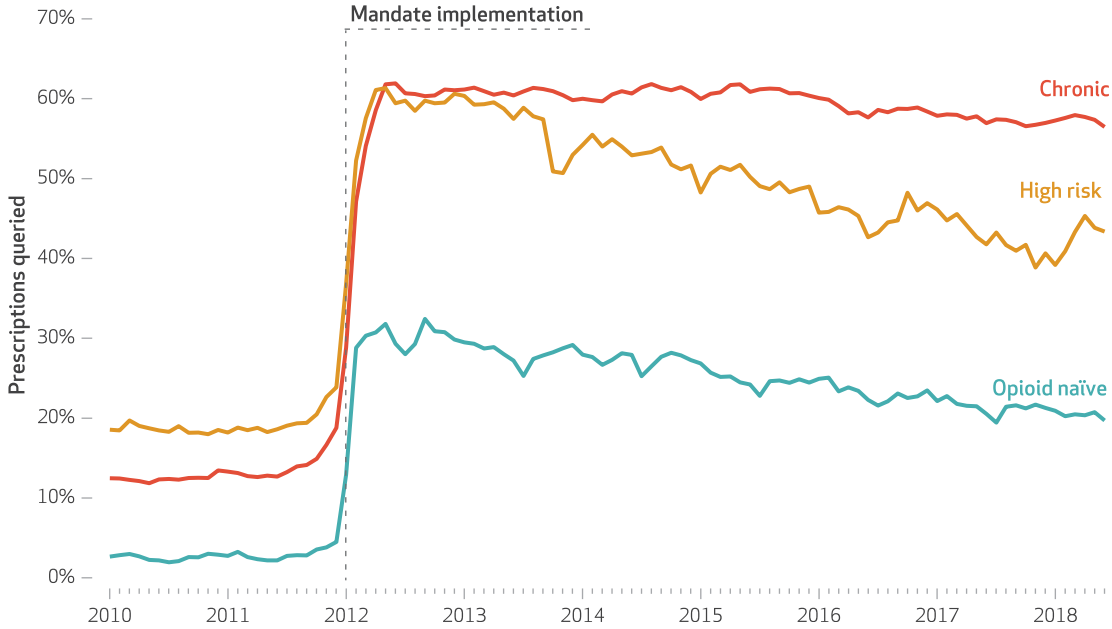
Consistent with prior studies, we found that the number of mandate-covered opioid prescriptions fell immediately after Kentucky's PDMP mandate went into effect, going from a peak of 366,370 in May 2012 to 290,731 in September 2012, and continued to fall steadily thereafter (see appendix exhibit S4).[22] By May 2018 the total number of monthly prescriptions was 34 percent lower than in 2012. This decline in prescriptions coincided with a large increase in the number of PDMP queries. This increase occurred sharply at the time of mandate implementation: Between May 2012 and September 2012 the share of mandate-covered prescriptions with an associated query increased from 16 percent to 52 percent.

Exhibit 1 reports the share of prescriptions queried by patient opioid history. Before the mandate, queries were most common for prescriptions written for high-risk patients, followed by chronic and opioid-naïve patients. Queries increased for all patient categories immediately after the mandate went into effect. The share of prescriptions that were queried tripled for high-risk patients and increased about sixfold for chronic patients to about 60 percent for both groups. The share of prescriptions queried increased from about 3 percent to 30 percent for opioid-naïve patients. Over time, however, the share of prescriptions queried fell for all patient groups. It decreased most for high-risk patients, to a low of 39 percent by May 2018. The share fell far less for other patients; by May 2018 it had declined to 57 percent for chronic patients

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EXHIBIT 1

Share of opioid prescriptions queried in Kentucky, by patient use history, July 2010–December 2018



SOURCE Authors' analysis of data from the Kentucky All Schedule Prescription Electronic Reporting system , 2010–18. **NOTES** Each line reports, for each patient use category, the share of mandate-covered prescriptions for which the provider queried the patient in the month of a prescription or the preceding four months. The vertical line is at July 2012, the month of mandate implementation.

and 22 percent for opioid-naïve patients.

The mandate had a substantial impact on the share of prescriptions queried for all provider specialties (exhibit 2). Both before and after the mandate, querying was most common among pain management specialists. Appendix exhibit S1 shows the share of prescriptions queried among providers categorized by the average number of monthly patients.[22] In both the pre and post periods, high-volume providers tended to query more frequently than low-volume providers.

Exhibit 3 presents the share of prescriptions queried by provider and patient characteristics. The first column reports the share of prescriptions in each category. A slight majority of prescriptions were written by primary care physicians, and nearly one-fifth were written by pain management specialists. High-volume prescribers wrote the majority of prescriptions; over 70 percent of prescriptions were written by providers who averaged fifty or more patients per month.

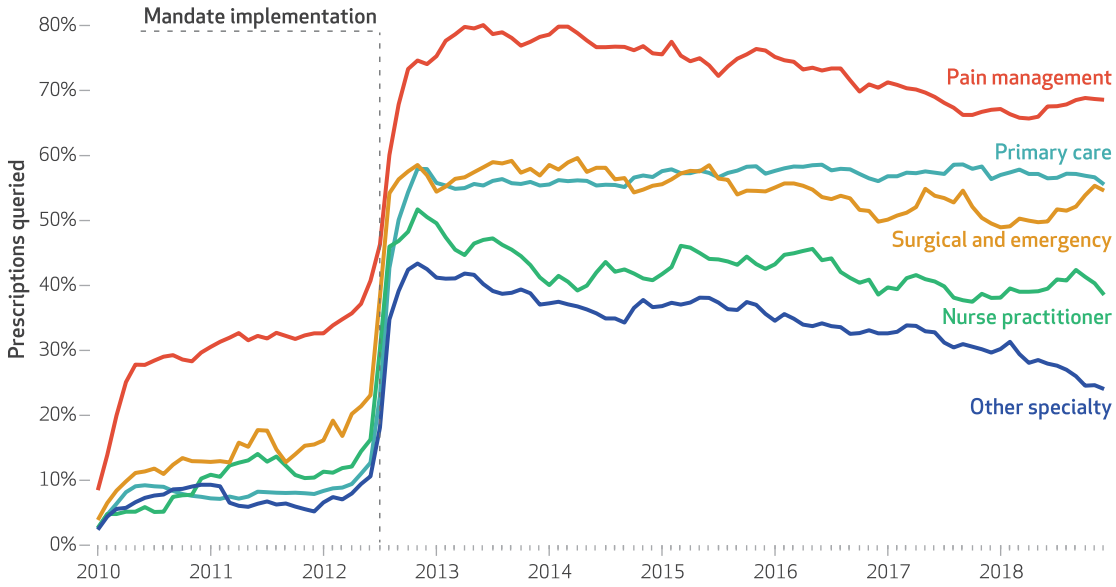
Exhibit 3 also reports the share of prescriptions queried in the pre- and postmandate periods for each characteristic, as well as raw and regression-adjusted differences. Among provider specialties, the share of prescriptions queried increased most among primary care physicians (48 percentage points, to 56 percent), although in the postmandate period, pain management specialists queried a larger share of their prescriptions (72 percent). Characterizing providers by the volume of their opioid-taking patients, those with fifty or more such patients per month increased the share of prescriptions queried by nearly 50 percentage points. Shares of prescriptions queried were low in both the pre and post periods for low-volume prescribers; those who prescribed to fewer than five patients per month only queried for 2 percent of prescriptions before the mandate and 20 percent after. However, these providers accounted for only 3 percent of all prescriptions. Shares of prescriptions queried in both periods were broadly similar across patient demographics, prescription ingredient or strength, and county characteristics (appendix exhibit S10).[22]

Results of our logistic regression show how each characteristic affected the probability of querying a prescription, with other characteristics controlled for, in the pre and post periods (appendix exhibit S2).[22] The results suggest that pain management physicians query a significantly larger share of their prescriptions than other provider types, even after adjustment for differences in their patient pools and prescription types. In addition, the share of prescriptions queried for opioid-naïve patients and low-volume prescribers remained low after adjust-

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EXHIBIT 2

Share of opioid prescriptions queried in Kentucky, by provider specialty, January 2010–December 2018



SOURCE Authors' analysis of data from the Kentucky All Schedule Prescription Electronic Reporting system, 2010–18. **NOTES** Each line reports, for each provider specialty, the share of mandate-covered prescriptions for which the provider queried the patient in the month of a prescription or the preceding four months. The vertical line is at July 2012, the month of mandate implementation.

ment for other characteristics.

In the "Regression adjusted" change column of exhibit 3, we report the pre-post difference in the predictive margins for each characteristic. These results indicate that the mandate had a broadly similar impact across provider and patient characteristics. However, there were significant differences in the adjusted change for the lowest-volume prescribers and chronic patients. The share of prescriptions queried by the lowest-volume prescribers increased less in the post period relative to other providers, and the share queried for chronic patients increased more compared with the shares queried for opioid-naïve or high-risk patients.

Exhibit 4 reports the share of prescriptions written by providers in each of four querying ranges in three periods and for each patient type. (Appendix exhibit S9 repeats exhibit 4 for provider specialty and volume categories.)[22] For each group, the total number of prescriptions in the pre period is normalized to 1.00, and the bars for the subsequent periods reflect the volume relative to the pre period.

In the pre period, opioid-naïve patients received 79 percent of their prescriptions from providers who queried 5 percent or fewer of their opioid prescriptions. Fewer than 1 percent of opioid-naïve patients received prescriptions from providers with query rates of 75 percent or higher. In contrast, chronic and high-risk patients were more likely to receive prescriptions from providers with higher query rates, although even for these patients nearly three-fifths of prescriptions were from providers who queried fewer than 5 percent of prescriptions.

In the early post period the number of opioid prescriptions decreased substantially for all three patient categories. Total opioid prescriptions fell by 21 percent for opioid-naïve, 11 percent for chronic, and 46 percent for high-risk patients (exhibit 4). For each group, as providers increased their querying, the share of prescriptions written by providers with low query rates decreased substantially, and the share written by those with higher rates increased.

By the late post period there were continued reductions in opioid prescribing, particularly among high-risk patients. The reduction in prescribing to the high-risk category was driven almost entirely by providers who queried at least half the time. These reductions suggest that many formerly high-risk patients transitioned to "chronic" status or stopped taking opioids altogether by the late post period (see the transition matrix in appendix exhibit S8).[22] However, the high-risk patient group continued to receive about the same number of prescriptions from providers who queried less than half the time. The fact that the remaining high-risk patients obtained opioids from low-querying providers explains the gradual decline in the

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EXHIBIT 3

Share of prescriptions queried before and after the mandate to query prescriptions in the Kentucky prescription drug monitoring program, by provider and patient characteristics, 2010–18

Characteristics	Percent of prescriptions	Percent of prescriptions queried		Pre-post change[a]	
		Premandate	Postmandate	Raw	Regression adjusted
Overall	100	12	56	44	—[b]
Provider specialty					
Primary care	55	8	56	48	45
Pain management	19	31	72	41	46
Nurse practitioner	10	10	42	32	33***
Surgical and emergency medicine	9	7	34	27	45
Other specialties	7	16	54	38	34***
Average no. of monthly patients[c]					
<5	3	2	20	18	21***
≥5 to <50	26	5	40	35	43
≥50 to <200	38	10	58	48	46
200 or more	33	22	68	46	45
Patient usage pattern[d]					
Opioid naïve	9	3	25	22	33***
Chronic	82	14	59	45	44
High risk	3	20	50	30	35***
Usage history not available	6	8	—[b]	—[b]	—[b]
Patient demographics					
Sex					
Female	55	12	56	44	43
Male	45	12	55	43	44
Age, years					
0–24	2	7	26	19	37***
25–39	13	16	51	35	40***
40–54	33	14	57	43	43
55–64	26	11	58	47	46
65–79	20	8	56	48	47
80+	5	3	49	46	45

SOURCE Authors' analysis of data from the Kentucky All Schedule Prescription Electronic Reporting system, 2010–18. **NOTES** "Regression adjusted" change was obtained by differencing the pre- and post-period predictive margins of a logistic regression model for querying. The model predicts whether each prescription is queried based on the set of characteristics reported above interacted with a dichotomous variable for the post period. The predictive margins are reported in appendix exhibit S2 (see note 22 in text). Asterisks denote whether the adjusted change is significantly different from the overall mean change. [a]Percentage points. [b]Not applicable. [c]Average number of monthly patients to whom providers wrote opioid prescriptions. [d]"Opioid naïve" means no opioid prescriptions in the previous six months; "chronic" means one or more opioid prescriptions, written by four or fewer prescribers and filled at four or fewer Kentucky pharmacies; and "high risk" means prescriptions from five or more providers or pharmacies. ***$p < 0.01$

querying rate for this patient group, apparent in exhibit 1.

Discussion

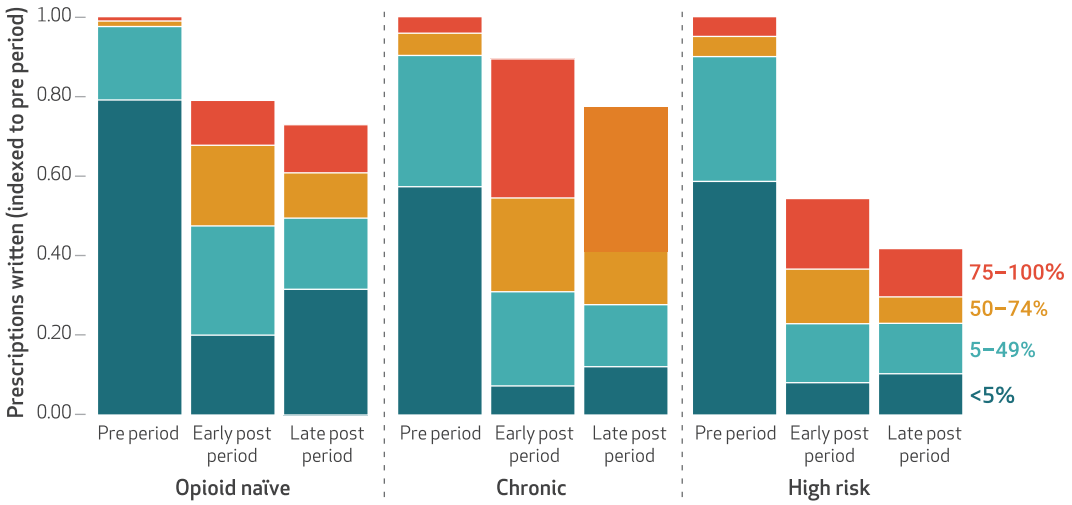
Kentucky's prescription drug monitoring mandate has been held up as a model law. The results of our analysis show that the mandate had the intended effect of increasing providers' use of the PDMP. Before the querying mandate, providers' use of KASPER was low: Only 12 percent of opioid prescriptions had a recent KASPER query. This finding is consistent with research indicating that when use of a PDMP is voluntary, very few providers access the system.[2–4] After the Kentucky mandate went into effect, the share of prescriptions queried rose by 44 percentage points. The mandate's effect was similar across various provider, patient, prescription, and county characteristics.

Even with this increase, however, many providers' use of the system falls short of the level required. After the mandate, query rates remained especially low for patients who had not received any opioid prescriptions in the previous six months. One possible explanation is that doctors may infer that the risk for misuse or diversion is low based on the reason for treatment and information they have on the patient from other sources. However, Kentucky's mandate explicitly requires providers to query the PDMP when prescribing an opioid for the first

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EXHIBIT 4

Opioid prescriptions, by provider share of prescriptions queried and patient type, before and after the mandate to query Kentucky's prescription drug monitoring program, 2010–18



SOURCE Authors' analysis of Kentucky All Schedule Prescription Electronic Reporting system data, 2010–18. **NOTES** Each bar shows the share of prescriptions written by providers in each of four query share categories during one of three time periods for patients in three different use categories. Prescriptions for each patient category are indexed to the number of monthly prescriptions in the pre period. Provider query share categories were 0–4 percent, 5–49 percent, 50–74 percent, and 75 percent or more mandate-covered prescriptions. The periods were pre period, before the law went into effect (July 2010–June 2012); early post period (July 2012–December 2015); and late post period (2016–18). The patient use categories are defined in the exhibit 3 notes.

time to a patient to guard against inappropriate opioid prescribing to patients who misrepresent their symptoms or conditions.

Our analysis of administrative data does not reveal why providers did not query all required prescriptions. Kentucky prescribers were surveyed after the mandate's implementation; a majority of respondents reported that the queries revealed useful information and that disruptions to workflow were limited to a short window after implementation.[19] During the sample period there was not widespread integration of KASPER reports into electronic health records in Kentucky, which would have further lowered the cost of using the PDMP and potentially increased provider engagement.[26] More research is needed on exactly how providers use PDMPs, whether they face barriers to querying, and whether increased querying would improve patient outcomes.

The increase in the share of prescriptions queried coincided with a large decrease in opioid prescriptions. In percentage terms, the decrease was greatest for the small number of patients with high-risk prescription histories, although we also found large decreases among chronic patients and those with no prior opioid use. This pattern is consistent with recent studies analyzing the impact of Kentucky's mandate.[15,18]

The mechanisms underlying these changes may be different for different patient types. Abby Alpert and colleagues suggest that the decline in prescribing for opioid-naïve patients may reflect the fact that physicians are not inclined to incur the "hassle cost" of conducting a PDMP query when the clinical benefit of opioids is not clear.[18] Similarly, in earlier work we found that a small but significant number of low-volume providers stopped prescribing opioids after Kentucky's mandate went into effect, which could be another response to the hassle cost of learning the new system.[15]

Our analysis suggests that for patients with a history of opioid use, the decrease in prescriptions was linked to the increase in queries. Exhibit 4 shows that the prescribing reductions to high-risk patients were concentrated among providers who queried at high rates. High-querying providers continued writing prescriptions to chronic patients whose query histories did not suggest high-risk use.

Our findings suggest that the Kentucky mandate had the desired impact: Providers responded to the information revealed from queries by reducing opioid prescribing to patients with high-risk patterns. A number of states have followed Kentucky's lead in implementing a comprehensive PDMP mandate, although providers' PDMP use is still voluntary in many states. Our findings suggest that these states could reduce opioid prescribing to high-risk patients by mandating use of their PDMPs. ■

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22 To access the appendix, click on the Details tab of the article online.

23 The law requires querying patients with ongoing opioid use every three months. We counted queries within the previous four months because we observed the date a prescription was dispensed, rather than the date it was written. Results were very similar if we counted queries written within the previous three months.

24 Katz N, Panas L, Kim M, Audet AD, Bilansky A, Eadie J, et al. Usefulness of prescription monitoring programs for surveillance—analysis of Schedule II opioid prescription data in Massachusetts, 1996–2006. Pharmacoepidemiol Drug Saf. 2010;19(2):115–23.

25 In exhibits 2 and 4 the first six months of prescriptions are used to generate the patient history categorizations. Thus, these exhibits reflect 23,242,623 prescriptions from 18,800 prescribers to 1,784,607 patients. Exhibit 3 and the logistic regression include prescriptions from this period as patient type "usage history not available."

26 Wang LX (Max Planck Institute; Munich, Germany). The complementarity of health information and health IT for reducing opioid-related mortality and morbidity [Internet]. Rochester (NY): SSRN; 2020 Sep 11 [cited 2021 Jan 6]. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3176809

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EXHIBIT C

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Brief Report

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Prescription drug monitoring program use by opioid prescribers: a cross-sectional study

Adam Sacarny[1,2,3,*], Ian Williamson[4], Weston Merrick[4], Tatyana Avilova[5], Mireille Jacobson[2,6,7]

[1]Department of Health Policy and Management, Mailman School of Public Health, Columbia University, New York, NY 10032, United States
[2]National Bureau of Economic Research, Cambridge, MA 02138, United States
[3]Abdul Latif Jameel Poverty Action Lab (J-PAL), Cambridge, MA 02142, United States
[4]Minnesota Management and Budget Agency, Saint Paul, MN 55155, United States
[5]Department of Economics, Bowdoin College, Brunswick, ME 04011, United States
[6]The Leonard Davis School of Gerontology, Los Angeles, CA 90089, United States
[7]The Schaeffer Center for Health Policy & Economics, Los Angeles, CA 90089, United States

*Corresponding author: Department of Health Policy and Management, Mailman School of Public Health, Columbia University, 722 W 168 St, 4th Floor, New York, NY 10032, United States. Email: ajs2102@columbia.edu

Abstract

Clinician use of prescription drug monitoring programs (PDMPs) has been linked to better patient outcomes, but state requirements to use PDMPs are unevenly enforced. We assessed PDMP use in Minnesota, which requires opioid prescribers to hold accounts and, in most cases, search the PDMP before prescribing, but where enforcement authority is limited. Using 2023 PDMP data, we found that 4 in 10 opioid prescribers did not search and 2 in 10 did not hold an account. PDMP use was strongly associated with prescribing volume, but even among the top decile of opioid prescribers, 8% never searched the PDMP. Thirty-two percent of opioid fills came from clinicians who did not search the PDMP. Failures to use the PDMP may be driven by a lack of information about state requirements, beliefs that these requirements are not enforced, and the costs of accessing the PDMP relative to the benefits. These results highlight the potential for policy makers to promote safer and better-informed prescribing of opioids and other drugs by addressing the forces that have limited PDMP use so far.

Key words: prescription drug monitoring programs; opioids; prescribing; controlled substances.

Introduction

Prescription drug monitoring programs (PDMPs), databases of controlled-substance dispensing that clinicians can query to monitor patient risk for overdose and other adverse events, currently operate in all states. Despite their ubiquity, research suggests that the benefits of PDMPs alone for patient outcomes are modest.[1] Mandates that require PDMP use have shown more promise, suggesting that clinician engagement is key to the success of these programs.[2,3] Consequently, most states now require that clinicians have PDMP accounts and check the database before prescribing, but these rules are unevenly enforced.[4,5] We examined PDMP use among opioid prescribers in Minnesota, where all controlled-substance prescribers are required to make accounts and search the PDMP before writing most opioid prescriptions but where administrators have limited authority to enforce this mandate.

Data and methods

We obtained data on the universe of Minnesota controlled-substance prescribing, PDMP searches, and PDMP accounts from the Minnesota Prescription Monitoring Program. We then analyzed PDMP search and account-holding by prescriber characteristics for the 180-day period starting February 1, 2023. To identify Minnesota-based prescribers, we used National Plan and Provider Enumeration System data. We identified opioid prescriptions with Centers for Disease Control and Prevention (CDC) opioid data and drug-name field searches.

To visualize the relationship between opioid-prescribing volume and PDMP use, we divided clinicians into deciles by volume as measured by total opioid-days supplied. To summarize this relationship in tabular form, we aggregated the deciles into 3 groups: below median, above median to below top decile, and top decile. We also classified clinicians by whether they queried the PDMP. Within each subgroup, we assessed clinical specialization, opioid prescribing, and PDMP use.

This study was overseen by Columbia University's Institutional Review Board. We considered P values less than .05 from 2-sided tests to be statistically significant and conducted analyses using Stata/MP 17 (StataCorp).

Results

There were 16 378 clinicians who prescribed opioids (Table 1). A slim majority were physicians and one-third were nurse practitioners or physician assistants. The average prescriber supplied 747 days of opioids to 31.9 distinct patients. While most opioid prescribers engaged with the

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Table 1. Specialization, prescribing, and PDMP use among opioid prescribers.

	All opioid prescribers	By opioid-prescribing volume[a]			By use of search[a]	
		Below median	Median to top decile	Top decile	No searches	Had searches
Specialization, No. (%)						
Primary care physician	4673 (28.5)	1576 (19.3)	2058 (31.2)	1039 (63.5)	1323 (19.4)	3350 (35.1)
Specialist physician	4537 (27.7)	2630 (32.3)	1810 (27.5)	97 (5.9)	2566 (37.6)	1971 (20.6)
Nurse practitioner	2745 (16.8)	1231 (15.1)	1194 (18.1)	320 (19.5)	798 (11.7)	1947 (20.4)
Physician assistant	2404 (14.7)	1083 (13.3)	1154 (17.5)	167 (10.2)	657 (9.6)	1747 (18.3)
Opioid prescribing, mean ± SD						
Days supplied	747 ± 2858	29 ± 26	474 ± 407	5422 ± 7508	200 ± 765	1138 ± 3636
Fills dispensed	57.1 ± 131.4	8.8 ± 9.5	63.6 ± 63.5	270.9 ± 313.9	32.3 ± 77.8	74.7 ± 156.5
Distinct patients	31.9 ± 54.2	8.2 ± 9.2	46.9 ± 54.7	89.5 ± 99.7	24.6 ± 50.3	37.1 ± 56.2
PDMP searching						
Any search, No. (%)	9555 (58.3)	3454 (42.4)	4592 (69.7)	1509 (92.2)	0 (0.0)	9555 (100.0)
EMR-integrated,[b] No. (%)	6995 (42.7)	2496 (30.6)	3353 (50.9)	1146 (70.0)	0 (0.0)	6995 (73.2)
No. of searches, mean ± SD	68.9 ± 301.5	17.2 ± 185.0	69.5 ± 249.3	324.3 ± 640.7	0.0 ± 0.0	118.1 ± 387.3
Has PDMP account, No. (%)	12 917 (78.9)	5812 (71.3)	5537 (84.1)	1568 (95.8)	3362 (49.3)	9555 (100.0)
No. of clinicians	16 378	8154	6587	1637	6823	9555

This table reports the characteristics of opioid prescribers overall, for subgroups defined by prescribing volume measured in days' supply, and for subgroups defined by whether the clinician searched the PDMP. Prescribing, searching, and account-holding were measured during the 180-day period starting February 1, 2023. Specialization derived from NPPES data. Specialization shares do not sum to 100% because specializations with small shares were omitted from the table. Primary care physicians are defined as those with specialization in Family Medicine, Internal Medicine, or General Practice. Searches that were conducted by a prescriber's PDMP delegates were attributed to that prescriber.
Abbreviations: EMR, electronic medical record; NPPES, National Plan and Provider Enumeration System; PDMP, prescription drug monitoring program; SD, standard deviation.
[a]Across all rows, all tests of equality of means across specified subgroups were statistically significant ($P < .001$).
[b]Prescribers with searches performed within an EMR system, which is possible when the EMR is integrated with the PDMP.

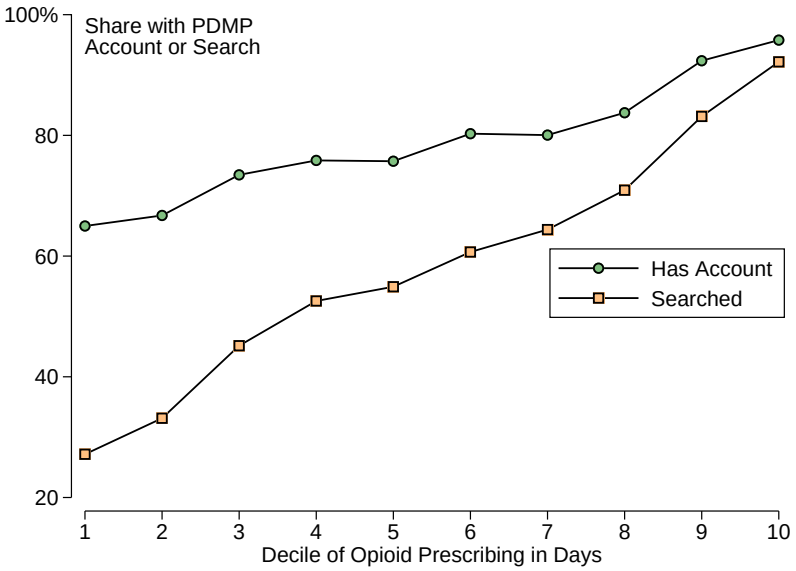


Figure 1. Rates of prescription drug monitoring program (PDMP) searching and account-holding by decile of opioid-prescribing volume. There were 16 378 clinicians who prescribed opioids during the study period. Prescribers are grouped into deciles according to their volume of opioid prescribing in total days supplied during the 180-day period starting February 1, 2023.

PDMP, many did not: 4 in 10 did not search the PDMP during this period and 2 in 10 did not hold an account.

Prescription drug monitoring program use was more common among higher prescribers (Figure 1). Moving up 1 decile of opioid-prescribing volume was associated with a 6.7% point increase in the probability of searching ($P < .001$) and a 3.2% point increase in the probability of holding an account ($P < .001$). The vast majority of the highest-decile opioid prescribers searched the PDMP. Still, 7.8% of the highest-decile opioid prescribers did not search and 4.26% did not even have an account (Table 1).

Clinicians who did not search the PDMP were disproportionately specialist physicians and generally prescribed less (Table 1). Nonetheless, 32.2% of opioid fills and 11.1% of opioid days came from clinicians who never searched the PDMP.

Discussion

Most clinicians are aware of the risks of opioid prescribing and prescribe opioids safely. Still, we found that a group of clinicians continues to prescribe opioids without using the

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tools available and required to ensure safe prescribing. The overrepresentation of low-volume prescribers in this group may reflect a lack of information about state mandates. That some of the highest-volume prescribers also do not use the PDMP, however, suggests that some prescribers believe that the mandate is not enforced and/or find the cost of engaging with the PDMP high relative to the benefits. Gaining access to and querying the PDMP may represent yet another time-consuming administrative burden for clinicians.[6-8] Limitations of this study include the use of data from 1 state and lack of detailed patient data.

Conclusion

Our analysis suggests that more work may be needed to engage clinicians in using PDMPs to assess patient opioid-prescribing history. Policy makers can leverage several evidence-based strategies to promote PDMP use based on 2 recent randomized trials. Integrating PDMPs with electronic medical records can increase query rates,[9] and messaging clinicians about state requirements encourages account-holding and querying.[10] These efforts could be paired with other work to reduce clinicians' administrative burdens and provide them with more time for high-value care activities. By addressing informational, administrative, and behavioral barriers, states and health care organizations can raise PDMP engagement and thereby encourage informed prescribing of opioids and other controlled substances.

Supplementary material

Supplementary material is available at *Health Affairs Scholar* online.

Conflicts of interest

Please see ICMJE form(s) for author conflicts of interest. These have been provided as supplementary materials. Drs. Avilova and Merrick report no conflicts.

Notes

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Variations in Prescription Drug Monitoring Program Use by Prescriber Specialty

Benjamin C. Sun, MD, MPP[1], **Nicoleta Lupulescu-Mann, MS**[2], **Christina J. Charlesworth, MPH**[2], **Hyunjee Kim, PhD**[2], **Daniel M. Hartung, PharmD, MPH**[3], **Richard A. Deyo, MD, MPH**[4], and **K. John McConnell, PhD**[1,2]

[1]Center for Policy Research-Emergency Medicine, Department of Emergency Medicine, Oregon Health and Science University, Portland, OR.

[2]Center for Health Systems Effectiveness, Oregon Health and Science University, Portland, OR.

[3]College of Pharmacy, Oregon State University / Oregon Health and Science University, Portland, OR.

[4]Department of Family Medicine, Department of Medicine, Department of Public Health and Preventive Medicine, and Oregon Institute of Occupational Health Sciences, Oregon Health and Science University, Portland, OR.

Abstract

Background—Although prescription drug monitoring programs (PDMPs) have been widely implemented to potentially reduce abuse of prescription opioids, there is limited data on variations in PDMP use by prescriber specialty. Such knowledge may guide targeted interventions to improve PDMP use.

Methods—Using data from Washington state Medicaid program, we performed a retrospective cohort study of opioid prescribers and their PDMP queries between Nov 1, 2013 to Oct 31, 2014. PDMP registration was mandatory for emergency physicians, but not for other providers. The unit of analysis was the prescriber. The primary outcome was any prescriber queries of the PDMP. We used multivariate regression models to identify variations in PDMP queries by prescriber specialty, as well as to explore explanatory pathways for observed variations.

Corresponding Author: Benjamin Sun, MD, MPP, sunb@ohsu.edu, Phone: 503-494-1193, Fax: 503-494-4640, Address: Mail Code CR114, 3181 SW Sam Jackson Park Rd, Portland, OR 97239.

Contributors

BCS developed the study question. BCS and KJM obtained funding. NLM and CJC had direct access to all data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. NLM and CJC performed all data management and analysis. BCS prepared the manuscript, and all authors made substantial edits and revisions. BCS has overall responsibility for this study.

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Conflict of Interest

The study team had full responsibility for the design of the study, in the collection, analysis, and interpretation of the data; in the preparation, review and approval of the study report. All the authors declare that they have no conflict interest.

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Results—We studied 17,390 providers who prescribed opioids, including 8,718 (50%) who were not registered with PDMP, 4,767 (27%) who were registered but had no recorded use of the PDMP, and 3,905 (23%) PDMP users (queries/ user: median 18, IQR 5-64). Compared to general medicine physicians, PDMP use was higher for emergency physicians (OR 1.4, 95%CI: 1.2-1.7), and lower for surgical specialists (OR 0.1, 95%CI:0.08-0.1), obstetrician-gynecologists (OR 0.2, 95%CI: 0.1-0.2) and dentists (OR 0.4, 95%CI: 0.4-0.5). Higher use by emergency physicians appeared to be mediated by higher registration rates, rather than by provider level predilection to use the PDMP.

Conclusions—A minority of opioid prescribers to Medicaid beneficiaries used the PDMP. We identified variations in PDMP use by prescriber specialty. Interventions to increase PDMP queries should target both PDMP registration and PDMP use after registration, as well as specialties with current low use rates.

Keywords

prescription drug monitoring program

1. Introduction

1.1. Background

Drug overdoses are now the top reason for unintentional mortality in the United States, and prescription opioid abuse is a major contributor to this public health crisis.(Seth, Scholl, Rudd, & Bacon, 2018; "CDC. Prescription opioid overdose data.," 2016) Nearly all states have adopted prescription drug monitoring programs (PDMPs) that track dispensed controlled substances to unique patients.(Gugelmann & Perrone, 2011) PDMP data may help providers improve opioid prescribing behaviors, particularly to patients with a prior history of high-risk prescription opioid use. State-level data suggest that introduction of PDMPs may be reduce opioid supply and opioid “shopping” behavior.(Buchmueller & Carey, 2017; Pardo, 2016)

1.2. Importance

Preliminary studies suggest that, in the past, prescribers and pharmacists rarely use PDMPs(Feldman, Williams, Coates, & Knox, 2011; McCauley, Leite, Melvin, Fillingim, & Brady, 2016; Perrone, DeRoos, & Nelson, 2012; H. W. Young, 2nd, Tyndall, & Cottler, 2017) due to logistic and time constraints.(Greenwood-Ericksen, Poon, Nelson, Weiner, & Schuur, 2016; Poon et al., 2016) States have responded with a variety of policies, including requirements for mandatory PDMP use prior to opioid prescribing(Buchmueller & Carey, 2017) and integrated systems that “push” PDMP data to emergency department physicians. ("Washington ACEP. EDIE and PMP Integration," 2015)

However, there are limited data on variation of PDMP use by prescriber specialty. Prior studies of prescriber PDMP use are limited by survey methodology, low response rates, and potential recall and selection bias.(Feldman et al., 2011; McCauley et al., 2016; Perrone et al., 2012; H. W. Young, 2nd et al., 2017) Furthermore, these surveys have typically targeted prescribers within specific specialties, limiting generalizability across all prescribers.

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Improving knowledge of prescriber use patterns is essential for developing targeted interventions to improve PDMP use (e.g. directed at low-utilizing specialties). Identifying potential mechanisms to improve PDMP use is particularly important for prescribers to Medicaid beneficiaries, who have an six-fold increased risk of opioid overdose compared to other insured populations.("CDC. Overdose deaths involving prescription opioids among medicaid enrollees - Washington, 2004-2007," 2009)

1.3. Goals of This Investigation

Using linked PDMP provider, query, and dispense files, we assessed prescriber specialty variation in PDMP use among opioid prescribers to Washington state Medicaid beneficiaries.

We further explored whether variations in PDMP query rates were mediated by registration rates or by predilection to use the PDMP among registrants. We exploited a natural policy experiment which required emergency physicians, but not other specialists, to register for the PDMP.

2. Methods

2.1. Study Design and Cohort Selection

We performed a retrospective cohort study of providers who prescribed opioids to Medicaid beneficiaries during the one-year period between November 1, 2013 and October 31, 2014. The Washington state PDMP started data collection on Schedule II III, IV, and V drugs starting October 2011. Prescriber and prescriber delegates could register for PDMP access using an online process. Starting in July 2012, all emergency physicians in Washington state were required to be registered with the PDMP.(Sun, Lupulescu-Mann, et al., 2017) Hospitals attested to compliance with this requirement. There have been no other registration or use requirements for other prescribers. In November 2014, Washington state began implementation of an automated PDMP query intervention in all non-federal emergency departments (EDs). This initiative increased the proportion of ED visits with a validated PDMP query from 4 to 70%.(Sun, Charlesworth, et al., 2017) To isolate the predictors of voluntary PDMP use from the effects of this policy intervention, we restricted the current study to the period prior to the automated ED PDMP queries.

We included health care providers if they wrote at least five opioid prescriptions for Medicaid beneficiaries during the study period and had a Drug Enforcement Agency number registered in Washington state.

The Washington state PDMP identified opioid prescribers to Medicaid beneficiaries, and provided dispense, prescriber, and query files to the study team. The dispense file included all instances of controlled substance dispensing to Medicaid beneficiaries. The prescriber file included specialty and PDMP registration status for unique prescribers in the dispense files. The query file included all PDMP queries on patients with a prior controlled substance dispense. Queries on patients without any prior controlled substance dispense are not recorded by the PDMP.

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The Institutional Review Boards of Washington State and of Oregon Health & Science University approved this study.

2.2. Outcomes

The primary outcome was any recorded PDMP query made by a prescriber during the study period.

2.3. Provider Specialty

The PDMP vendor linked self-reported National Prescriber Identifier specialty data to the prescriber file.("Center for Medicare and Medicaid Services. National Provider Identifier Registry," 2017) We aggregated specialty categories that were provided in the prescriber file (Appendix Table).

2.4. Co-variates

Increased volume of opioid prescribing may be correlated with PDMP use. If true, then measures of opioid prescribing frequency would potentially confound the relationship between specialty and PDMP use. To control for confounding, we used PDMP dispense data to create variables that describe past opioid prescribing. These variables included the total number of patients that each provider prescribed opioids for during the one year study period, as well as the total dispensed morphine milligram equivalents (MMEs) prescribed by each provider. We calculated MMEs using the following conversion factors("Centers for Medicare and Medicaid Services. Opioid Morphine Equivalent Conversion Factors," 2015; "Oregon Health & Science University. Guideline for Safe Chronic Opioid Therapy Prescribing For Patients with Chronic Noncancer Pain," 2014; Paulozzi, Kilbourne, & Desai, 2011): codeine-0.15; fentanyl citrate-0.13; fentanyl patch-7.2; hydrocodone-1; hydromorphone-4; levorphanol-11; meperidine-0.1; methadone-3; morphine- 1; oxycodone-1.5; oxymorphone-3; and tapentadol- 0.4. We only considered oral / transdermal formulations.

2.5. Analysis

We wished to explore two possible, non-exclusive mechanisms for variations in PDMP use by specialty. First, there may be variations in registration by specialty, i.e. non-registered prescribers never have the opportunity to query the PDMP. Second, there may be variation in PDMP use among registered prescribers by specialty.

We generated descriptive tables of the prescriber cohort, stratified by the following three categories (1) Not registered with the PDMP, (2) Registered with the PDMP, but with no recorded PDMP query, and (3) Registered with the PDMP, and has at least one recorded PDMP query for the study year.

We used a multivariate logistic regression model to assess the association between any recorded PDMP query and prescriber specialty. The model included the two potential confounders described above. The unit of analysis was an individual prescriber, and all prescribers were included in the regression analysis regardless of PDMP registration status.

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Because of right skewed data, we parameterized continuous variables using indicators for quintile values.

Using the same variables, we performed two additional logistic regression analyses to understand the reason for differences in PDMP use by specialty. First, we assessed the association between provider level variables and PDMP registration. Second, we assessed the association between provider level variables and PDMP use among those prescribers who were registered for the PDMP.

All data management and statistical analyses were performed in R version 3.3.2("R: A language and environment for statistical computing," 2015) and STATA MP 14.0.

3. Results

Our study cohort included 17,390 providers (Figure 1) who prescribed controlled substances to 506,249 Medicaid beneficiaries, including 1,739,672 opioid prescriptions Table 1 describes 8,718 (50%) prescribers who were not registered with PDMP, 4,767 (27%) who were registered but had no recorded use of the PDMP during the study period, and 3,905 (23%) PDMP users.

There were a total of 339,731 PDMP queries. Among PDMP users, there was large variation in the annual number of PDMP queries with a right skewed distribution (Median 18, IQR 5-64 Mean 87.0, SD 413.1). Comparing PDMP users to registered non-users, and registered non-users to unregistered prescribers, there were higher numbers of patients receiving prescription opioids, and a higher number of MMEs per prescriber.

There was marked variation by prescriber specialty in PDMP registration and use. General medicine and emergency medicine physicians had the highest rates of registration and use, whereas surgical specialists, obstetrician-gynecologists, and dentists had lower rates of registration and use.

The adjusted association between prescriber specialty and recorded PDMP use are presented in Table 2. Compared to general medicine practitioners, PDMP use was higher for emergency physicians (OR 1.4, 95%CI: 1.2-1.7), and lower for surgical specialists (OR 0.1, 95%CI: 0.08-0.1), obstetrician-gynecologists (OR 0.2, 95%CI: 0.1-0.2) and dentists (OR 0.4, 95%CI: 0.4-0.5). Prescribers aggregated into the “other” category were slightly less likely to use the PDMP (OR 0.8, 95%CI: 0.7-0.9).

Association of prescriber specialty with PDMP registration is presented in Table 3. Compared to general medicine practitioners, PDMP registration was highest for emergency physicians (OR 4.2, 95%CI 3.3-5.4), which is consistent with state mandates. Registration of all other specialty types was significantly lower than general medicine practitioners.

Finally, association between prescriber specialty and any recorded PDMP use conditional on PDMP registration is presented in Table 4. Compared to general medicine practitioners, PDMP use was similar for emergency physicians (OR 0.9, 95%CI: 0.7-1.0), and lower for

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surgical specialists (OR 0.3, 95%CI: 0.2-0.5), obstetrician-gynecologists (OR 0.2, 95%CI: 0.2-0.3) and dentists (OR 0.6, 95%CI: 0.5-0.7).

4. Discussion

A minority of opioid prescribers to Washington state Medicaid beneficiaries used the PDMP. Half of prescribers were not registered with the PDMP. Of prescribers who were registered to use the PDMP, over half had no evidence of using the PDMP during the study year. We also identified variations in PDMP use by prescriber specialty. PDMP registration mandates specific to emergency medicine providers appear to have been effective, and increased PDMP use by emergency medicine providers is attributable primarily by higher registration rates rather than greater predilection to use the PDMP among registrants. Interventions to increase PDMP queries should target PDMP registration and specialties with current low use rates.

Our study builds on prior literature by using objective PDMP registration, query, and dispense data across all prescribing specialties. Most prior studies that attempted to quantify PDMP use have been based on physician surveys and have targeted specific specialties (e.g. toxicologists, dentists, or emergency physicians).(Feldman et al., 2011; McCauley et al., 2016; Perrone et al., 2012; H. W. Young, 2nd et al., 2017) Survey response rates in these studies have ranged from 4-61%, and reported PDMP use was not verified against objective data.

We found that general medicine and emergency medicine physicians had the highest rates of registration and use, whereas surgical specialists, obstetrician-gynecologists, and dentists had lower rates of registration and use. Our findings are concordant with a prior study by Irvine et.al. that combined Oregon PDMP registry data with a prescriber survey.(Irvine et al., 2014) They found that emergency medicine, pain and addiction, and primary care specialties were heavily represented in the any-user group, whereas surgeons, dentists, and psychiatrists were more heavily represented in the non-user group. Registered users of the PDMP reported prescribing all classes of controlled substances more often than non-registrants. However, many non-registrants also reported frequent prescribing of controlled substances.

During the study period, Washington state had PDMP registration mandates for emergency medicine specialists but not for any other specialties. Our results demonstrated that overall use of the PDMP by emergency medicine providers were driven by increased registration rates, rather than a greater tendency to use the PDMP despite multiple policies aimed at reducing emergency department opioid prescribing. (Sun, Lupulescu-Mann, et al., 2017) These results provide support of the effectiveness of Washington state's registration mandate, and suggest potential approaches to improving PDMP use consistent with the recommendations of a prior expert panel process. First, PDMP enrollment should be mandatory for all prescribers.(Greenwood-Ericksen et al., 2016) Over 20 states already have such requirements. To minimize burden on prescribers, PDMP enrollment could be automated and linked with renewal of state professional licensure. Second, policy makers should consider mandatory PDMP use prior to opioid prescription. Recent evaluations suggest that the requirement for mandatory PDMP use is associated with reduced opioid

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prescribing to high-risk patients and less “shopping” behavior (multiple prescribers and/ or pharmacies for controlled substances)(Buchmueller & Carey, 2017; Pardo, 2016), and at least ten states already have such requirements.(Buchmueller & Carey, 2017) Third, logistical barriers to PDMP use should be minimized. A time-motion study of the Massachusetts PDMP found that a single query required nearly 4 minutes of provider time.(Poon et al., 2016) A potential solution is to automate PDMP queries and to integrate these data into existing EMRs. For example, Washington state has recently implemented an automated PDMP query system for all non-federal emergency departments.(Sun, Charlesworth, et al., 2017)

We did note that 12.7% of self-identified emergency physicians were not registered with the PDMP. Hospitals attested to the compliance of their eligible providers for the mandated PDMP registration requirement. However, to our knowledge, there was no state verification of compliance. Two possible reasons for the observed non-registration rate include: 1. Eligible providers did not register; 2. Self-reported classification was inaccurate (e.g. provider did not work in an ED environment at the time of the study. Our findings suggest that compliance with registration mandates be verified by objective PDMP data.

We found evidence of differential PDMP registration and use by specialty. These findings may be influenced by differences in practice culture and knowledge about the PDMP among specialties. These data could support professional society specific efforts to educate members about the opioid crisis and best prescribing practices. For example, there is increasing interest focused on opioid prescribing behaviors of dentists(Denisco et al., 2011) and surgeons.("American College of Surgeons. Surgeon Stewardship of the Opioid Epidemic," 2017)

Our recommendations are predicated on the assumption that PDMP use results in better patient outcomes through fewer overdose events. There is conflicting evidence on PDMP efficacy. Recent studies support the efficacy of PDMP in reducing opioid shopping behavior and overdose events(Bao et al., 2016; Buchmueller & Carey, 2017;Moyo et al., 2017; Patrick, Fry, Jones, & Buntin, 2016; Wen, Schackman, Aden, & Bao, 2017), although these findings are not universal.(Deyo et al., 2017; Nam, Shea, Shi, & Moran, 2017; Sun, Charlesworth, et al., 2017; Yarbrough, 2017) PDMP characteristics such as mandatory registration(Wen et al., 2017), mandatory use(Brown et al., 2017; Buchmueller & Carey, 2017; Pardo, 2016; Suffoletto, Lynch, Pacella, Yealy, & Callaway, 2017), clinical decision support, and monitoring of high risk activity(Pardo, 2016) are associated with greater efficacy. Several studies also suggest that providers alter prescribing behavior when given unsolicited PDMP data.(Baehren et al., 2010; Gonzalez & Kolbasovsky, 2012; L. D. Young, Kreiner, & Panas, 2017)

There are limitations of our study. First, the Washington state PDMP only captured queries on patients with prior controlled substance use. This is mitigated as an estimated 60% of opioid recipients in our study had evidence of controlled substance use prior to the study period. Second, our data were restricted to opioid prescribers of Washington Medicaid beneficiaries, and our findings need confirmation in other populations. However, we believe it is unlikely that ED providers change their PDMP query habits conditional on patients’

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insurance coverage. Third, we did not include queries by delegates. However, we found that <0.4% of prescribers were associated with delegate queries only, suggesting minimal impact of whether prescribers are classified as PDMP users. Fourth, provider specialty was self-reported with a significant rate of missing data. This may potentially introduce bias into our results. Finally, to avoid confounding with a state-wide automated PDMP policy, we studied data prior to November 2014, and it is possible that PDMP use patterns have changed since then.

5. Conclusions

In summary, the PDMP was used by a minority of prescribers to Medicaid beneficiaries, despite a high prevalence of risky opioid use in patients who received opioid prescriptions. Interventions to increase PDMP queries should target both PDMP registration as well as specialties with current low use rates.

Acknowledgments

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Appendix Table 1.: Specialty Definitions

Category	Included specialties
General	Internal Medicine, Family Medicine, Hospitalist, General Practice
Surgical	Surgery, Orthopaedic Surgery, Urology, Otolaryngology, Neurological Surgery, Plastic Surgery, Thoracic Surgery (Cardiothoracic Vascular Surgery), Colon & Rectal Surgery, Transplant Surgery
Dentist	Dentist, Oral & Maxillofacial Surgery
Pediatrics	Pediatrics
Psychiatry & Neurology	Psychiatry & Neurology
Emergency Medicine	Emergency Medicine
Obstetrics & Gynecology	Obstetrics & Gynecology
Other	Specialist, Podiatrist, Anesthesiology, Pathology, Radiology, Dermatology, Preventive Medicine, Student in an Organized Health Care Education/Training Program, Physical Medicine & Rehabilitation, Ophthalmology, Nuclear Medicine, Allergy & Immunology, Optometrist, Independent Medical Examiner, Clinic/Center, Neuromusculoskeletal Medicine & OMM, Health Maintenance Organization, Pharmacist, Neuromusculoskeletal Medicine, Pain Medicine, Psychoanalyst, Registered Nurse, Phlebology, Nurse Practitioner, Psychologist, Occupational Therapist, Medical Genetics, Veterinarian, General Acute Care Hospital, Physical Therapist, Legal Medicine, Audiologist, Physician Assistant, Chiropractor, Acupuncturist

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Highlights

- The minority of opioid prescribers used the Prescription Drug Monitoring Program
- There are substantial variation in PDMP use by prescriber specialty
- Mandatory registration was associated with higher use by emergency physicians

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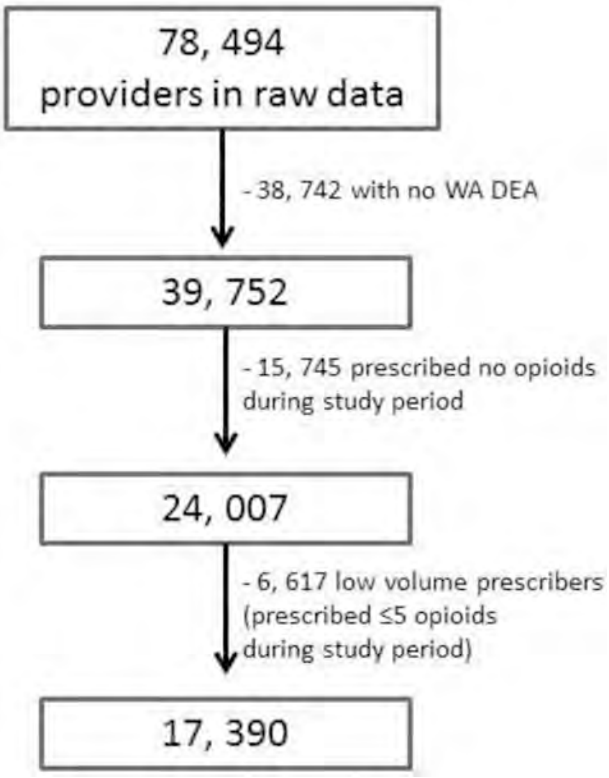


Figure 1.
Study Cohort

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Table 1:

Prescriber Characteristics

	PDMP Registration and Use		
	Not registered	**Registered, Never Used PDMP**	**Registered, Used PDMP**
	(N= 8,718)	**(N= 4,767)**	**(N= 3,905)**
Prescribing profile – mean(SD); *median [IQR]*			
Total patients that provider	34.5 (52.0);	58.2 (86.8);	73.2 (90.6);
prescribed opioids for	*19 [9-41]*	*30 [13-68]*	*44 [21-89]*
Total MME prescribed by provider	57,470 (269,377); *7,716 [2,550-26,416]*	123,738 (445,562); *16,715 [4,834-72,178]*	324,989 (1,139,451); *38,945 [9,130-201,380]*
Specialty – N (row%)			
General Medicine	1,783 (37.9)	1,457 (31.0)	1,461 (31.1)
Emergency Medicine	92 (12.7)	349 (48.0)	286 (39.3)
Surgical Specialty	1,059 (75.2)	294 (20.9)	56 (4.0)
Obstetrics & Gynecology	448 (74.4)	118 (19.3)	36 (6.3)
Other Specialty	909 (56.0)	383 (23.0)	331 (21.0)
Missing specialty	2,851 (49.0)	1,509 (25.9)	1,460 (25.1)
Dentist	1,576 (62.8)	657 (26.2)	275 (11.0)
Total number of PDMP queries			
– mean(SD);	0 (0);	0 (0);	87.0 (413.1);
median [IQR]	*0 [0-0]*	*0 [0-0]*	*18 [5-64]*

*p-value from chi-square test; all other p-values from ANOVA

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Table 2.

Association between Provider Specialty and Any PDMP Use

Provider Characteristic	Odds Ratio	95% CI
Total Number of Patients[1]	-	-
1st Quintile (<10)	*ref*	
2nd Quintile (10-18)	1.57	(1.36 - 1.82)
3rd Quintile (19-34)	2.31	(2.00 - 2.68)
4th Quintile (35-69)	2.68	(2.31 - 3.12)
5th Quintile (≥70)	3.81	(3.26 - 4.46)
Total Prescribed MMEs[1]		
1st Quintile (0-2,742)	*ref*	
2nd Quintile (2743-8,049)	0.95	(0.81 - 1.11)
3rd Quintile (8,050-21,729)	0.96	(0.82 - 1.13)
4th Quintile (21,730-84,052)	1.43	(1.22 - 1.68)
5th Quintile (≥84,053)	2.11	(1.78 - 2.50)
Prescriber Specialty		
General Medicine	*ref*	
Emergency Medicine	1.43	(1.19 - 1.72)
Surgical Specialty	0.1	(0.08 - 0.13)
Obstetrics & Gynecology	0.16	(0.11 - 0.23)
Dentist	0.44	(0.37 - 0.52)
Other	0.81	(0.70 - 0.93)
Missing	0.89	(0.81 - 0.98)

[1]Categorized by quintiles

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Table 3.

Association between Provider Specialty and PDMP Registration

Provider Characteristic	Odds Ratio	95% CI
Total Number of Patients[1]	-	-
1st Quintile (<10)	*ref*	
2nd Quintile (10-18)	1.45	(1.31 – 1.61)
3rd Quintile (19-34)	1.76	(1.58 – 1.96)
4th Quintile (35-69)	2.02	(1.80 – 2.27)
5th Quintile (≥70)	3.27	(2.88 – 3.71)
Total Prescribed MMEs[1]		
1st Quintile (0-2,742)	*ref*	
2nd Quintile (2743-8,049)	0.95	(0.85 – 1.06)
3rd Quintile (8,050- 21,729)	1.09	(0.97 – 1.23)
4th Quintile (21,730-84,052)	1.51	(1.33 – 1.71)
5th Quintile (≥84,053)	2.42	(2.10 – 2.79)
Prescriber Specialty		
General Medicine	*ref*	
Emergency Medicine	4.19	(3.31 – 5.35)
Surgical Specialty	0.23	(0.19 – 0.28)
Obstetrics & Gynecology	0.22	(0.19 – 0.25)
Dentist	0.57	(0.50 – 0.64)
Other	0.65	(0.58 – 0.74)
Missing	0.75	(0.69 – 0.82)

[1]Categorized by quintiles

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Table 4.

Association between Prescriber Characteristics and PDMP Use, Conditional on PDMP Registration

Provider Characteristic	Odds Ratio	95% CI
Total Number of Patients[1]	-	-
1st Quintile (<10)	*ref*	
2nd Quintile (10-18)	1.27	(1.07 – 1.50)
3rd Quintile (19-34)	1.76	(1.49 – 2.09)
4th Quintile (35-69)	1.88	(1.58 – 2.24)
5th Quintile (≥70)	2.15	(1.80 – 2.57)
Total Prescribed MMEs[1]		
1st Quintile (0-2,742)	*ref*	
2nd Quintile (2743-8,049)	0.99	(0.82 – 1.18)
3rd Quintile (8,050- 21,729)	0.90	(0.75 – 1.08)
4th Quintile (21,730-84,052)	1.17	(0.98 – 1.41)
5th Quintile (≥84,053)	1.48	(1.21 – 1.81)
Prescriber Specialty		
General Medicine	*ref*	
Emergency Medicine	0.86	(0.70 – 1.04)
Surgical Specialty	0.32	(0.22 – 0.47)
Obstetrics & Gynecology	0.21	(0.15 – 0.28)
Dentist	0.57	(0.48 – 0.69)
Other	1.03	(0.87 – 1.22)
Missing	1.06	(0.95 – 1.18)

[1]Categorized by quintiles

EXHIBIT E

EXHIBIT E

National Estimates and Physician-Reported Impacts of Prescription Drug Monitoring Program Use

Chelsea Richwine, PhD and Jordan Everson, PhD

Office of Technology, Office of the National Coordinator for Health Information Technology, Washington, DC, USA.

BACKGROUND: Despite widespread adoption of state prescription drug monitoring programs (PDMPs), it is unclear how often PDMPs are accessed through an electronic health record system (EHR-PDMP integration), or whether efforts to make PDMPs easier to access and use have improved their utility.

OBJECTIVE: To produce national-level estimates on the use of PDMPs among office-based physicians and benefits associated with their use.

DESIGN: We use nationally representative survey data to produce descriptive statistics on PDMP use and associated benefits among office-based physicians in the USA.

PARTICIPANTS: 1398 office-based physicians who prescribe controlled substances.

MAIN MEASURES: We examined physician-reported ease and frequency of PDMP use, and how EHR-PDMP integration affects frequency and ease of use. Multivariate models were used to assess whether characteristics of PDMP use were related to physician-reported benefits such as reduced prescribing of controlled substances and perceived improvements in clinical decision-making.

KEY RESULTS: In 2019, two-thirds of office-based physicians in the USA reported frequent use of their state PDMP and over three-quarters reported they were easy to use. Both frequency and ease of use were positively correlated with PDMP integration status. Respondents who frequently checked their state's PDMP were 8.7 percentage points (95% CI −.4 to 17.8) more likely to report perceived benefits and reported 2.2 (95% CI 1.54 to 2.83) more benefits. Respondents who indicated their PDMP was easy to use were 12.7 percentage points (95% CI .040 to .214) more likely to report perceived benefits and reported 0.94 (95% CI 0.26 to 1.61) more benefits.

CONCLUSIONS: Our findings suggest efforts to make PDMPs easier to access and use aided physicians in making informed clinical decisions that may not be captured by reduced prescribing alone. Efforts to further increase frequency and ease of use—including advancing a standards-based approach to PDMP and EHR data interoperability—may further increase the benefit of PDMPs.

KEY WORDS: prescription drug monitoring programs; physicians; opioid prescribing; electronic health records; quality.

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INTRODUCTION

Statewide prescription drug monitoring programs (PDMPs)—state-run databases that contain patient-specific prescription information—have been implemented in nearly all US states and the District of Columbia.[1,2] However, PDMPs are only useful if clinicians check the PDMP prior to prescribing controlled substances. Recent efforts, such as mandates requiring PDMP use and projects aimed at integrating PDMPs into electronic health record (EHR) systems ,[3–5] have focused on increasing the frequency of PDMP use and the usability of information contained in them.[6]

Few studies have examined how PDMPs are used nationally and whether variation in frequency of use, ease of use, and EHR-PDMP integration impacts benefits of using the PDMP to inform clinical decisions and reduce opioid overprescribing. To date, national and multi-state studies focused on the impact of PDMPs have largely examined the status of PDMPs and supporting laws, and how they relate to changes in rates of opioid prescribing or subsequent outcomes like opioid-related deaths, finding mixed results.[7–12] While focused on valuable outcomes, such studies are unlikely to capture other important benefits of PDMP use and how greater PDMP usability relates to improvements in the treatment process. For instance, overall prescribing of controlled substances or opioid-related mortality metrics might miss instances where PDMP use led to consultation with other clinicians and greater care coordination. A focus on overall opioid prescribing metrics would also fail to capture instances where the PDMP led clinicians to confirm the clinical appropriateness of an opioid prescription rather than reduce its dosage or frequency.

A parallel literature focused on local PDMP use has identified several factors related to physicians' views on PDMPs but has infrequently demonstrated a link between variation in PDMP use and associated treatment processes or outcomes.[12–21] For instance, some research has heralded the integration of PDMPs into health information exchanges, pharmacy dispensing software systems, and EHRs, both in terms of *system* integration—meaning the PDMP can be directly accessed through this system as

opposed to through a separate portal (referred to here as "EHR-PDMP integration")—and in terms of the ability to access, exchange, and use specific data elements from the PDMP (referred to here as "EHR-PDMP interoperability"), as a promising strategy for improving the usability of PDMPs.[4,5,13,15] Further, it is possible that poor data quality, inadequate patient matching, or usability issues within an integrated system mitigate the benefits of integration.

Our study contributes to the literature on the impact of PDMPs by shedding light on whether efforts to make PDMPs easier to access and use improve their utility for making informed clinical decisions and reducing opioid overprescribing. We use nationally representative survey data to produce descriptive statistics on PDMP use and associated benefits among office-based physicians in the USA and to evaluate the relationship between EHR-PDMP integration, ease and frequency of PDMP use, and physician-reported experience of nine types of benefits related to PDMP use.

METHODS

Data

Data used come from the 2019 National Electronic Health Records Survey (NEHRS) Public Use File (PUF).[22] The NEHRS is an annual mixed-mode survey conducted by the National Center for Health Statistics (NCHS) that collects information on the adoption and use of health information technology among office-based physicians in the USA. For the present study, we leveraged information on physicians' prescribing of controlled substances and use of a PDMP prior to prescribing controlled substances to a patient for the first time to explore the relationship between characteristics of use and physician-reported benefits that result from PDMP use.

Study Population

The target population for this study includes non-federally employed office-based physicians in the USA who are primarily engaged in patient care activities. Among the 10,302 physicians that were initially recruited to complete the survey, 5684 were deemed ineligible due to practicing in non-office-based settings, not seeing ambulatory patients, or no longer being in practice or not locatable. Among those who were eligible or whose eligibility could not be determined, NCHS estimated an unweighted response rate of 41.0% and the final sample included 1524 respondents.

We further restricted the sample to physicians that prescribe any controlled substances (N = 1398). The NEHRS over-samples small states to facilitate generation of state-level estimates. We used the survey weights included in the NEHRS PUFs to adjust for this over-sampling and for non-response bias. Full details on the sampling frame and adjustments for non-response can be found in the 2019 NEHRS PUF Documentation.[23]

Measures and Outcomes

We examined three characteristics of PDMP use: (1) frequency of use, (2) ease of finding patient information, and (3) EHR-PDMP integration (i.e., when asked "How do you or your designated staff check your state's PDMP?" respondents indicated, "Use EHR system" vs "Use system outside of EHR (e.g., PDMP portal or secure website)."). In the descriptive arm of the study, frequency and ease of use were defined as categorical variables. Frequency of checking the PDMP prior to prescribing controlled substances to a patient for the first time were defined on a scale from 1 to 4, where 1 = "often," 2 = "sometimes," 3 = "rarely," and 4 = "never." Ease of finding patient information in the PDMP were also defined on a scale from 1 to 4, where 1 = "very easy," 2 = "somewhat easy," 3 = "somewhat difficult," and 4 = "very difficult."

In multivariable analyses, PDMP use characteristics were re-defined as binary variables to facilitate interpretation. Frequent use equals one for physicians who "often" or "sometimes" check their PDMP prior to prescribing controlled substances, and zero otherwise. Ease of use equals one for physicians who reported it is "very" or "somewhat" easy to find patient information using their state's PDMP, and zero otherwise. EHR-PDMP integration equals one for physicians who checked their state's PDMP using an EHR, and zero for those who used a system outside their EHR.

The main outcomes measured include nine physician-reported benefits that result from checking the PDMP. We created two composite outcomes: one is a binary variable indicating whether the respondent reported at least one perceived benefit, and the other is a count variable capturing the number of perceived benefits, ranging from 0 to 9. We included supplementary outcomes based on distinct benefits listed in Table 2 including (1) reduced prescribing of controlled substances, (2) confirmed appropriateness of treatment, (3) confirmed patients' misuse of prescriptions, (4) referred new or additional treatments (a binary variable treated as positive if the respondent reported any of the following distinct benefits: changing to non-opioid pharmacologic or non-pharmacologic therapy; prescribing naloxone; or referring for additional treatment), and (5) consulted with others as a result of PDMP use (a binary variable treated as positive if the respondent reported either of the following distinct benefits: consulting with other prescribers listed in the PDMP report or consulting with other members of the care team).

Analysis

To understand how PDMPs are used nationally, we reported descriptive national statistics on the frequency of PDMP use among office-based physicians. Among those who indicated using their state's PDMP, we described physician-reported ease of finding patient information and methods used to access

the PDMP. Next, we examined how EHR-PDMP integration affects frequency and ease of use.

We then used regression to model the relationship between PDMP use characteristics and physician-reported benefits that result from checking the PDMP. We examined whether frequent PDMP use, ease of use, and EHR-PDMP integration were related to whether respondents reported at least one perceived benefit from PDMP use in logistic regression models and, in a complementary model, the number of benefits perceived using a Poisson model because the outcome variable was a count. All models controlled for physician and practice location characteristics including physician demographics, specialty, practice size, ownership, Independent Practice Association (IPA) or Physician-Hospital Organization (PHO) affiliation, percent of patients insured by Medicaid, and EHR certification status. We next ran separate logistic regressions to examine whether frequent PDMP use, ease of use, and EHR-PDMP integration were significantly related to five types of benefits listed above. We reported all relationships in terms of the average marginal effect. Analyses were performed using Stata version 15.[24]

RESULTS

Among respondents that prescribe controlled substances, 51% worked in primary care, 21% in a medical specialty, and 28% in a surgical specialty (Table 1). Less than half (45%) of respondents were in practices with 3 or fewer physicians and 61% worked in a physician-owned practice. Respondents were predominantly male and over the age of 50 (69% and 75%, respectively).

Overall, most physicians who prescribed controlled substances indicated checking their state's PDMP prior to prescribing controlled substances to a patient for the first time: 65% reported using the PDMP often, 27% used the PDMP sometimes or rarely, while only 8% never used the PDMP (Fig. 1). Among physicians that reported any PDMP use, less than a quarter (23%) indicated their PDMP was integrated with their EHR, while 77% used a system outside of their EHR to check the PDMP. Regardless of the method of access, physicians were generally satisfied with the ease by which they could access their state's PDMP (42% "very easy" and 36% "somewhat easy").

Both frequency and ease of use were correlated with PDMP integration status. Eighty-five percent (85%) of physicians with PDMP-EHR integration reported accessing their PDMP often compared to 70% of physicians that accessed their PDMP through a system outside the EHR (Fig. 2; difference = 14.4 percentage points, 95% CI 5.8 to 23.1, $P = .001$). Sixty percent of physicians (60%) with PDMP-EHR integration indicated their system was very easy to use compared to 39% that accessed their PDMP through an outside system (difference = 20.7 percentage points, 95% CI 8.7 to 32.8, $P = .001$).

Table 1 Sample Characteristics

	Prescriber sample (N = 1398)		*Analytical sample (N = 1025)*	
	N	**Weighted %**	***N***	**Weighted %**
Gender				
Female	408	31%	293	30%
Male	990	69%	732	70%
Age				
< 50 years	402	25%	293	26%
50+ years	996	75%	732	74%
Physician specialty				
Primary care	734	51%	598	57%
Medical	305	21%	186	18%
Surgical	359	28%	241	25%
Practice size				
1 physician	333	25%	241	26%
2–3 physicians	254	20%	184	19%
4–10 physicians	421	30%	302	28%
11–50 physicians	234	14%	180	15%
> 50 physicians	154	12%	118	13%
Ownership				
Physician or physician group	803	61%	572	59%
Hospital or health center	490	31%	379	33%
Other	100	8%	74	8%
IPA or PHO affiliation				
Yes	358	33%	272	34%
No	704	46%	524	45%
Don't know	336	22%	229	21%
Participate in value-based care or incentive program				
PCMH, ACO, P4P	715	50%	566	52%
MIPS, APM, MU	818	59%	626	61%
% patients insured by Medicaid				
Blank	115	9%	78	9%
0%	155	15%	113	16%
1–24%	653	43%	491	44%
25–50%	360	24%	261	23%
> 50%	115	9%	82	8%
Certified EHR				
Yes	991	74%	761	78%
No	178	12%	115	11%
Don't know	229	14%	149	11%

Notes: The original NEHRS 2019 Public Use File contains observations for 1524 physicians, of which 1398 prescribe controlled substances. The analytical sample used for multivariate analyses only includes respondents who prescribe opioids and excludes those that do not check their state's PDMP (N = 202) and did not know or did not respond to survey questions about methods of access or ease of using their state's PDMP (N = 165). The exclusion of these respondents, along with 6 missing covariate values, yields a final analytical sample of N = 1025 respondents. Value-based care initiatives include Patient-Centered Medical Homes (PCMH), Accountable Care Organizations (ACO), and Pay-for-Performance (P4P) arrangements. Incentive programs include Merit-Based Incentives Programs (MIPS), Advanced Alternative Payment Models (APM), and Medicaid EHR Incentive Programs (e.g., Meaningful Use (MU) Program). Hospital or health center ownership includes medical/academic health centers, community health centers, hospitals, and health care corporations. "Other" types of ownership include insurance companies, health plans, HMOs, and other ownership types. Respondents without a certified EHR (i.e., an EHR system that meets meaningful use criteria, also called promoting interoperability, as defined by the Department of Health and Human Services) include N = 152 respondents that indicated they do not have any type of EHR

Among physicians that reported any PDMP use, 85% reported experiencing at least one of nine benefits listed on the survey as a result of using the PDMP. On average, these physicians reported 3.4 benefits (Table 2). The most reported benefit was having "Reduced or eliminated controlled substance prescriptions for a patient," reported by

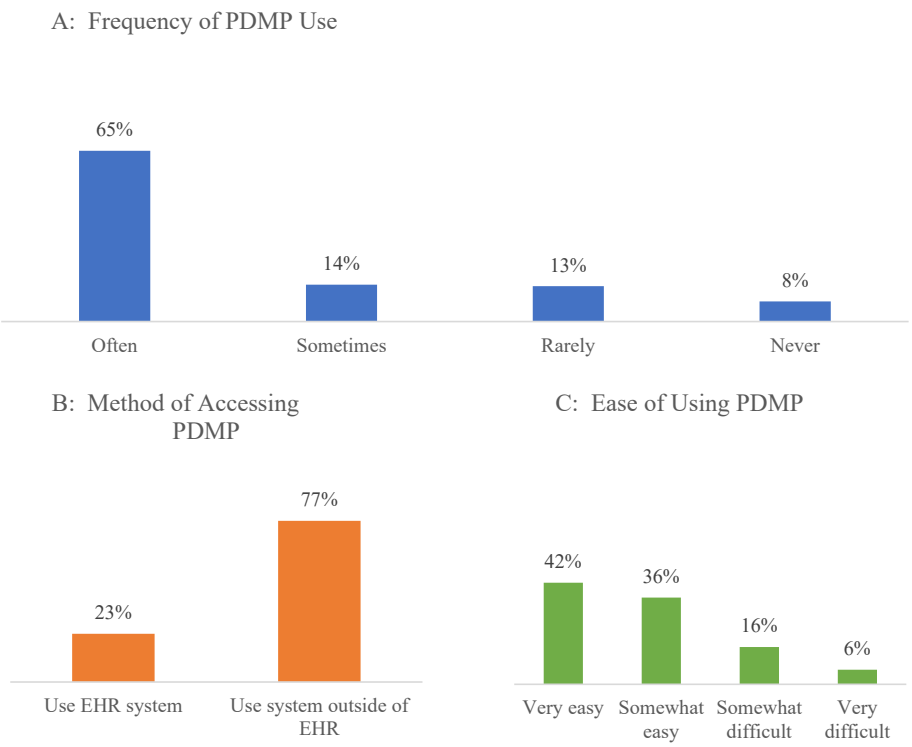


Figure 1 Panel A illustrates how often physicians or designated staff check their state's PDMP prior to prescribing controlled substances to a patient for the first time ($N = 1317$). Among respondents who reported checking their state's PDMP, panel B illustrates methods of access used to check the PDMP ($N = 1097$) and panel C reports the level of ease or difficulty associated with using the PDMP to find patient information ($N = 1072$). Denominators do not sum to $N = 1398$ due to missing data and item non-response.

61% of physicians, followed by "Confirmed appropriateness of treatment," reported by 53% of physicians. The least commonly reported benefit was "Prescribed naloxone," reported by only 12% of physicians.

In multivariable analyses, physicians that frequently used the PDMP were 8.7 percentage points more likely to report any benefit from the system (95% CI −0.4 to 17.8, $P = .062$) and reported 2.2 more benefits on average (95% CI 1.54 to 2.83, $P < .001$) than respondents that infrequently used the PDMP (Table 3). Respondents that said it was easy to use the PDMP were 12.7 percentage points more likely to report any benefit from the system (95% CI 4.0 to 21.4, $P = .004$) and reported 0.94 more benefits on average (95% CI 0.26 to 1.61, $P = .007$) compared to those who said it was somewhat or very difficult to use the PDMP.

Across the five distinct benefits related to PDMP use we assessed, respondents that indicated frequent PDMP use were more likely to report experiencing a given benefit from the PDMP. Respondents that indicated frequent use were 22.6 percentage points more likely to report having reduced or eliminated controlled substance prescriptions (95% CI 7.9 to 37.3, $P = .003$), 22.5 percentage points more likely to report having confirmed patients' misuse of prescriptions (95% CI 7.9 to 37.0, $P = .003$), 25.1 percentage points more likely to report having confirmed the appropriateness of treatment (95% CI 9.6 to 40.5, $P = .001$), 28 percentage points more likely to report having referred new or additional treatment (95% CI 11.6 to 44.3, $P = .001$), and 36.8 percentage points more likely to report having consulted with others (95% CI 24.1 to 49.5, $P < .001$).

Respondents indicating ease of use were 17.4 percentage points more likely to confirm the appropriateness of treatment (95% CI 4.6 to 30.2, $P = .008$) and 14.1 percentage points more likely to consult with others (95% CI 1.5 to 26.7, $P = .028$). For all benefits, the direction of coefficients indicated greater likelihood of benefits with greater reported ease of use and $P < 0.10$ for four of five outcomes.

While EHR-PDMP integration was associated with greater frequency and ease of use in bivariate analyses, it was not associated with a greater likelihood of experiencing specific benefits of PDMP use. In subsequent robustness tests, we excluded frequency and ease of use because we were concerned these variables may be suppressing the relationship between integration and benefits (i.e., if integration was related to benefits through greater frequency and ease of use). However, the association between EHR-PDMP integration and benefits was null in models excluding frequency and ease of use variables.

DISCUSSION

In a 2019 national survey, most opioid-prescribing physicians reported checking their state's PDMP prior to prescribing controlled substances to a patient for the first time, of which,

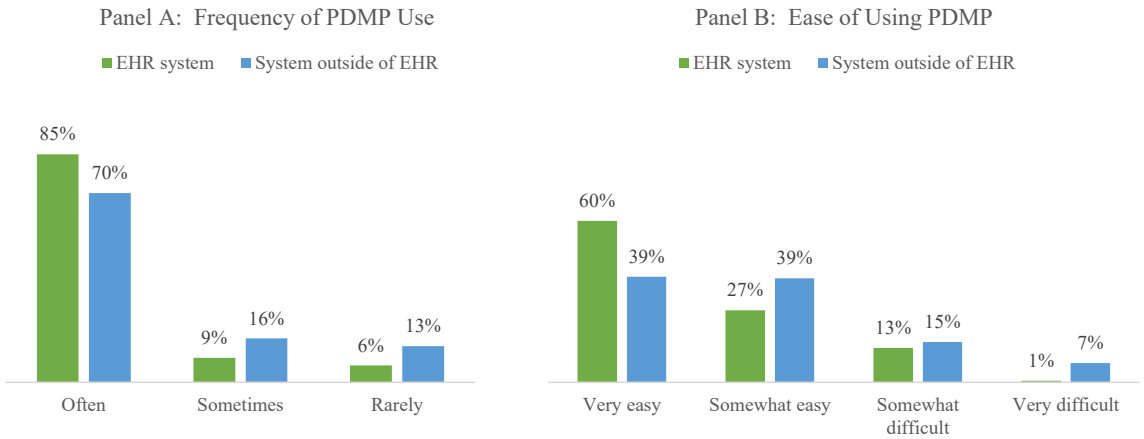


Figure 2 Panel A illustrates the frequency of PDMP use among respondents who used an EHR system versus external system (e.g., portal or secure website) to check their state's PDMP (*N* = 223 and *N* = 874 respectively). Panel B demonstrates the level of ease or difficulty associated with using the PDMP to find patient information among respondents who use an EHR system versus external system to check their state's PDMP (*N* = 205 and *N* = 826 respectively).

a majority reported experiencing at least one benefit from using the PDMP. More frequent PDMP use and greater ease of PDMP use were related to a greater likelihood of experiencing several different benefits from PDMP use, not all of which would be directly captured by examining prescribing rates.

Though PDMPs have been in place for many years, a range of barriers have limited their widespread success.[13,25] Our findings indicate that following substantial public policy, progress has been made to increase the frequency of PDMP use and perceived ease of use, with nearly half of physicians indicating the PDMP was very easy to use.[18] Assessing ease of use is important as it relates to how quickly physicians can access the information they need, which can improve workflow efficiency. We also observed several physician-reported benefits from PDMP use. Prior multi-state and national studies of the benefits of PDMP use have primarily focused on changes in the number and strength of opioids prescribed or the occurrence of negative events related to opioids following PDMP-related policy change and resulted in mixed evidence on the impact of PDMPs.[26–28] One challenge of these approaches is that by relying on aggregate data on opioid prescribing, potential secular trends in opioid prescribing or other ongoing policy initiatives may result in biased estimates of the relationship between PDMP-related policies and prescribing patterns. Our study is not subject to this limitation because it focuses on characteristics of PDMP use and associated benefits as reported by physicians, rather than relying on inference from aggregate trends.

Table 2 Physician-Reported Benefits of PDMP Use

Q: Have you done any of the following as a result of using the PDMP?	Weighted %	*N*
1. Reduced or eliminated controlled substance prescriptions for a patient	61%	728
2. Confirmed appropriateness of treatment	53%	644
3. Confirmed patients' misuse of prescriptions	51%	621
4. Changed controlled substance prescriptions to non-opioid pharmacologic or non-pharmacologic therapy	42%	496
5. Consulted and/or coordinated with other members of the care team	35%	410
6. Referred additional treatment (e.g., substance abuse treatment, psychiatric or pain management)	33%	385
7. Consulted with other prescribers listed in PDMP report	30%	350
8. Assessed pain and function of patient (e.g., PEG)	24%	255
9. Prescribed naloxone	12%	128
At least 1 reported benefit†	85%	1004
Mean number reported by respondents‡	3.4	

Data source: 2019 NEHRS PUF
Notes: Only includes respondents who check their state's PDMP. Multiple responses to the survey question were possible. Thus, percentages do not sum to 100. †Defined as having at least one of the benefits identified in Q29-d(1–9). ‡Defined as the arithmetic mean number of the nine potential benefits reported by respondents

Our data complement the literature by assessing important metrics of physician-reported benefits associated with PDMP use that would not be captured by changes in opioid prescriptions. Both more frequent use and greater ease of use were associated with a greater likelihood of consulting with others. Given challenges related to comorbidities, polypharmacy, and polysubstance abuse in populations treated with opioids, greater coordination could have important benefits beyond initial prescribing decisions.[29–31] Similarly, the relationship between more frequent use of the PDMP and a greater likelihood of confirming the appropriateness of treatment is important because of ongoing challenges ensuring pain is adequately treated, especially amidst concerns of overprescribing or doctor shopping.[32,33] The potential for PDMPs to assuage concerns about the appropriateness of treatment highlights the value of making information more accessible to ensure prescribing decisions are robustly informed.

The finding that physicians reporting greater frequency of use reported more benefits should not be taken for granted. Because public policy in 32 states mandates use,[34] it would be reasonable to expect that physicians made frequent use of the PDMP due to mandates and not perceived benefits. Instead, the relationship between frequency of use and experienced

Table 3 Marginal Effects of PDMP Characteristics on Experiencing Benefits Associated with PDMP Use

Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Any benefit	Number of benefits	Reduced prescribing	Confirmed patient misuse	Confirmed appropriate treatment	Referred new or additional treatment	Consulted with others
EHR-PDMP integration	−.021 [−.088 to .046]	−0.255 [−.828 to .317]	−0.050 [−.155 to .056]	−.031 [−.142 to .080]	.014 [−.096 to .124]	−.045 [−.154 to .064]	−.023 [−.135 to .088]
Frequency of use	.087 [−.004 to .178]	2.185 [1.536 to 2.84]	.226 [.079 to .373]	.225 [.079 to .370]	.251 [.096 to .405]	.280 [.116 to .443]	.368 [.241 to .495]
Ease of use	.127 [.040 to .214]	0.935 [0.257 to 1.61]	.116 [−.007 to .239]	.052 [−.067 to .172]	.174 [.046 to .302]	.118 [−.010 to .246]	.141 [.015 to .267]
Observations	1025	1025	1025	1025	1025	1025	1025

Data source: 2019 NEHRS PUF

Notes: Columns (1) and (3)–(7) report estimates from separate logistic regressions. Column (2) reports estimates from a Poisson regression. All estimates reflect average marginal effects (ME), with 95% confidence intervals reported in brackets. Coefficients represent the change in probability that respondents reported the related benefit based on the three focal independent variables. All models control for physician and practice location characteristics including physician demographics, specialty, practice size, ownership, Independent Practice Association (IPA) or Physician-Hospital Organization (PHO) affiliation, percent of patients insured by Medicaid, and EHR certification status. The sample excludes respondents who do not check their state's PDMP (N = 202) and did not know or did not respond to survey questions about methods of access or ease of using their state's PDMP (N = 165). The exclusion of these respondents, along with six missing covariate values, yields a final analytical sample of N = 1025 respondents

benefit indicates that physicians that more regularly engaged with the PDMP found it more helpful than physicians who rarely used it, consistent with the relatively intuitive notion that the PDMP will not always but often does contain useful information.

Despite these positive signs, we also observed that 15% of physicians who checked their state's PDMP did not report any benefit from PDMP use and only about half reported confirming the appropriateness of treatment via the PDMP. Policymakers at the state and federal levels, including the Centers for Disease Control and Prevention (CDC), continue to pursue an array of approaches to improve the value of PDMPs by supporting routine, universal use of PDMPs—which is a critical step towards reaping the benefits of use; ensuring timely availability of prescribing information; and pursuing proactive reporting of potential concerns from the PDMP.[5,6,35,36] Additional efforts to simplify access and use, such as streamlined PDMP registration processes, including automatic enrollment with license registration and renewal, could be effective approaches to facilitate greater use while minimizing the burden imposed on providers.

Finally, we found that EHR-PDMP integration was positively correlated with both frequency of PDMP use and ease of use. However, our data did not support the direct impact of EHR-PDMP integration (measured here as the ability to access the PDMP through the EHR) on perceived benefits for the relatively small proportion—23%—of physicians that reported system integration. Nevertheless, the positive relationships between EHR-PDMP integration, frequency, and ease of use indicate that EHR-PDMP integration is one potential lever to improve the experience of using PDMPs. It may be that EHR-PDMP integration is only one path towards high ease of use, and pursuit of other strategies—such as simplified single sign-on to the PDMP and effective data presentation—may be equally effective at realizing benefits from PDMP use.

Importantly, our data do not directly speak to the value of forms of integration beyond simple access to the PDMP. Data-level interoperability could be substantially more impactful in achieving benefit from the PDMP by combining PDMP data with complementary data in the EHR and directly driving insights into clinical workflows; however, research and related data collection do not always distinguish between system-level integration (measured here) and data-level interoperability.[4,5,13,15] While few states currently have laws and regulations in place that allow PDMP data to be retained in EHRs and exchanged with health IT systems, doing so may allow for PDMP data to be presented through effective clinical decisions support within the EHR, such as that being developed through efforts supported by the Office of the National Coordinator for Health Information Technology and the CDC.[37]

Limitations

Our study is subject to a number of limitations. One important limitation is the reliance on a cross-sectional, self-report survey, which does not allow for rigorous causal inference and

does not directly reflect benefit for patients. Nevertheless, the survey approach allows for more targeted measurement of PDMP use and associated benefits than studies relying on prescribing rates. Moreover, several of these nuanced benefits are likely only measurable via physician reporting, thereby complementing existing literature. A second set of study limitations relates to the sample. Sample size—particularly the small sub-sample of physicians indicating their PDMP was integrated with their EHR—may have limited our ability to detect an association between EHR-PDMP integration and perceived benefits. Moreover, the sample does not contain information on geographic location, which limits our ability to account for state-level differences in state PDMPs, including the usability of different systems. A third limitation is our inability to account for differences in state PDMP legislation or underlying variation in physicians' use of PDMP information that may have led to different state policies around PDMP integration and use. Our study is focused on a more detailed examination of one piece of the causal chain linking efforts to make PDMPs easier to access and use to improve the utility of PDMPs. This focus logically complements work examining the impact of PDMP-related policies on subsequent PDMP use to provide a link between those policies and the realization of diverse benefits.[38]

CONCLUSION

In a 2019 national survey of office-based physicians, the majority of respondents reported frequently using a PDMP, that their PDMP was easy to use, and that using the PDMP had resulted in reduced prescribing of controlled substances, confirming the appropriateness of treatment and confirming patient's misuse of prescriptions. However, 15% of physicians that used the PDMP reported no benefit from it, indicating that more progress could be made. Physicians reporting more frequent and easier PDMP use were more likely to indicate having experienced certain benefits as a result of checking the PDMP. While less than a quarter of physicians reported accessing their PDMP through their EHR, EHR-PDMP integration was associated with more frequent and greater ease of use. Taken together, our findings suggest efforts to increase integration and achieve interoperability may improve the usability of PDMPs, which in turn can help physicians reap the benefits of PDMP use. Continued efforts to improve the accessibility of PDMPs are necessary to maximize the value of PDMPs for the broadest group of physicians.

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Corresponding Author: *Chelsea Richwine, PhD; Office of Technology, Office of the National Coordinator for Health Information Technology, Washington, DC, USA (e-mail: Chelsea.Richwine@hhs.gov).*

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Author Contribution *Drs Richwine and Everson had full access to the data and take responsibility for the integrity and accuracy of the data analysis. Both authors contributed to the study concept and design, data analysis, interpretation of results, as well as drafting and revising the manuscript.*

Declarations:

Conflict of Interest: *The authors have no conflicts of interest to disclose.*

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37. Flanigan, M. Electronic Clinical Decision Support (CDS) Tools that Support the Implementation of the CDC Guideline for Prescribing Opioids for Chronic Pain. Available from: https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Electronic+Clinical+Decision+Support+%28CDS%29+Tools+that+Support+the+Implementation+of+the+CDC+Guideline+for+Prescribing+Opioids+for+Chronic+Pain
38. **Strickler GK, Zhang K, Halpin JF, Bohnert AS, Baldwin GT, Kreiner PW.** Effects of mandatory prescription drug monitoring program (PDMP) use laws on prescriber registration and use and on risky prescribing. Drug Alcohol Depend. 2019;199:1-9.

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EXHIBIT F

EXHIBIT F

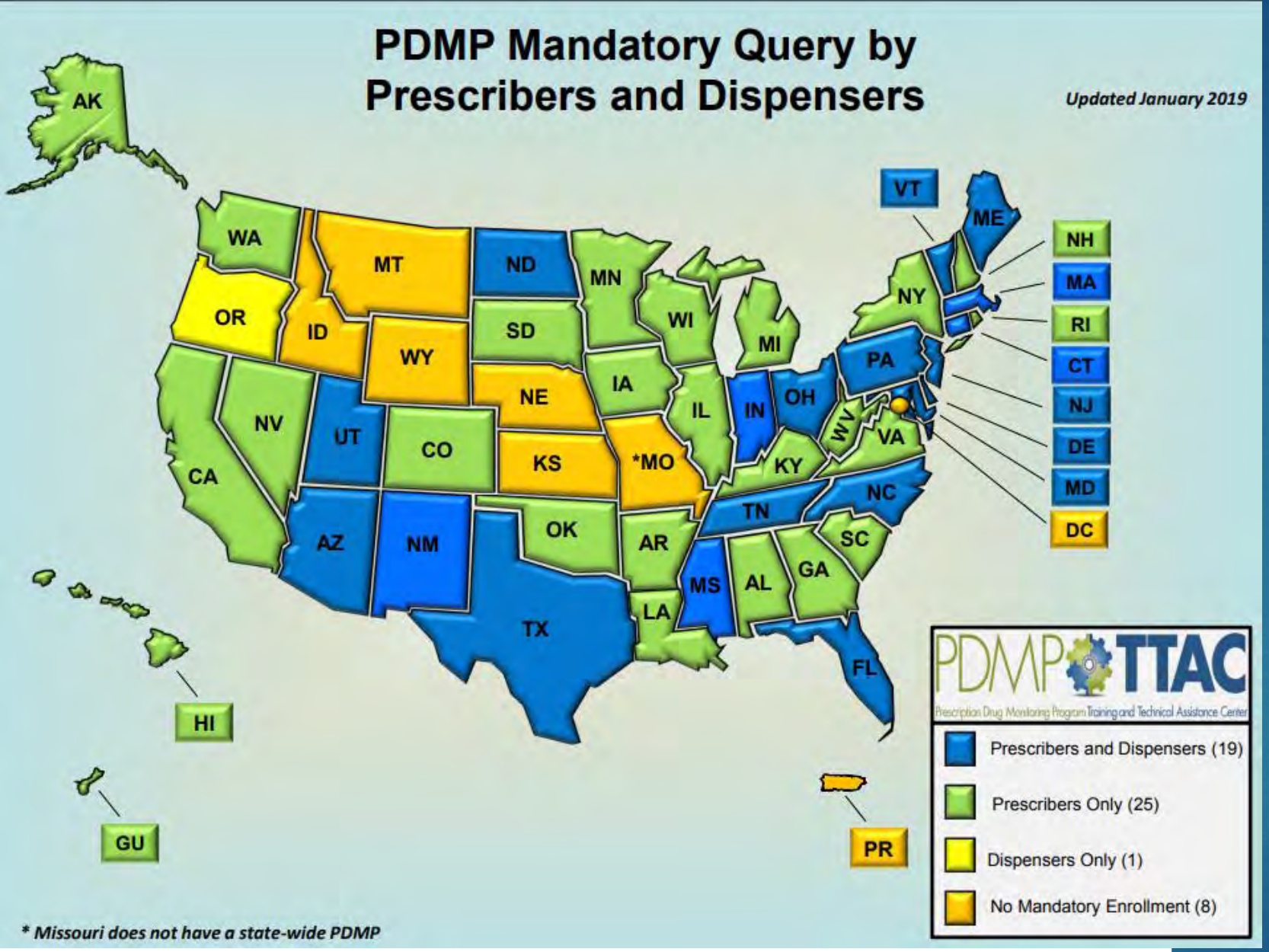
PMP Data Quality and Pharmacy Compliance

HAROLD ROGERS PDMPS AND COAP GRANTEES NATIONAL MEETING

DARLA ZARLEY, PHARM.D.

GRANT AND PROJECT ANALYST

JUNE 27,2019



Mandatory PMP Query

- 44 states – mandatory query by prescribers
- 19 states- mandatory query by dispensers

Prescription Drug Monitoring Program Training and Technical Assistance Center. PDMP Mandatory Query by Prescribers and Dispensers. Accessed June 6, 2019. Available at: https://www.pdmpassist.org/pdf/Mandatory_Query_20190115.pdf

Possible Sources of Error

- Omission (pharmacy data submission non-compliance)
- Pharmacy data entry error
- Transmission software error

Data Submission Non-Compliance

Technological

- Computer/server connection
- Dispensers unaware data not transmitting

Lack of Knowledge

- Unaware of law or regulations

Intentional Non-compliance

- Not or only partially transmitting data → may be engaged in unlawful activities (i.e., RX fraud, pill mill)
- Do not feel obligated to report
- Honor system does not work

Prescription Drug Monitoring Program Training and Technical Assistance Center, PDMP Suggested Practices to Ensure Pharmacy Compliance and Improve Data Integrity. Accessed June 6, 2019. Available at: http://www.pdmpassist.org/pdf/Pharmacy_compliance_data_quality_TAG__FINAL_20150615.pdf

Pharmacy Data Entry Errors

Type of Error	Error	Possible Causes	
Patient	Missing/incorrect/ misspelled address or phone #	-Variation in street or city name abbrev. (e.g. Avenue or Ave) -Pt has no address or phone # -Pick list (outdated info)	-Written, electronic, or telephoned RX is incomplete, inaccurate, or illegible -Transcribing errors -Procedural flaws
	Missing/incorrect DOB	-RX issued or filled date entered -Current day or future date entered	
	Misspelled name	-Variations in name spelling (e.g. Catherine, Cathy, Cat; Richard, Dick) -Hyphenated last names -First, middle, last names out of order -Alias used -Special characters in name field	
	Wrong patient	-Pick list (wrong patient selected) -Owner's rather than animal's name on veterinary RXs	

Prescription Drug Monitoring Program Training and Technical Assistance Center, PDMP Suggested Practices to Ensure Pharmacy Compliance and Improve Data Integrity. Accessed June 6, 2019. Available at: http://www.pdmpassist.org/pdf/Pharmacy_compliance_data_quality_TAG__FINAL_20150615.pdf

Pharmacy Data Entry Errors

Type of Error	Error	Possible Causes	
Prescription	Incorrect days supply, incorrect quantity dispensed	-Instructions for administration or # of days unclear -Mislabeled units of measure (e.g. mg vs ml) -Wrong info in partial fill field; partial fill not indicated	-Written, electronic, or telephoned RX is incomplete, inaccurate, or illegible -Transcribing errors -Procedural flaws
	Incorrect date written or date dispensed	-DOB in wrong field -Transposing written and dispensed date -Transposing date values (e.g. MM/DD/YY or YY/MM/DD)	
	Incorrect drug name; inactive rather than active ingredient reported for a compound	-Missing NDCs for ingredients in a compounded RX -Bad NDC # -Wrong NDC #	

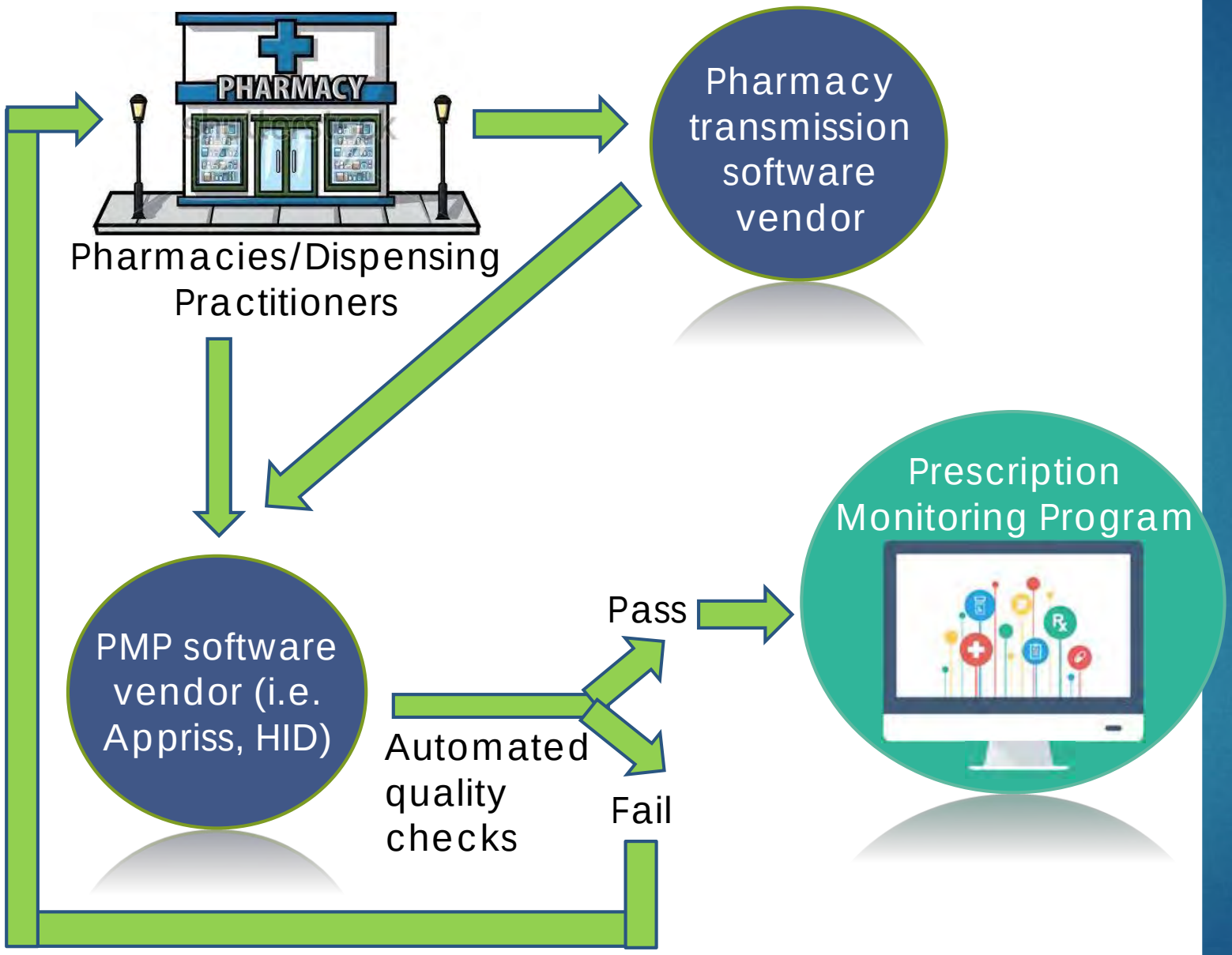
Prescription Drug Monitoring Program Training and Technical Assistance Center, PDMP Suggested Practices to Ensure Pharmacy Compliance and Improve Data Integrity. Accessed June 6, 2019. Available at: http://www.pdmpassist.org/pdf/Pharmacy_compliance_data_quality_TAG__FINAL_20150615.pdf

Pharmacy Data Entry Errors

Type of Error	Error	Possible Causes	
Prescriber	Incorrect DEA #	-Use of incorrect DEA # for a prescriber with multiple DEA #s -Use of the "X" DEA # instead of the provider DEA #	-Written, electronic, or telephoned RX is incomplete, inaccurate, or illegible -Transcribing errors -Procedural flaws
	Wrong prescriber	-Pick list (wrong prescriber selected) -DEA # not associated with the correct prescriber	

Type of Error	Error	Possible Causes
Others	Duplicate RXs; multiple transmissions of the same data file	-Procedural flaws
	Transmission of a corrected RX mislabeled as a new RX	-Procedural flaws
	RX data transmitted even though RX not dispensed to patient	?

Prescription Drug Monitoring Program Training and Technical Assistance Center, PDMP Suggested Practices to Ensure Pharmacy Compliance and Improve Data Integrity. Accessed June 6, 2019. Available at: http://www.pdmpassist.org/pdf/Pharmacy_compliance_data_quality_TAG__FINAL_20150615.pdf



Automated Quality Checks

- RX data transmitted to the PMP undergoes automated quality checks prior to being uploaded.
- RX records that fail receive error message, are rejected, allowing dispenser to correct and re-transmit data.
- Automated quality checks can detect missing info or incorrect characters in a data field, but generally cannot detect *incorrect info* → erroneous data transmitted to PMP

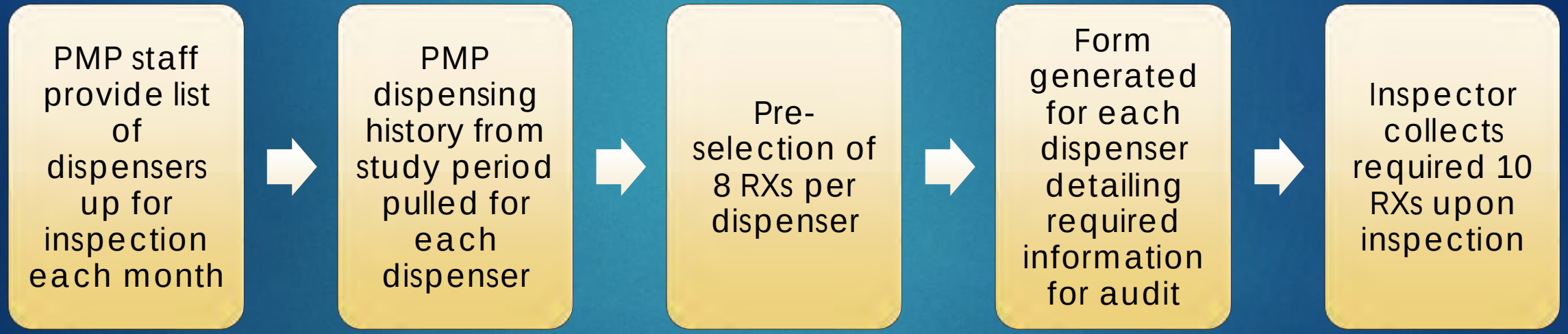
Nevada 2017 Audit Project

- Official PMP audit project launched February 2017
  - Hired a part-time Project Analyst through Harold Rogers Grant
  - Collaboration with Roseman University of Health Sciences

- Program Goal: Determine Nevada's PMP data accuracy by:
  - Implementing a standardized process for evaluating its accuracy
  - Taking the necessary steps to correct the data if errors are identified
  - Prevent incidences of errors

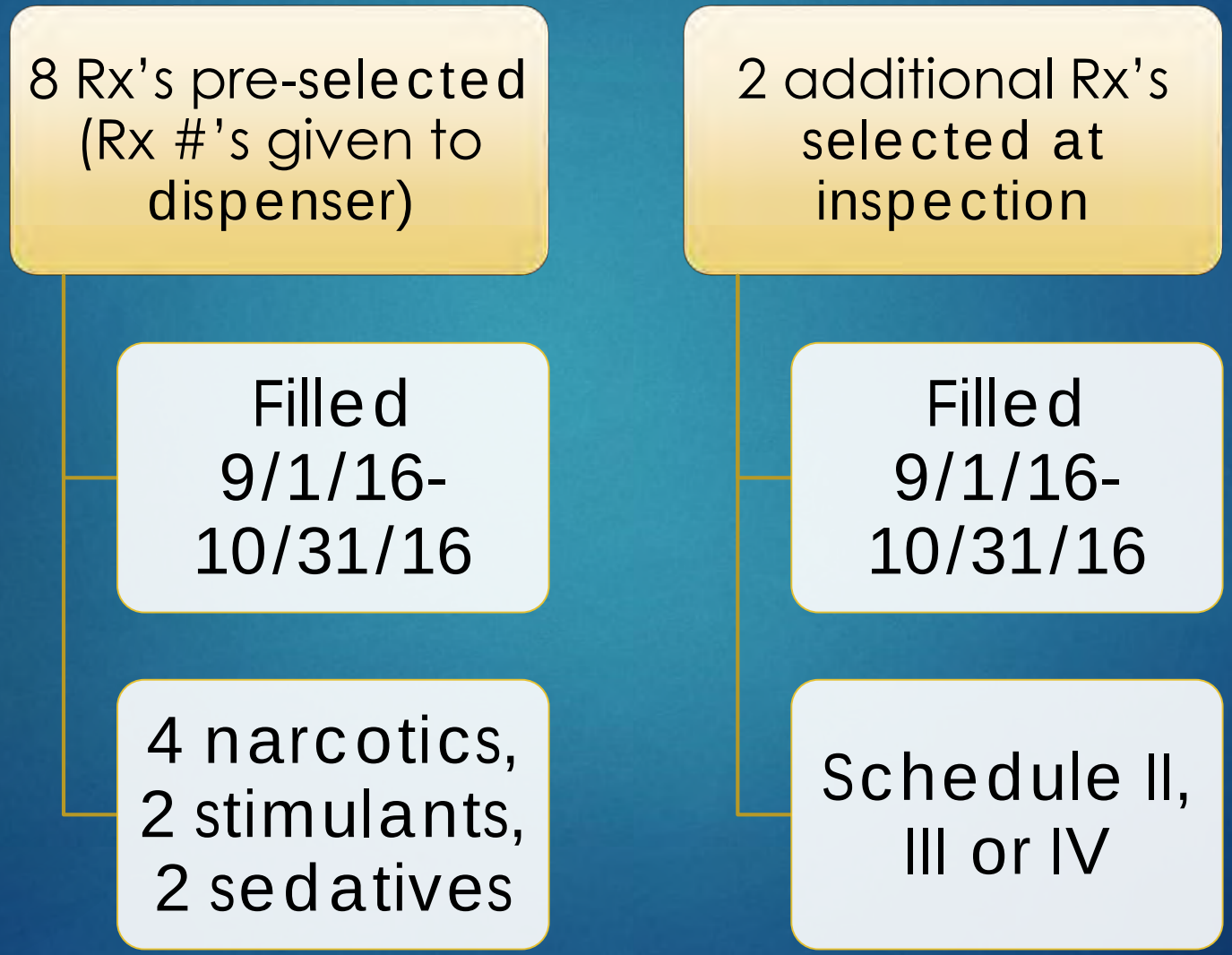
Audit Methodology

- All licensed pharmacies and dispensing practitioners in Nevada undergo an annual Board of Pharmacy (BOP) inspection per regulation



Audit Methodology

- 10 RXs collected from each dispenser



Error Categorization

Minor (1-2)	Major (3-4)	Severe (5-12)
1. Missing/incorrect/misspelled phone # or address of the pt 2. Incorrect days supply	3. Incorrect quantity dispensed; not indicating partial fill 4. Incorrect date issued or date dispensed	5. Missing/incorrect pt DOB 6. Misspelled pt name 7. Wrong pt 8. Wrong drug; incorrect drug name; inactive rather than active ingredient reported for a compound 9. Missing/incorrect prescriber DEA# 10. Wrong prescriber 11. RX not reported to the PMP (noncompliance, wrong ASAP file format, vendor software error) 12. MISFILL – REFER to Pharmacy Board

Data Submission Non-Compliance and Error Correction Process

**Only for "Severe" errors (types 5-12)*

Data Submission Non-Compliance/Data Error Identified by Project Analyst

1st Notification- Email
(1 week to correct)

2nd Notification- Email
(1 week to correct)

Final Notice
Certified letter from BOP

Disciplinary Action

Corrections made within time period

Case Closed: Documented in an electronic file

Error Correction

- Dispensers that have not corrected errors by the deadline given in the letter from the BOP will face possible disciplinary action by the Board.

- If data errors are discovered which caused harm to a patient, potential harm to patient, or issues for a prescriber the PMP team members will directly refer this matter to the BOP through the BOP complaint process.

Nevada Regulations

- Nevada regulation (NAC 639.926) require pharmacies/dispensers to transmit controlled substance RX (II-V) info to the PMP
- Failure to transmit the info can result in a fine of $100 for each day of the violation up to a fine of $10,000

Audit Project Timelines

- Year 1 (February 2017 – January 2018)
- January 2018 Newsletter – education provided to dispensers on initial audit results
- Year 2 (July 2018 - June 2019)

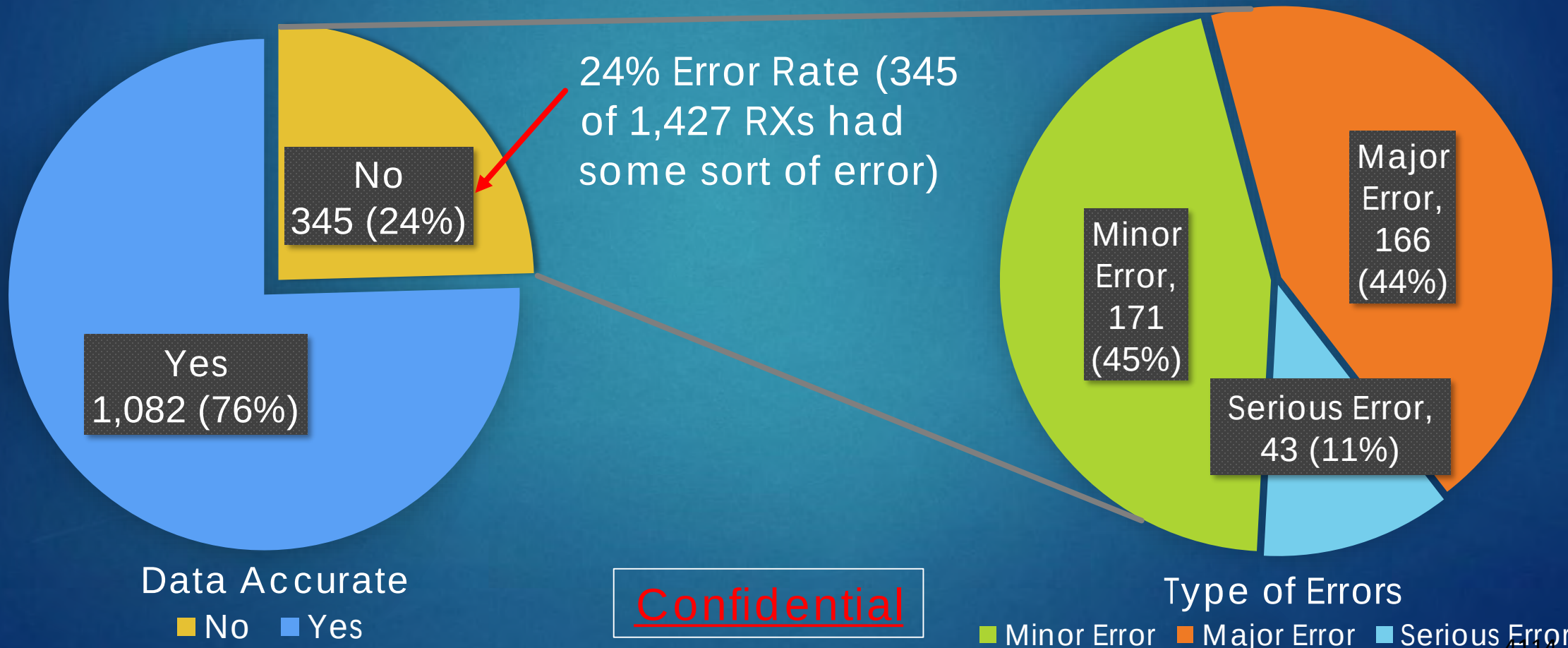
Legislation Changes

- Assembly Bill (AB) 474 Effective January 1, 2018
  - Requires practitioners to clearly indicate their DEA number and all controlled substance prescriptions
  - Days supply to be provided by the practitioner

PRELIMINARY* Findings

Feb 1st, 2017 – Feb 1st, 2018

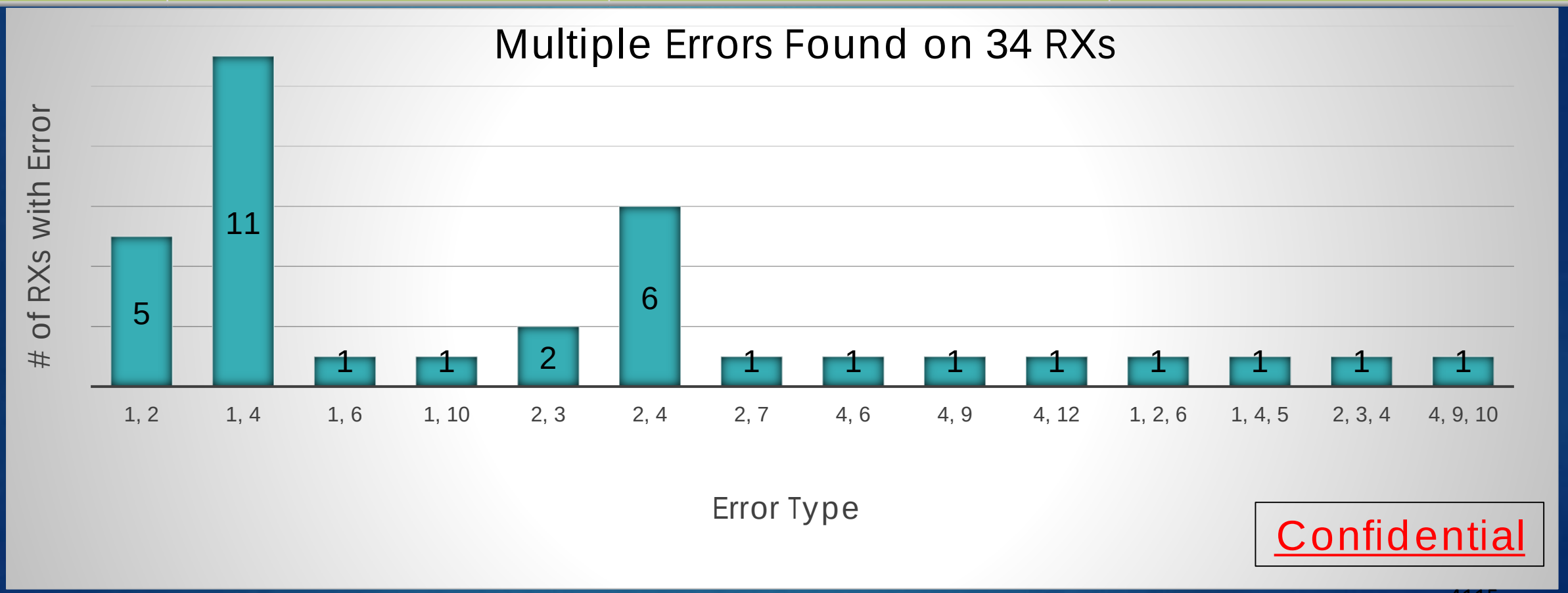
1,427 RXs audited (a few *pharmacies did not have all 10 RXs)*



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* The information above is from preliminary research and may not reflect the actual numbers.

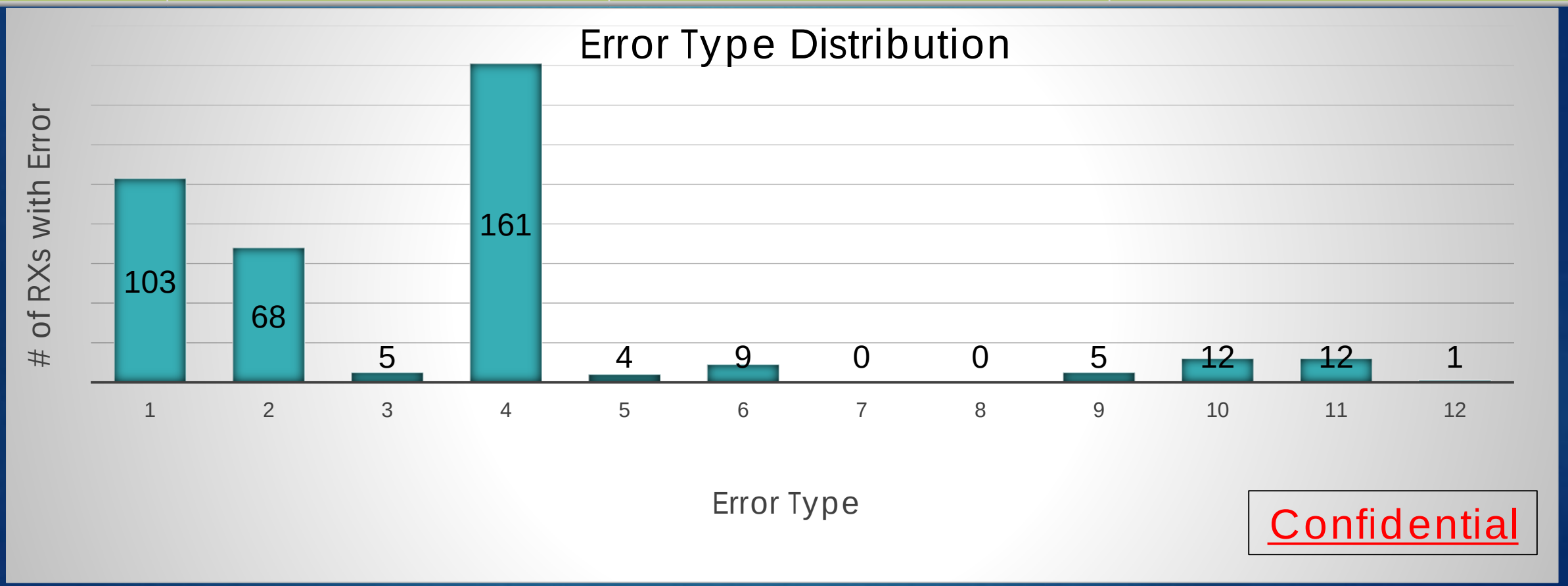
Error Key			
Minor: 1-2 **Serious: 3-4** **Fatal: 5-12**	**1. Missing/incorrect/misspelled phone # or address of pt** **2. Incorrect days supply** 3. Incorrect quantity dispensed; not indicating partial fill **4. Incorrect date issued or date dispensed**	5. Missing/ Incorrect pt DOB 6. Misspelled pt name 7. Wrong pt 8. Wrong drug; incorrect drug name; inactive rather than active ingredient reported for a compound	9. Missing/incorrect prescriber DEA# 10. Wrong Prescriber 11. RX not reported to the PMP (noncompliance, wrong ASAP file format, vendor software error) 12. MISFILL – Refer to Pharmacy Board



Confidential

* The information above is from preliminary research and may not reflect the actual numbers.

Error Key			
Minor: 1-2 **Major: 3-4** **Serious: 5-12**	**1. Missing/incorrect/misspelled phone # or address of pt** **2. Incorrect days supply** 3. Incorrect quantity dispensed; not indicating partial fill **4. Incorrect date issued or date dispensed**	5. Missing/ Incorrect pt DOB 6. Misspelled pt name 7. Wrong pt 8. Wrong drug; incorrect drug name; inactive rather than active ingredient reported for a compound	9. Missing/incorrect prescriber DEA# 10. Wrong Prescriber 11. RX not reported to the PMP (noncompliance, wrong ASAP file format, vendor software error) 12. MISFILL – Refer to Pharmacy Board



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* The information above is from preliminary research and may not reflect the actual numbers.

Challenges

- Informing pharmacies of new inspection process
- Time consuming
  - Pharmacy inspectors
  - Pharmacy personnel
  - Shear number of errors – error correction process

Challenges

- Pharmacies have different processes or use different vendors to transmit PMP data → difficult to provide guidance to pharmacies who need to correct/address PMP data errors

- Dispensers' miscommunication and frustration with their data transmission software vendor and with PMP software vendor

Questions?

Darla Zarley, Pharm.D.
Grant & Project Analyst
Nevada Prescription Monitoring Program
Email: dzarley@pharmacy.nv.gov
Ph: 775-687-5694

EXHIBIT G

EXHIBIT G

MINUTES OF THE
SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES

Seventy-ninth Session
May 17, 2017

The Senate Committee on Health and Human Services was called to order by Chair Pat Spearman at 3:34 p.m. on Wednesday, May 17, 2017, in Room 2149 of the Legislative Building, Carson City, Nevada. The meeting was videoconferenced to Room 4412 of the Grant Sawyer State Office Building, 555 East Washington Avenue, Las Vegas, Nevada. Exhibit A is the Agenda. Exhibit B is the Attendance Roster. All exhibits are available and on file in the Research Library of the Legislative Counsel Bureau.

COMMITTEE MEMBERS PRESENT:

Senator Pat Spearman, Chair
Senator Julia Ratti, Vice Chair
Senator Joyce Woodhouse
Senator Joseph P. Hardy
Senator Scott Hammond

STAFF MEMBERS PRESENT:

Megan Comlossy, Policy Analyst
Eric Robbins, Counsel
Martha Barnes, Committee Secretary

OTHERS PRESENT:

Michael J. Willden, Chief of Staff, Office of the Governor
Elyse Monroy, Health and Human Services Policy Analyst, Office of the Governor
John DiMuro, D.O., Chief Medical Officer, Division of Public and Behavioral Health, Department of Health and Human Services
Michael Hillerby, State Board of Nursing; State Board of Pharmacy
Elizabeth MacMenamin, Retail Association of Nevada
Catharine O'Mara, Nevada State Medical Association
Susan L. Fisher, State Board of Osteopathic Medicine
Kathleen Conaboy, Nevada Orthopaedic Society
George Ross, Comprehensive Cancer Centers of Nevada
Regan Comis, Nevada Association of Health Plans

Nick Vander Poel, Nevada Osteopathic Medical Association
Stephanie Woodard, Division of Public and Behavioral Health, Department of Health and Human Services

CHAIR SPEARMAN:
We will postpone the work session until tomorrow and begin the hearing on Assembly Bill (A.B.) 474.

ASSEMBLY BILL 474 (1st Reprint): Makes various changes relating to drug overdoses and prescribing and using drugs. (BDR 40-1102)

MICHAEL J. WILLDEN (Chief of Staff, Office of the Governor):
The Legislature and the Executive Branch have been working on the prescription drug reform issue for several years. We have been working hard at it since 2012 when we participated in the National Governors Association Policy Academy on Prescription Drug Abuse Prevention. There have been a couple academies, and Nevada participated in the second round. Starting in 2014, the Governor named a number of people to a work group which met several times during 2014 throughout the State. This resulted in S.B. No. 459 of the 78th Session. It was called the Good Samaritan Drug Overdose Act. The group addressed the Good Samaritan laws, the naloxone programs, continuing education for prescribers, dispensing issues and some modifications to the prescription drug monitoring program. This was a very successful piece of legislation last Session, and we have been working on implementing it. When I say we, I mean several of the boards and the Division of Health and Human Services (DHHS).

In the spring of 2016, northern Nevada had a very significant event involving a prescriber and law enforcement. Many issues occurred, causing the Governor to refocus on this issue. A planning group was created in June 2016 to reexamine the prescribing and opioid world and to review the implementation of S.B. No. 459 of the 78th Session.

The planning group was fairly large with a couple of Legislators, judges, and district attorneys. The outcome of the planning group was a summit that was held the last day of August and the first day of September 2016 with approximately 500 people attending. The planning summit was held at the MGM Grand Resort and Casino in Las Vegas. From this summit, a number of recommendations were made which resulted in A.B. 474.

ELYSE MONROY (Health and Human Services Policy Analyst, Office of the Governor):

Assembly Bill 474 is the Governor's Controlled Substance Abuse Prevention Act, and it is a priority bill for the Governor.

Opioid and prescription drug overdoses continue to be a growing problem in the State. The Governor's Office has provided a data sheet with facts (Exhibit C) for your review.

In response to a situation in 2016, the Governor held the State Summit on Prescription Drug Abuse to identify and highlight areas in which Nevada must improve efforts to reduce and eliminate prescription drug abuse and overdose. During the Summit and the planning meeting, we heard heartbreaking stories from people whose opioid addiction started with a legitimate pain prescription.

The Centers for Disease Control and Prevention tells us of the people who are most at risk for prescription drug abuse. Of this at-risk population, 15 percent report buying their prescriptions from a drug dealer; 27 percent reported receiving prescriptions from their own doctors; 26 percent report getting prescriptions for free from a friend or relative; and 23 percent report buying prescriptions from a friend or relative.

The abuse, misuse and diversion of prescription medications are real problems. The Governor's Controlled Substance Abuse Prevention Act before you today was developed through review of the Summit recommendations, literature, State best practices and lessons learned. The Act was developed in collaboration with the DHHS subject-matter experts, various stakeholder groups and the State's occupational licensing boards.

Assembly Bill 474 is a comprehensive measure that addresses five main areas: prescriber education, prescribing practices, occupational licensing boards, data collection and the prescription drug monitoring program. The Governor's Office has provided the Committee with a section-by-section breakdown of A.B. 474 (Exhibit D).

Assembly Bill 474 makes the collection of data specific to overdose and suspected overdose permanent. *Nevada Revised Statutes* (NRS) 441A, Infectious Diseases; Toxic Agents, is used to capture diseases and illnesses that

are of public health importance. In the past, this has been typically related to communicable diseases and infections and illnesses stemming from biological, chemical and radiological events. As has been clearly shown, the opioid epidemic is of public health importance. The use of opioids is causing ongoing morbidity, addiction issues and death for our residents. The Division of Public and Behavioral Health (DPBH) already reviews suspected overdose data from hospital discharge billing forms, and some of the data is shown in the infographic you have been provided, Exhibit C. This is identifiable data, but there is such a delay that an immediate public health response is not possible. Assembly Bill 474 will allow for more immediate analysis, response and an ability to target interventions. Data will be reported directly to the State. Through regulation, DPBH will specify the methods of reporting, specify what will constitute a suspected overdose and specify the variables to be reported.

Assembly Bill 474 includes language requiring licensing boards to adopt mandatory continuing education requirements for prescribers of controlled substances, makes existing permissive language mandatory and increases the requirement to two hours of continuing education from one hour per license year. This request came from the prescriber community during the development of the protocols.

Assembly Bill 474 adds information to be included on the prescriptions for controlled substances. These changes are needed for the prescribing protocol initiative to be implemented. Pharmacies will need to collect additional data points including the specific number of days a prescription is to be used and the specific diagnosis codes. This bill also makes changes to the Prescription Drug Monitoring Program (PDMP).

Assembly Bill 474 clarifies that licensing boards have access to the PDMP for the purpose of investigations and administrative review of inappropriate prescribing. This bill clarifies that the State Board of Pharmacy can use the PDMP system to identify inappropriate prescribing and requires the Board to notify a licensing board when it has identified unusually high or otherwise inappropriate prescribing.

Assembly Bill 474 also requires prescribers to show proof of enrollment in the PDMP in order to renew or receive their controlled substance licenses. Since the passage of S.B. No. 459 of the 78th Session, the State Board of Pharmacy has seen a sharp increase in the number of prescribers enrolled in the system, going

from 16 percent of prescribers to 81 percent. There are still prescribers that are not using the system. By requiring proof of enrollment in the system before prescribers receive their controlled substance licenses, we can ensure that all prescribers have access to the system before being given permission to prescribe controlled substances.

Assembly Bill 474 requires occupational licensing boards to ensure that Nevada has a system for the identification and remedy of inappropriate prescribing. While inappropriate prescribing comes in many forms, generally, it is prescribing outside of the standard of care for a prescriber's practice, specialty or otherwise outside the medical need of the patient. Under this measure, licensing boards are now required to take action when they receive a report of potential inappropriate prescribing. This bill allows for the administrative review and dismissal of inappropriate prescribing notifications. Additionally, A.B. 474 will allow for the summary suspension of a controlled substance license if inappropriate prescribing is taking place and is deemed an immediate public health and safety risk.

With these changes, we are placing the responsibility of identifying inappropriate prescribing on the State's licensing boards. During the summit planning meeting, we in the Governor's Office were surprised to hear that while all occupational licensing boards have been receiving unsolicited reports on high or otherwise inappropriate prescribing, only some of the boards were taking action on these reports. We worked with the boards to understand their processes for communicating with their licensees and for their investigations. Allowing for the administrative review of controlled substance complaints makes the complaints actionable without complicating the investigation process.

We want to make sure the record reflects our appreciation for the licensing boards working with the Board in drafting A.B. 474.

This bill establishes mandatory prescribing protocols for prescribers that are treating pain with controlled substances: schedule II, III and IV drugs. These protocols are being proposed for NRS 639, the statute that governs the Board. Assembly Bill 474 requires all licensed prescribers to follow the prescribing protocol and requires all licensing boards to enforce the prescribing protocol established in NRS 639. This is the core of the Controlled Substance Abuse Prevention Act.

Nevada's approach to addressing the prescription drug abuse epidemic is to preserve individual patient treatment and recalibrate the standard of care for the treatment of pain and prescribing of controlled substances. These mandated protocols ensure patient safety and seek to end misuse, abuse and diversion of addictive prescribed controlled substances. These prescribing protocols place the responsibility of identifying patient misuse, abuse and diversion on the prescriber.

The prescribing protocols before you today are a product of months of hard work and complex conversations about prescribing, pain management, behavioral health, addiction and patient care with prescribers in Nevada. We appreciate the time that many prescribers and leaders of their trade associations took to help create prescribing protocols that are meaningful, reasonable and implementable. These protocols are accomplished through an initiative that we are calling Prescribe 365, which ensures no patient receives more than 365 days of controlled substances in a 365-day period.

There are two limits on prescriptions contained in this bill. They are the 365-day limit and a 14-day limit on initial prescriptions for acute pain. Many states have established limits for acute pain, and Nevada's limit will appear more liberal than the three-, five- or seven-day limits that other states have enacted. This is because we were sensitive to the State's access to care issues in our urban and rural areas. At this time, I will turn over the testimony to Dr. DiMuro to walk through the prescribing protocols.

JOHN DIMURO, D.O. (Chief Medical Officer, Division of Public and Behavioral Health, Department of Health and Human Services):
In developing the prescriber protocols of A.B. 474, we recognize the importance of prioritizing patient safety while upholding the integrity of the patient-prescriber relationship. These protocols require prescribers to adhere to a standard of care which includes the application of clinical judgement in the use of controlled substances for the treatment of pain. Commonsense measures need to be developed that would account for the complexity of the management of pain across populations and minimize the risk associated with the use of controlled substances for the treatment of pain. We reviewed available research literature, evaluated consensus guidelines established by subject matter experts, assessed the impact of policy decisions in other states and engaged the provider community in extensive discussion.

Prescription misuse, abuse, diversion and risk for adverse events, including overdose, present unique challenges for prescribers and patients alike. The complexity of management of pain using controlled substances and the mitigation of risk from such medications require a multitude of evidence-based interventions. We must recognize the limitations of each intervention, acknowledging it is the cumulative impact of multiple efforts that have the best chance of keeping patients safe and empowering prescribers to practice within a standard of care.

The prescribing protocols in A.B. 474 establish standards of care from the initiation of a prescription of controlled substances for pain through ongoing prescribing for the long-term treatment of pain. Please refer to page 12 of Exhibit D which details the provider requirements in Prescribed 365.

Prior to an initial prescription, a provider must check the PDMP database to ensure they have a full record of the patient's current and past prescriptions for controlled substances. The PDMP review is a well-established clinical practice aimed at providing prescribers with some of the information they need in order to make prescribing decisions. Assembly Bill 474 closes a small but critical loophole that was left in S.B. No. 459 of the 78th Session by now mandating the PDMP checks all initial prescriptions regardless of duration. Previously, prescriptions of less than seven days did not require a review by the PDMP. This bill also limits initial prescriptions of a controlled substance for pain in both duration and dosage. Over the past year, nine states have enacted similar regulations and at least seven additional states have similar limits under consideration through legislation. Assembly Bill 474 limits initial prescriptions to 14 days and to no more than 90 morphine milligram equivalents daily. Unlike other states that limit initial prescriptions to 5 or 7 days, we chose a maximum of 14 days to account for known issues relating to access to care in Nevada. This is proactive in ensuring this limit would be reasonably implemented. If the controlled substance prescribed is an opioid, we establish maximum morphine milligram equivalence to 90 morphine milligram equivalents for patients who are not nor were recently issued an opioid prescription.

This standard of care allows for a continuity of care for patients who may be currently prescribed opioids while establishing a maximum daily dosage for opioid naïve patients. This maintains the prescriber's ability to prescribe based on individual patient history and in no way prohibits patients from receiving the care they require.

Identifying and mitigating risk is of utmost importance when evaluating factors that may compromise the patient's ability to safely and effectively use controlled substances for pain. In addition to the PDMP check, we believe it is important for prescribers to have the information they need to make clinical prescribing decisions. Prior to prescribing, A.B. 474 requires prescribers to assess the patient's risk factors through medical history, physical examination, and a good faith effort to obtain and review medical records in addition to the risk assessment measure.

Patients have a right to be active participants in determining the course of care. Written and informed consent provides the patients information needed to understand the risks and benefits associated with taking a controlled substance for pain, the proper use of their prescription, on alternative treatments for pain, on their plan of treatment, on risks of dependency, or addiction, overdose, safe storage and provider expectations.

Once treatment has been established and the patient and prescriber agree that pain management with controlled substances will exceed 30 days, a medication management agreement is required to be completed. Medication agreements go beyond the information contained in the written informed consent. The agreements delineate goals of the treatment, consent for testing to monitor compliance when medically necessary, requirements for information sharing between prescriber and patient and reasons when a practitioner may change or discontinue a course of treatment. Medication agreements must be updated annually or whenever there are changes made to the treatment plan. The intent of the changes to the medication agreements is to ensure they are updated with the goals of treatment or when the goals of treatment change. If changes to medications and goals of those changes are clearly detailed within the treatment plan, medication treatments do not need to be updated with every medication change. The intent behind requiring updates to the medication agreements is to ensure they are aligned with the treatment plans when the goals of treatment change.

Assembly Bill 474 establishes additional protocols prior to prescribing controlled substances for the treatment of pain of a patient who has a controlled substance for 90 consecutive days or more. The 90-day visit must be in person or through telehealth and include, at a minimum, an assessment of risk, a PDMP review, and a review of the treatment plan. The prescriber must also conduct an evaluation of the patient to determine an evidence-based diagnosis for the cause

of the pain prior to prescribing controlled substances for the pain beyond 90 days. This combined with our Prescribe 365 Program will help to best guide the prescriber-patient-prescription relationship. The treatment plan must then be updated annually or as previously stated, when there is a change in the course of the patient's care. These provisions taken together are a reasonable plan to improve Nevada's safety related to controlled substances.

SENATOR HARDY:
In section 7, subsection 1, paragraph (e), subparagraph (2), it states: "each state in which the patient to whom the controlled substance was prescribed." We do not have access to each state, but we do have access to each state which is on the PDMP.

The NRS 630, 632, 636, 635 have 60 days; NRS 631 and 633 have 180 days. Is there a reason for the difference?

MS. MONROY:
This is the language specific to the summary suspension, and we aligned the language in A.B. 474 with the existing procedures language within each chapter. Some of the boards had 60 days and some boards had 180 days.

SENATOR HARDY:
Do the optometrists in NRS 636 use controlled substances?

MS. MONROY:
Yes, the licensing boards have optometrist prescribers that have controlled substance licenses, but I do not know how many optometrists have controlled substance licenses.

SENATOR HARDY:
Regarding the new wording in section 51, the word "new" was confusing to me. The "initial prescription" means a prescription originated for a new patient of a practitioner and it goes on, "The term does not include any act concerning an ongoing prescription that is issued by a practitioner to continue a course of treatment for a new or existing patient of the practitioner."

MS. MONROY:
We established the definition in S.B. No. 459 of the 78th Session for "initial prescription," but as we were working through the creation of this policy, we

realized that there was an unintended gap when a patient had to transfer to a new prescriber. If a patient started a prescription for a controlled substance with his or her primary care provider and got to the 30 days supply, but the primary care provider felt the patient needed to be referred to a pain management specialist, it would then be an initial prescription with a 14-day limit with an ongoing course of treatment.

DR. DIMURO:
The idea is if you are a physician and you give a 90-day prescription, it could be considered a new prescription, but since you are the continued provider, it would not be a new prescription. Thus, the language does not include any act concerning an ongoing prescription.

SENATOR HARDY:
The language states new patient or a new or existing patient, it does not state new prescription. In one place it states it applies, and in the other it states it does not apply.

There are also not enough pain doctors under network that the primary care physicians can refer people to.

Section 60, subsection 1, paragraph (b), uses the word "the" controlled substance as opposed to "any." I understand it is the intent that we are not going to prescribe "any" controlled substance whatsoever, not just the one he or she was using, abusing or misusing.

DR. DIMURO:
Yes. There could be multiple prescriptions for the same drug filled within days of each other. The intent of this section is to make sure that any prescriber who has not been prescribing the controlled substance checks the PDMP to see if the patient has been on that controlled substance. If the patient has been on that controlled substance, then the prescriber would not prescribe that particular controlled substance.

SENATOR HARDY:
Would prescribers be able to prescribe another controlled substance?

DR. DIMURO:
Yes, they would.

CHAIR SPEARMAN:
In section 60, subsection 1, paragraph (b), it states, "If the practitioner determines from the patient utilization report or from any other source that the patient has been issued such a prescription, the practitioner shall not prescribe the controlled substance." We spoke earlier concerning synthetics. Is it possible to look at what is being prescribed and if there were another drug that could be prescribed that would work as well, would the practitioners consider those?

DR. DIMURO:
We want to have the clinicians remain practicing medicine. There are many instances where multiple drugs from the same drug class are prescribed. We do not want to inhibit physicians from prescribing from multiple drug classes, especially when it comes to pain medicine. That is why the wording is specific about the prescribing of the drug and a specific drug that has already been prescribed.

SENATOR HARDY:
If I know that someone is using, abusing or overusing a narcotic of one kind, and I am interested in getting them off it without getting them in a withdrawal issue, then I may be interested in using a narcotic-related medicine that will get them off the narcotic that they are abusing. Does this make sense?

DR. DIMURO:
Yes.

MICHAEL HILLERBY (State Board of Nursing; State Board of Pharmacy):
We are in support of A.B. 474.

ELIZABETH MACMENAMIN (Retail Association of Nevada):
We are in support of A.B. 474.

CATHARINE O'MARA (Nevada State Medical Association):
We are in support of A.B. 474. We believe there is more work to do on this bill regarding regulations, and we want to be part of that.

SUSAN L. FISHER (State Board of Osteopathic Medicine):
We are in support of A.B. 474.

CHAIR SPEARMAN:
Ms. O'Mara, did you state there were some regulations that may be problematic, or is it that you want to make sure that you are working alongside the Governor's Office to address some of the issues?

MS. O'MARA:
There will be a few regulations that we anticipate will need to be promulgated during the regulatory period. We do not expect them to be issues. One example is the Pharmacy Board will be defining what inappropriate prescribing means. We look forward to being part of those discussions.

KATHLEEN CONABOY (Nevada Orthopaedic Society):
We are in support A.B. 474.

GEORGE ROSS (Comprehensive Cancer Centers of Nevada):
We are in support of A.B. 474.

REGAN COMIS (Nevada Association of Health Plans):
We are in support of A.B. 474.

NICK VANDER POEL (Nevada Osteopathic Medical Association):
We are in support of A.B. 474.

MS. MONROY:
May we clarify one of the questions from Senator Hardy, specific to section 51?

STEPHANIE WOODARD (Division of Public and Behavioral Health, Department of Health and Human Services):
I am the Co-Occurring Disorder Director for Rural Community Health Services. The way the initial prescription was written would create some unintended consequences. In section 51, language was added that states, "The term does not include any act concerning an ongoing prescription that is issued by a practitioner to continue a course of treatment for a new or existing patient of the practitioner." The language was added to the definition because of the way it had originally been defined. If you were being treated by a physician and that physician transferred care to another prescriber, under the original definition, the new prescriber would have been limited to only 14 days of a prescription. We are saying that if new prescribers were going to continue an existing course of treatment through the continuity of care, they would not be limited to the

14 days. They would be able to pick up that prescription and prescribe to the user as they saw fit.

SENATOR HARDY:
I understand it perfectly, but on paper, it is not as clear.

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CHAIR SPEARMAN:
I am closing the hearing on A.B. 474. There being no public comment or further business before this Committee, this meeting is adjourned at 4:18 p.m.

RESPECTFULLY SUBMITTED:

Tammy Lubich,
Committee Secretary

APPROVED BY:

Senator Pat Spearman, Chair

DATE:

EXHIBIT SUMMARY				
Bill	**Exhibit / # of pages**		**Witness / Entity**	**Description**
	A	2		Agenda
	B	3		Attendance Roster
A.B. 474	C	1	Elyse Monroy / Office of the Governor	Fact Sheet
A.B. 474	D	12	Elyse Monroy / Office of the Governor	Section by Section Breakdown

EXHIBIT H

EXHIBIT H

Nevada Opioid Crisis Needs Assessment

December 2018

Division of Public and Behavioral Health

Opioid State Targeted Response to the Opioid Crisis Grant Program

Steve Sisolak

Governor

State of Nevada

Julie Kotchevar, PhD

Administrator

Division of Public and Behavioral Health

Richard Whitley, MS

Director

Department of Health and Human Services

Ihsan Azzam, PhD, MD

Chief Medical Officer

Division of Public and Behavioral Health

Acknowledgements

Prepared by and additional information:

Division of Public and Behavioral Health
State of Nevada
4126 Technology Way, Suite 201
Carson City, Nevada 89706
(775) 684.5895

Stephanie Woodard, PsyD
DHHS Senior Advisor on Behavioral Health
Opioid State Targeted Response Project Director
opioidstrgrant@health.nv.gov

Thank you to the following for providing leadership, data and technical support for this report:

Kyra Morgan, MS
Chief Biostatistician
Department of Health and Human Services
State of Nevada

Jen Thompson
Health Program Specialist II
Division of Public and Behavioral Health
State of Nevada

Laurel Brock-Kline
Opioid Biostatistician II
Division of Public and Behavioral Health
State of Nevada

Sandra Atkinson
Health Resource Analyst II
Division of Public and Behavioral Health
State of Nevada

Center for the Application of Substance Abuse Technologies (CASAT)
University of Nevada, Reno

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Purpose

The purpose of this needs assessment is to identify the opioid use disorder (OUD) crisis in Nevada related to:

- the geographical and demographic areas where opioid misuse and related harms are most prevalent;
- all existing activities and funding sources in the state/jurisdiction that address opioid use prevention, treatment and recovery activities; and
- gaps in the existing services and resources to be addressed.

The needs assessment will inform decision making on how to best address the opioid crisis.

Executive Summary

There is variation in the racial/ethnic backgrounds or counties with the highest prevalence of opioid-related indicators, depending on the measure considered. Racial/ethnic, county or regional-level data was obtained for 13 indicators. Several indicators did not have significant differences. Differences are outlined below.

Opioid painkiller prescribing rates have decreased since 2012, while benzodiazepine prescribing rates only began decreasing in 2017. Nevada counties with the highest prescription rates for both opioid painkillers and benzodiazepines are Nye and Storey counties. Death rates are highest for individuals between the ages of 45-64 and lowest among Asian/Pacific Islander and Hispanic/Latino individuals. Death trends differed by type of opioid. Heroin deaths increased from 2010-2015, remained stable from 2015-2016, then increased from 2016-2017. Synthetic opioid deaths (i.e. fentanyl) increased from 2015-2017. Methadone overdose deaths decreased from 2010-2017. Overdose deaths containing both heroin and methamphetamines have been increasing since 2014.

Self-reported use of heroin and other opioids while pregnant and corresponding neonatal abstinence syndrome have been increasing since 2013. Few pregnant women in need of opioid use disorder treatment are receiving it.

Naloxone administration increased in emergency departments (ED) from 2010-2016. Opiate-related hospital admissions increased during this period as well for both ED visits and inpatient (IP) admissions. The category of opioid-involved poisonings shifted. Opioid poisonings from heroin increased in the ED and IP. Opioid poisonings from methadone and other opioid and narcotics increased in ED and decreased in IP admissions.

The current sociopolitical climate in Nevada is favorable to addressing the opioid crisis. Key legislation was passed in the 2015 and 2017 legislative sessions to combat the opioid crisis. Nevada is one of only two states to meet all six key actions for ending the opioid crisis (National Safety Council, 2018). Gov. Brian Sandoval has been instrumental in increasing awareness of the problem, bringing together state and national experts, and introducing legislation to address the crisis. Attorney General Adam Laxalt has played a key role in legislation and statewide prevention efforts.

Through multiple funding sources, EMTs, healthcare providers, mental health professionals, drug court professionals, and interested parties have received varying levels of training on overdose education and naloxone distribution. Naloxone is available without a prescription in CVS and Walgreens pharmacies, Walmart, and Smith's Food and Drug Stores, with coverage of naloxone available through Medicaid and certain commercial insurance companies. Naloxone is available free of charge through Trac-B Exchange in Las Vegas, Northern Nevada HOPES in Reno, community coalition events, and Integrated Opioid Treatment and Recovery Center outreach. Community coalitions have conducted presentations statewide to educate parents, youth, seniors, real estate agents, and veterans on prescription drug abuse. Media campaigns and drop box/take back events have taken place in the majority of communities. One recovery community organization exists in Las Vegas, offering a wide variety of services.

Some gaps exist in addressing the crisis. Opioid Treatment Programs (OTP) only exist in Clark County, Washoe County and Carson City. Office-Based Opioid Treatment (OBOT) providers are only available to prescribe to patients in 10 counties, none of which are prescribing at capacity. OBOTs cite no time for additional patients, insufficient reimbursement rates, and a lack of patients looking for Medication

Assisted Treatment (MAT) as reasons for not prescribing MAT to more patients. Providers are looking for more information on counseling resources in their local areas to be able to give to patients.

Introduction

The opioid crisis is impacting the entire country. Since 1999, the amount of prescription opioids dispensed in the United States and the number of overdose deaths involving opioids have both quadrupled (CDC, 2017). Nevada ranks 12th highest in opioid painkiller prescribing rates (CDC, 2018) and 26th highest for opioid overdose deaths (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2018).

While heroin seizures in Nevada more than doubled from 2014 to 2015, the market stabilized in 2017 (Nevada HIDTA, 2016; Nevada HIDTA, 2018). Over the last three years, methamphetamine seizures have risen 40% (Nevada HIDTA, 2018). Overdose deaths for concurrent heroin and methamphetamines have increased 29% in Clark County and 89% in Washoe County over the same time period (Washoe County Regional Examiner's Office, 2018; Southern Nevada Health District, 2018). Nevada has the highest methamphetamine overdose death rate in the country (Seth, Scholl, Rudd, & Bacon, 2018).

Neonatal exposure to substances has increased each year since 2012 (Nevada Division of Child & Family Services, 2017). At the same time, only 15% of pregnant women with an opioid use disorder received treatment (DHHS, 2018).

The crisis is complex and multifaceted and will need a coordinated effort to address it. Nevada's vast geography and healthcare provider shortage contribute to the challenge of the addressing the problem. Ninety percent (90%) of Nevada's population is concentrated Clark County, Washoe County, and Carson City. The remaining 10% is dispersed throughout the remaining 14 rural and frontier counties, where the distance between major rural towns averages 100 miles. The number of licensed alcohol, drug, and gambling counselors has declined from 45.0 to 42.1 per 100,000 since 2008 (Griswold et al., 2017). On the other hand, the number of healthcare providers who are Data 2000 waivered to prescribe buprenorphine has increased from 98 in 2013 to 250 in 2018 (Levi, et al., 2013; SAMHSA, 2018). Even where there is access, stigma and lack of knowledge about services reduce the number of persons who enter opioid use disorder treatment.

The Substance Abuse and Mental Health Services Administration (SAMHSA) released two years of funding to combat the crisis through the Opioid State Targeted Response (STR) to the Opioid Crisis Grant. To determine how to focus programming, a needs assessment was completed, taking into account areas of highest use and consequences, resources and efforts already in existence, and gaps between need and resources. This needs assessment is considered a living document, and as such, will be updated as more information becomes available.

Data Sources

The secondary data contained in this report was drawn from the following sources:

- Department of Health and Human Services (DHHS) Office of Analytics,
- Nevada Prescription Monitoring Program (PMP),
- Nevada Electronic Death Registry System,
- Nevada Division of Health Care Financing and Policy,
- Center for Health Information Analysis for Nevada,
- Hospital Inpatient and Emergency Department Billing Data,

- Centers for Disease Control and Prevention (CDC) Wonder,
- Youth Risk Behavior Surveillance (YRBS),
- Behavior Risk Factor Surveillance System (BRFSS),
- National Emergency Medical Services Information System (NEMSIS),
- Southern Nevada Health District Office of Epidemiology and Disease Surveillance
- Washoe County Regional Medical Examiner's Office
- Nevada High Intensity Drug Trafficking Areas Threat Assessment (HIDTA)
- Data reported from Nevada Opioid Treatment Providers, and
- Coalition behavioral health reports.

Additional data collection was conducted through an online survey. A request to complete the survey was sent to all Data 2000 waivered physicians through the Chief Medical Officer and the Board of Pharmacy with follow-up reminders.

Please see pages 38-39 for definitions of terms of relevance to the document.

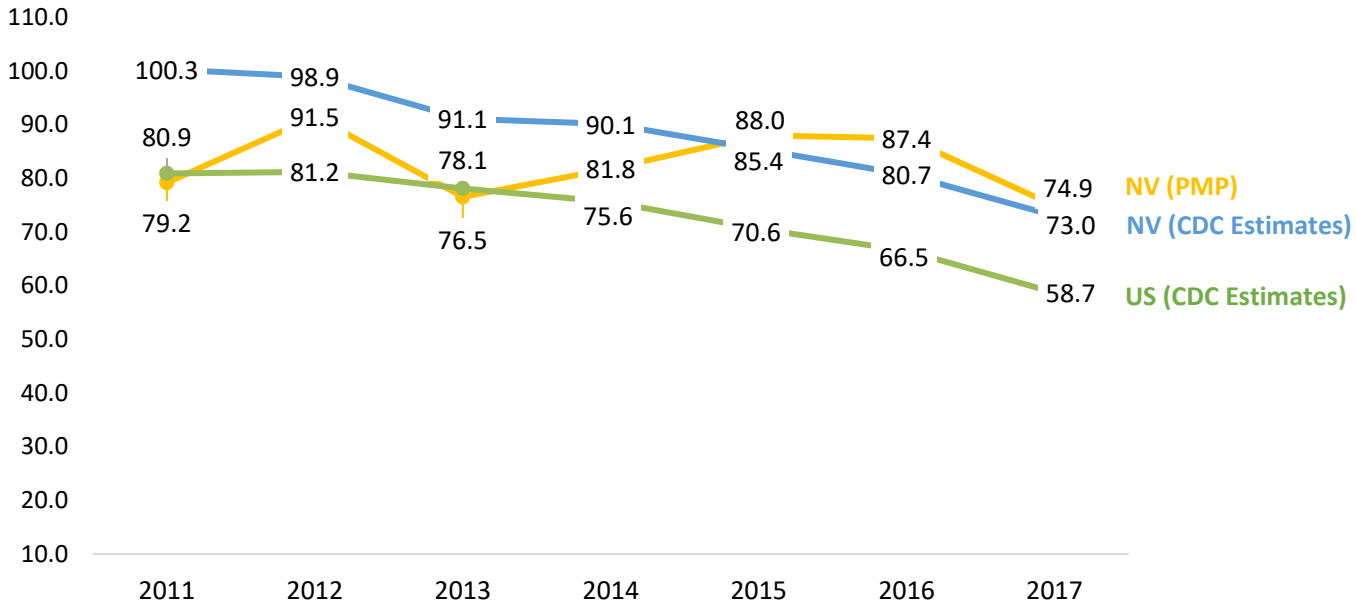
Prescribing Rates

The most recent annual data on opioid painkiller and benzodiazepine prescribing rates available from Nevada's PMP and the CDC are summarized below.

Nevada had the 12th highest opioid painkiller prescribing rate in the country in 2017, decreasing from 80.7 to 73.0 (CDC, 2018).

Based on data from the Nevada PMP and the CDC, Nevada's opioid painkiller prescribing rate is decreasing. The two sources use different definitions of opioids and population. The CDC rates are estimates based on a sample of pharmacies.

Figure 1. Opioid Painkiller Prescriptions per 100, 2011-2017



*Definitions vary slightly between CDC and PMP opioid prescriptions and populations used to calculate rates

(Sources: Guy et al., 2017; DHHS Office of Analytics; Prescription Monitoring Program)

Opioid prescribing rates were highest in Nye County (129.3), Storey County (125.2), Mineral County (118.5), and Lyon County (111.2). Opioid prescribing decreased 17% statewide from 2016 to 2017. All counties decreased except for Lincoln County which increased 39%. The largest decreases in opioid prescribing rates were in Mineral County (25%) and Esmerelda County (21%). All prescriptions are reported by county where the patients live. This may be different than the county where the prescription was written. See Table 1 for prescribing rates for each county.

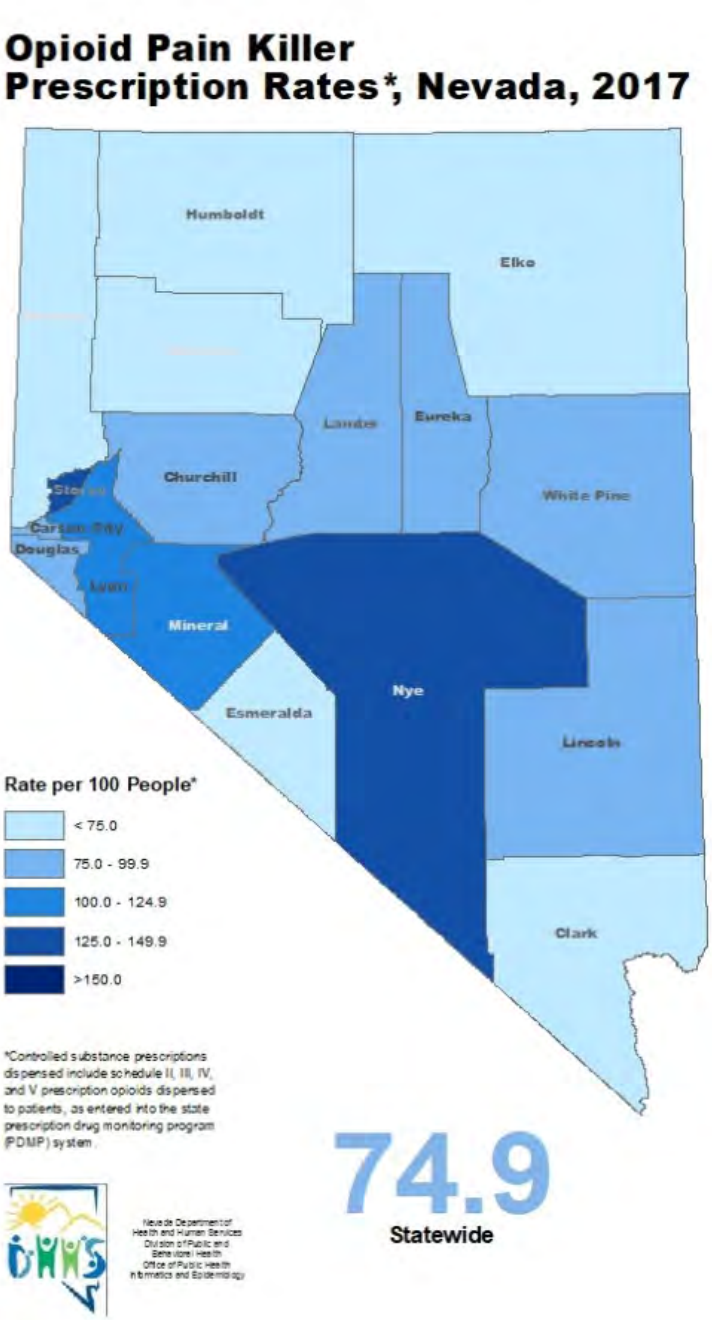


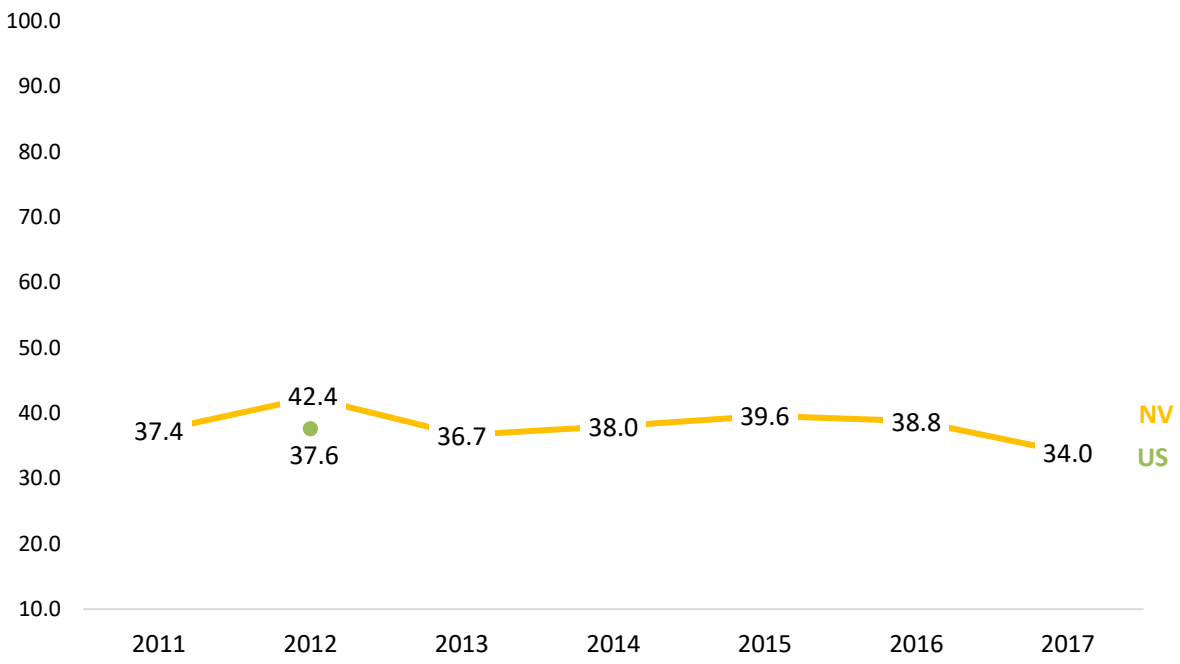
Table 1. Opioid Painkiller Prescribing Rates Per 100, by County, 2017

County	Rate
Carson City	91.1 (90.3-91.8)
Churchill	98.0 (96.7-99.2)
Clark	72.2 (72.1-72.3)
Douglas	91.1 (90.2-91.9)
Elko	63.3 (62.6-63.9)
Esmeralda	57.0 (52.3-61.8)
Eureka	85.6 (81.4-89.7)
Humboldt	66.7 (65.4-67.9)
Lander	76.7 (74.5-78.9)
Lincoln	84.6 (58.5-62.8)
Lyon	129.9 (129.0-130.9)
Mineral	158.1 (154.5-161.8)
Nye	155.6 (154.4-156.7)
Pershing	69.4 (67.4-71.3)
Storey	146.9 (143.2-150.6)
Washoe	87.4 (87.1-87.7)
White Pine	99.9 (97.9-101.8)
Nevada	87.4 (87.3-87.6)

(Sources: DHHS Office of Analytics; PDMP)

Nevada's benzodiazepine prescribing rate remained stable from 2013 to 2016, then decreased 12% in 2017.

Figure 2. Benzodiazepine Prescriptions Per 100, 2011-2016



(Sources: Paulozzi, et al., 2014; DHHS Office of Analytics; Prescription Monitoring Program)

The benzodiazepine prescribing rate is highest in Nye County (54.3) and Storey County (50.9)—each significantly higher than the state prescribing rate of 33.9. The benzodiazepine prescribing rate decreased in all counties except for Lincoln County as well. Lincoln County increased by 34% from 2016 to 2017, following a 46% increase from 2015 to 2016. The prescribing rate percent change decreased

the most in Mineral County (41%), White Pine County (25%), and Esmerelda County (25%) from 2016 to 2017.

The top two opioid prescribing counties—Nye and Storey Counties—are the same counties as the top two Benzodiazepine prescribing counties, indicating these counties are at highest risk for overprescribing.

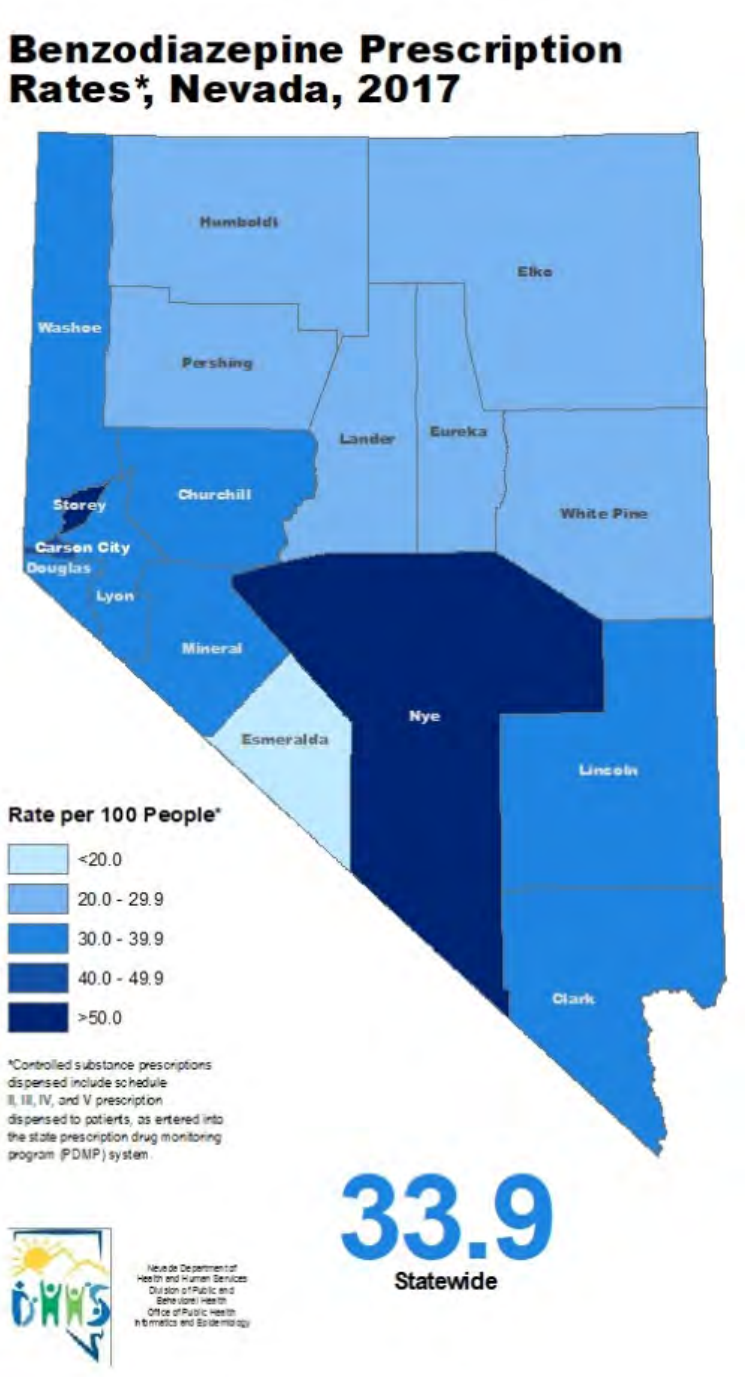


Table 2. Benzodiazepine Prescription Rates Per 100 by County, 2017

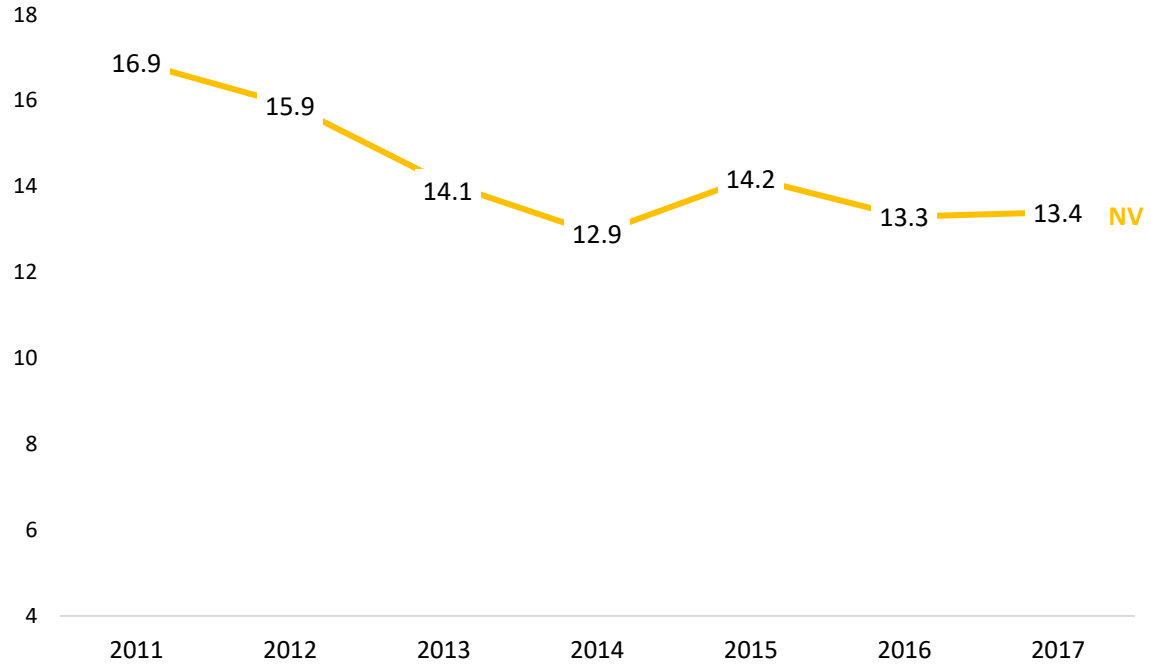
County	Rate
Carson City	42.0 (41.5-42.5)
Churchill	34.2 (33.4-34.9)
Clark	33.7 (33.6-33.8)
Douglas	39.2 (38.7-39.8)
Elko	24.1 (23.7-24.5)
Esmeralda	16.8 (14.2-19.4)
Eureka	26.9 (24.6-29.2)
Humboldt	24.3 (23.5-25.0)
Lander	24.0 (22.7-25.2)
Lincoln	36.9 (35.2-38.6)
Lyon	37.6 (37.1-38.1)
Mineral	34.5 (32.8-36.2)
Nye	54.9 (54.3-55.6)
Pershing	21.6 (20.6-22.7)
Storey	53.1 (50.9-55.4)
Washoe	33.4 (33.2-33.6)
White Pine	25.8 (24.9-26.8)
Nevada	34.0 (33.9-34.1)

(Sources: DHHS Office of Analytics; PDMP)

Opioid-Involved Overdose Deaths

The most recent annual data available for Nevada's opioid-involved overdose deaths are summarized below. There has been a 21% decrease in overdose-related deaths since 2011.

Figure 3. Opioid-Related Deaths per 100,000, 2011-2017



*Data are preliminary and subject to change.
**Includes ICD-10 codes as underlying cause of death: X40-X44, X60-X64, X85, Y10-Y14, as contributing cause of death: T40.0-T40.4, T40.6
(Sources: CDC Wonder; DHHS Office of Analytics; Electronic Death Registry System)

The table below shows age-adjusted opioid overdose death rates by county in 2017. Rates are age-adjusted so that they can be compared across regions and with other states and national statistics.

Table 3. Opioid Overdose Death Rates Per 100,000 by County, 2017

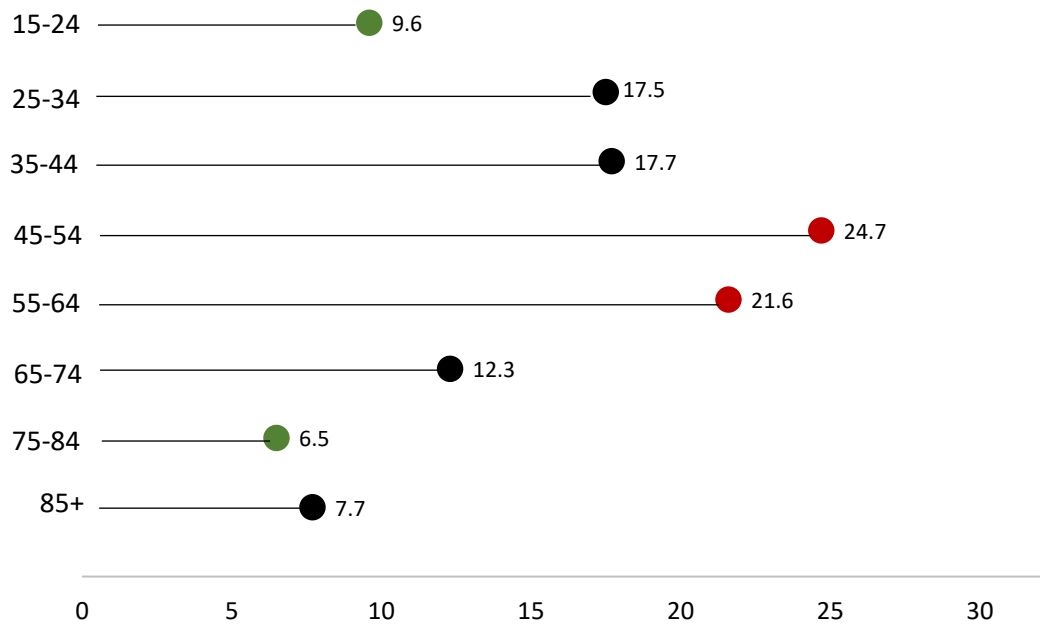
County	Number	Age-Adjusted Rate
Carson City	13	20.3 (9.3-31.3)
Churchill	4	15.2 (0.3-30.0)
Clark	275	12.3 (10.8-13.7)
Douglas	4	7.7 (0.2-15.2)
Elko	3	6.6 (0.0-14.0)
Esmeralda	0	-
Eureka	0	-

County	Number	Age-Adjusted Rate
Humboldt	2	15.9 (0.0-38.1)
Lander	0	-
Lincoln	0	-
Lyon	14	27.9 (13.3-42.5)
Mineral	0	-
Nye	8	14.7 (13.3-24.9)
Pershing	1	15.7 (0.0-46.6)
Storey	0	-
Washoe	74	15.1 (11.7-18.6)
White Pine	3	26.9 (0.0-57.3)
Statewide	401	13.0 (11.8-14.3)

*Data are preliminary and are subject to change.
(Sources: DHHS Office of Analytics; Electronic Death Registry System)

Age groups affected greatest by opioid deaths were ages 45-54 and ages 55-64, with death rates significantly higher.

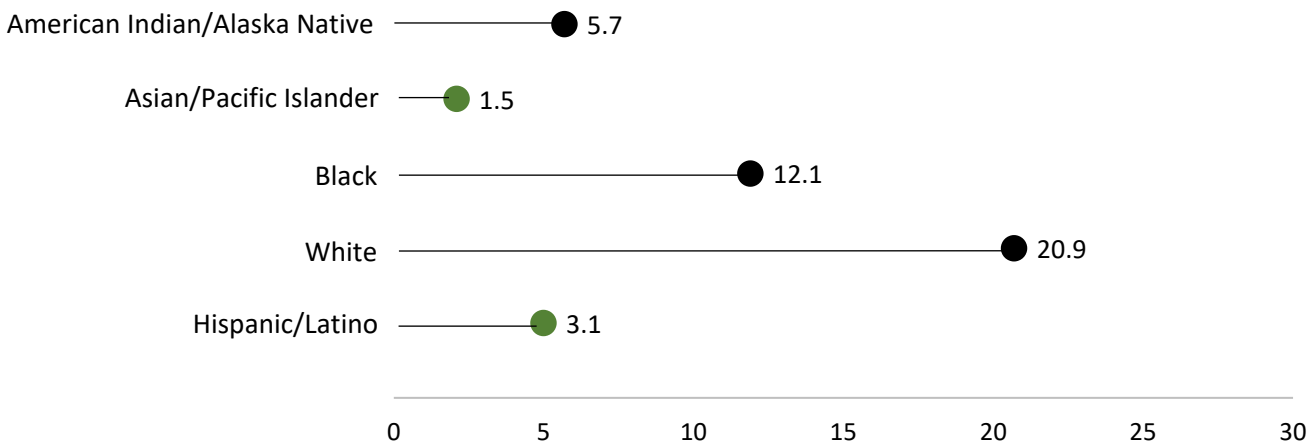
Figure 4. Opioid Overdose Death Rates, by Age, 2017



(Sources: DHHS Office of Analytics; Electronic Death Registry System)

Opiate-involved overdose deaths were significantly lower among Hispanic and Asian/Pacific Islander residents.

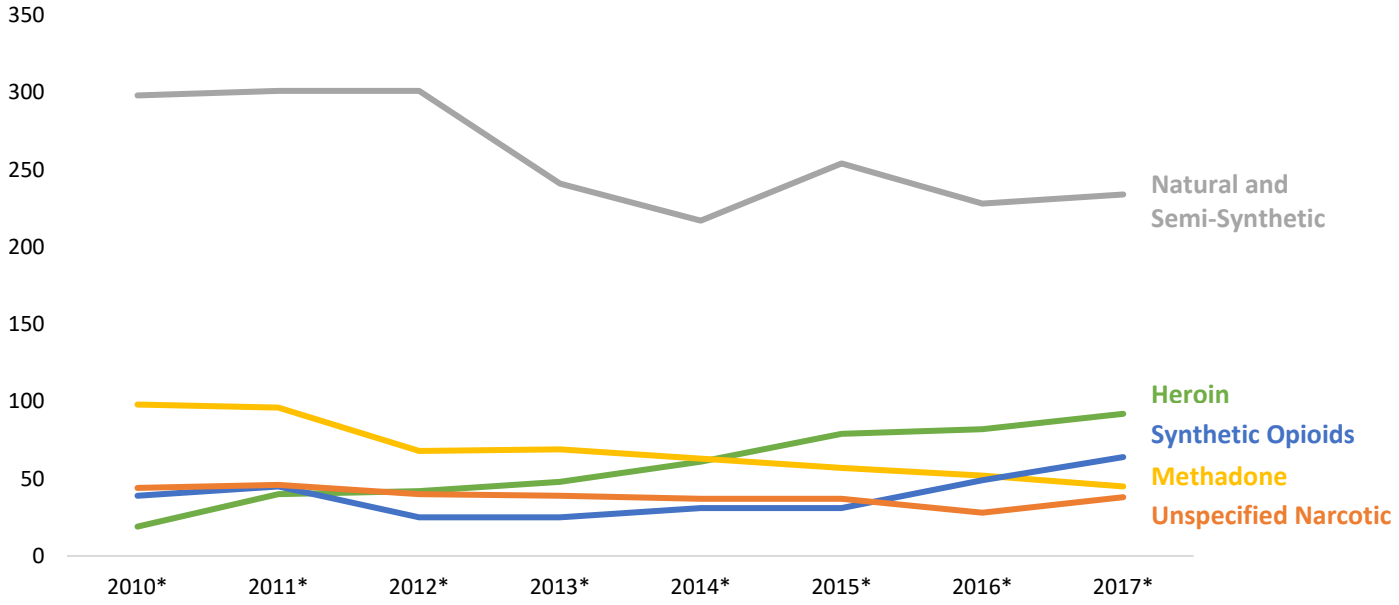
Figure 5. Opioid Overdose Death Rates, by Race/Ethnicity, 2017



(Sources: DHHS Office of Analytics; Electronic Death Registry System)

Opioid overdose deaths were significantly greater for natural and semi-synthetic (i.e. hydrocodone) opioids for all years displayed. Natural and semi-synthetic deaths are on a decreasing trend since 2012. From 2010-2015, heroin deaths increased, remained stable from 2015-2016, then increased again from 2016-2017. For the last three years, 2015-2017, synthetic opioid deaths (i.e. fentanyl) increased. Methadone overdose deaths decreased from 2010-2017.

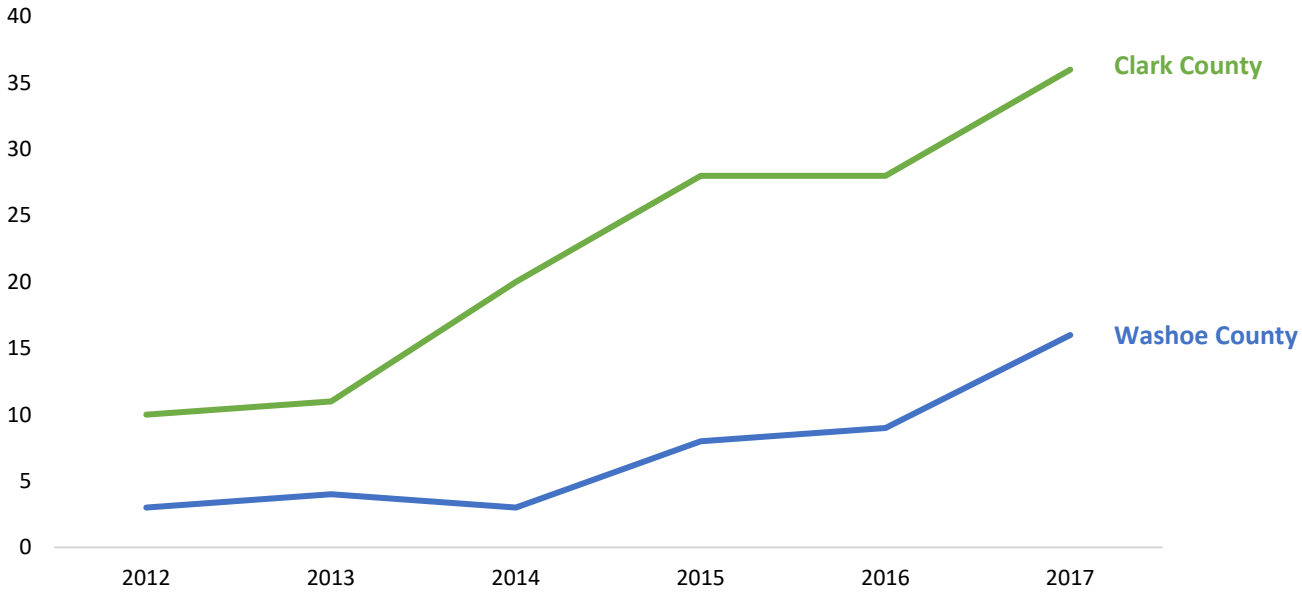
Figure 6. Opioid Overdose Deaths by Drug Category, Nevada Residents, 2010-2017



(Source: DHHS Office of Analytics)
*Data are preliminary and are subject to change.
**A person can be included in more than one drug group, and therefore the counts above are not mutually exclusive.

From 2012 to 2017, overdose deaths from methamphetamine and heroin increased 260% in Clark County and 433% in Washoe County. Half of the heroin deaths in Clark County and Washoe County included methamphetamine in 2017.

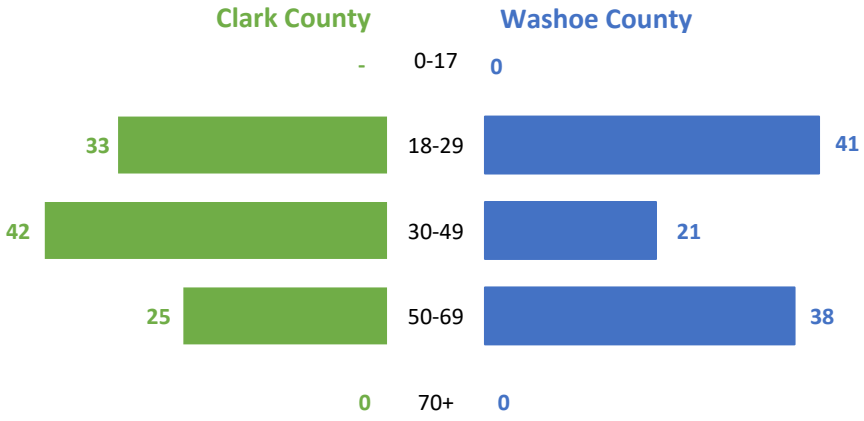
Figure 7. Methamphetamine and Heroin Overdose Deaths, by County, 2012-2017



(Sources: Southern Nevada Health District Office of Epidemiology and Disease Surveillance; Washoe County Regional Medical Examiner's Office)

Heroin overdose deaths were highest among individuals 30-49 years (42%) in Clark County, compared to Washoe County heroin overdose deaths which were highest among individuals 18-29 years (41%) and 50-69 years (38%).

Figure 8. Heroin Overdose Deaths, by Age, 2017



(Sources: Southern Nevada Health District Office of Epidemiology and Disease Surveillance; Washoe County Regional Medical Examiner's Office)
*Cell counts with less than five are suppressed.

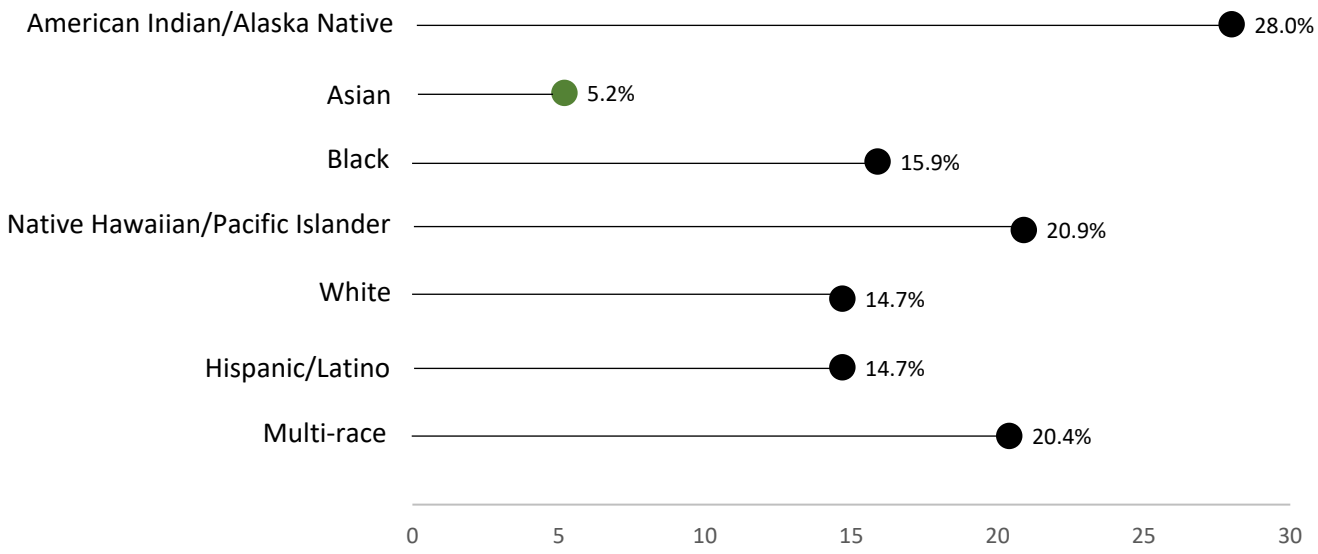
Misuse and Related Harms

Adolescent Misuse

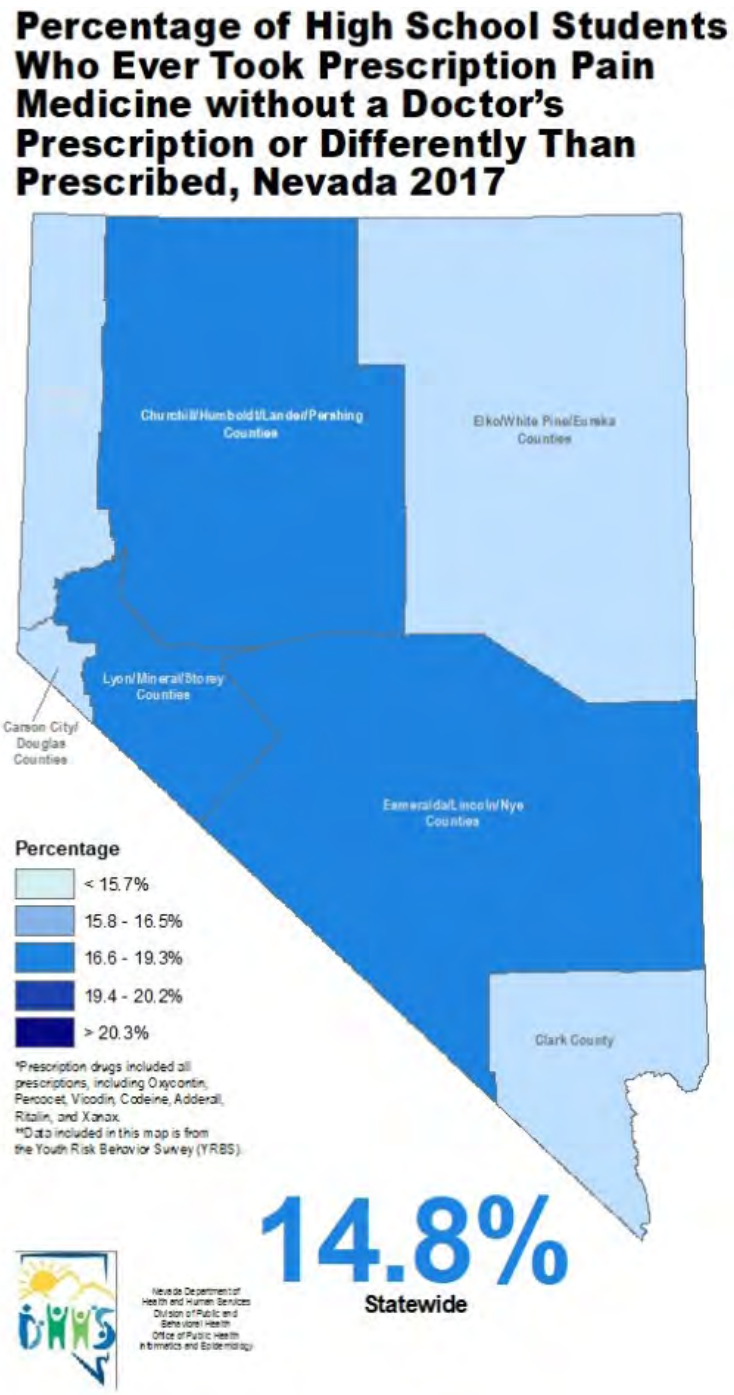
The proportion of high school students who self-reported ever using a prescription drug without a doctor's prescription decreased, though not significantly, from 20.2% to 16.9% from 2011-2015. Prescription drugs were defined as any prescription drugs including, but not limited to: Oxycontin, Percocet, Vicodin, Codeine, Adderall, Ritalin, or Xanax. Due to this broad definition, the question was more of a proxy for prescription opioid use rather than a direct measurement. In 2017, the question was updated to more accurately assess prescription painkiller use. The question now asks if the student has ever used a prescription pain medicine without a doctor's prescription or differently than prescribed. The lifetime prevalence was 14.8% and use in the past 30 days was 7.0%.

Weighted lifetime prescription drug use was significantly lower among Asian students (5.2%). The same disparity existed for past 30-day prescription drug use, with 2.3% of Asians reporting current use, compared to 7.0% of the state sample.

Figure 9. Lifetime Prescription Painkiller Use, by Race/Ethnicity, 2017



(Source: Lensch et al., 2017)

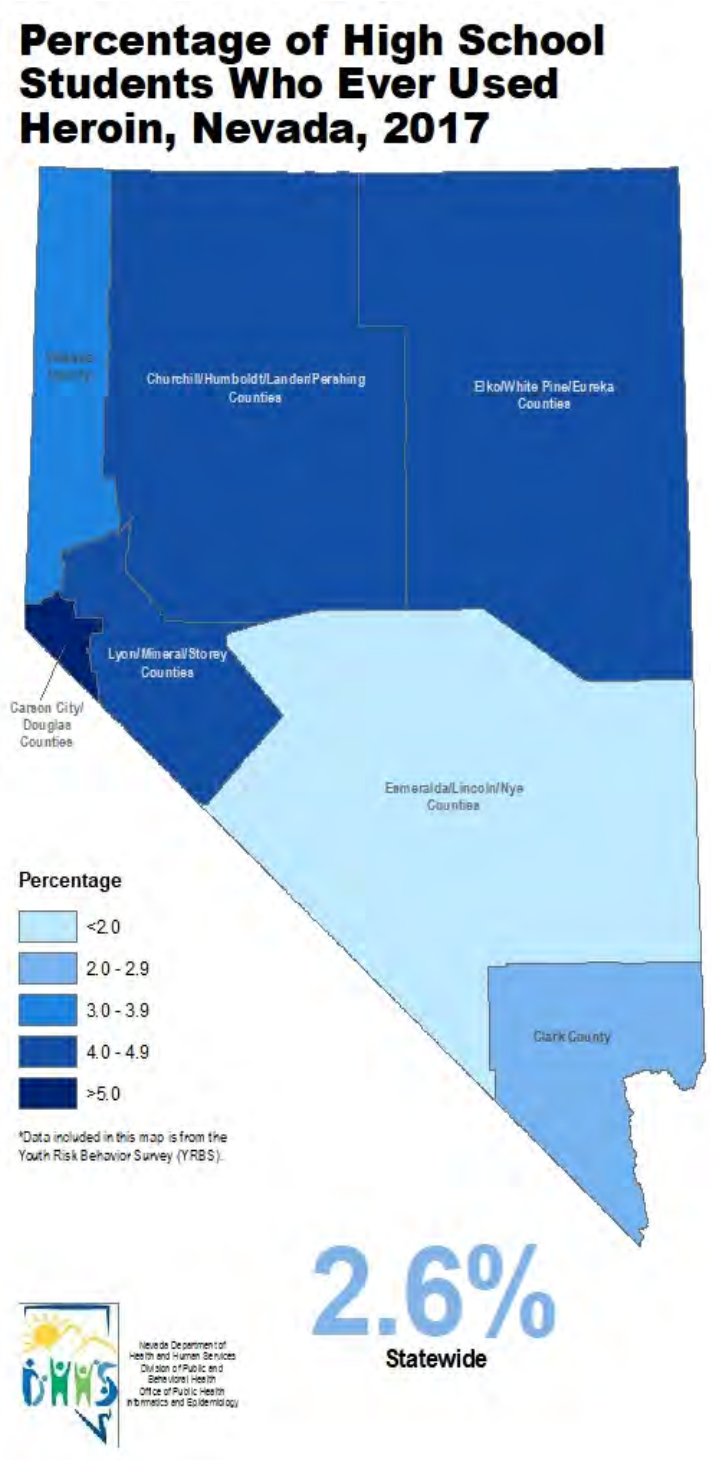


Lifetime use of a painkiller without a prescription did not vary significantly from county to county. The source of the high school data aggregates some counties together; therefore, it is not known if the county groupings increased or decreased the total percentage.

Table 4. Percentage of High School Students Who Ever Took Prescription Pain Medicine without a Doctor's Prescription or Differently Than Prescribed, 2017

County	Percentage
Carson City/Douglas	15.5% (8.1-22.9)
Churchill/Humboldt/ Lander/Pershing	18.1% (13.7-22.6)
Clark	14.5% (12.5-16.5)
Elko/White Pine/ Eureka	14.2% (9.9-18.4)
Lincoln/Nye	12.5% (7.6-16.9)
Lyon/Mineral/Storey	18.7% (12.4-25.1)
Washoe	14.8% (11.8-17.9)
Statewide	14.8% (13.2-16.4)

(Source: YRBS)



Self-reported lifetime heroin use in high school did not change significantly from 2013 to 2017. Lifetime heroin use did not differ significantly by county. Prevalence was significantly lower among Native Hawaiian/Pacific Islander respondents. Again, the high school data aggregates multiple counties which may affect rankings.

Table 5. Percentage of High School Students Who Ever Used Heroin, 2017

Counties	Percentage
Carson City/Douglas	5.1% (0.0-10.7)
Churchill/Humboldt/ Lander/Pershing	4.3% (2.4-6.3)
Clark	2.1% (1.2-3.1)
Elko/White Pine/ Eureka	4.1% (1.4-6.8)
Lincoln/Nye	1.9% (0.5-3.3)
Lyon/Mineral/Storey	4.6% (1.0-8.2)
Washoe	3.2% (2.1-4.3)
Statewide	2.6% (1.8-3.3)

(Source: YRBS)

Adult Misuse

According to the National Survey on Drug Use and Health (NSDUH), Nevada ranks fourth for the percentage of people aged 12 or older who used prescription pain relievers nonmedically in the past year from 2012-2014 (5.20%), down from second from 2010-2012 (5.92%) (Lipari et al., 2017).

The Behavior Risk Factor Surveillance System instead assesses past 30-day use of a painkiller to get high, where 0.7% of adults in Nevada indicated yes, in aggregated data from 2013-2016.

Table 6. Past Month Percentage Who Used a Painkiller to Get High, by County, 2013-2016

County	Percentage
Carson City	0.7%
Churchill	0.1%
Clark	0.6%
Douglas	1.2%
Elko	0.7%
Esmeralda	0.0%
Eureka	0.0%
Humboldt	0.0%
Lander	0.0%
Lincoln	0.0%
Lyon	1.5%
Mineral	1.2%
Nye	0.5%
Pershing	0.0%
Storey	0.3%
Washoe	1.0%
White Pine	0.0%
Statewide	0.7%

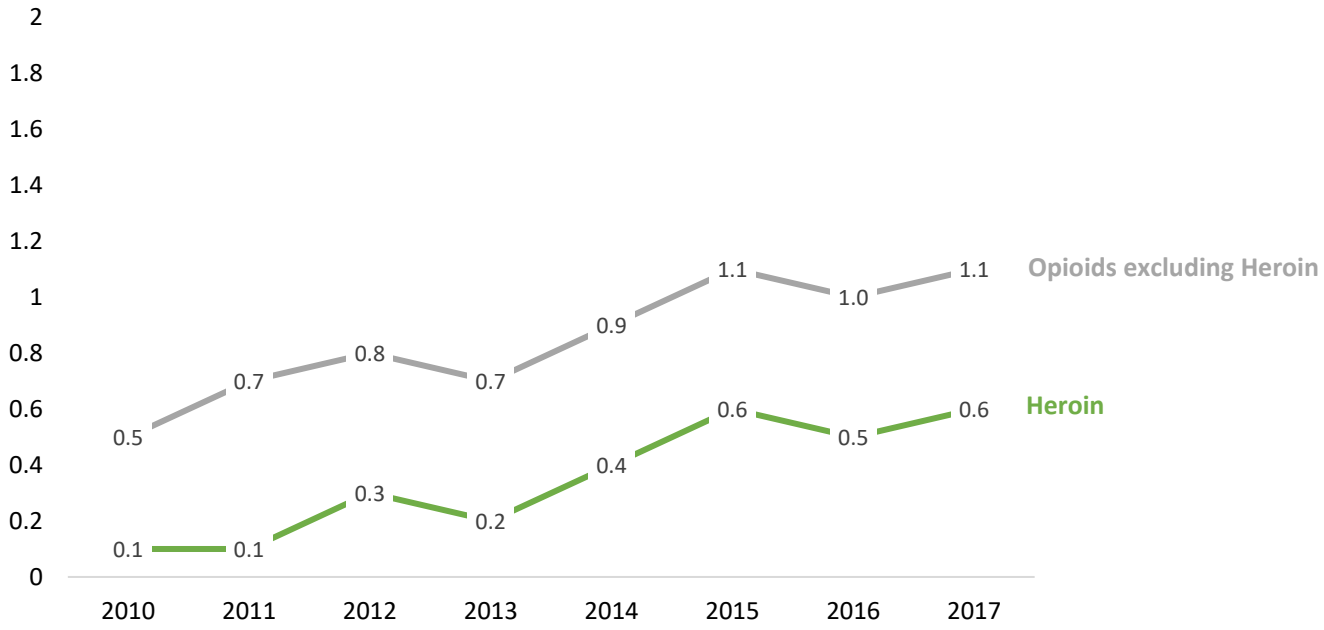
(Source: Behavioral Risk Factor Surveillance System)

Past year heroin use in Nevada among those aged 12 or older was the same as the national average of 0.33% in 2014-2015 (SAMHSA, 2017).

Prenatal Substance Misuse

Self-reported use of heroin and other opioids has been on an increasing trend since 2011. Because substance use during pregnancy is self-reported by mothers, reported rates are likely lower than actual rates due to underreporting, and expectant mothers may be reluctant to be fore forthcoming on the birth record for a variety of reasons.

Figure 10. Self-Report Prenatal Substance Misuse Rates, 2010-2017



(Source: Nevada Electronic Birth Registry System)
*Rates per 1,000 live births

Self-reported heroin use and opiate use while pregnant by county is listed in Table 7.

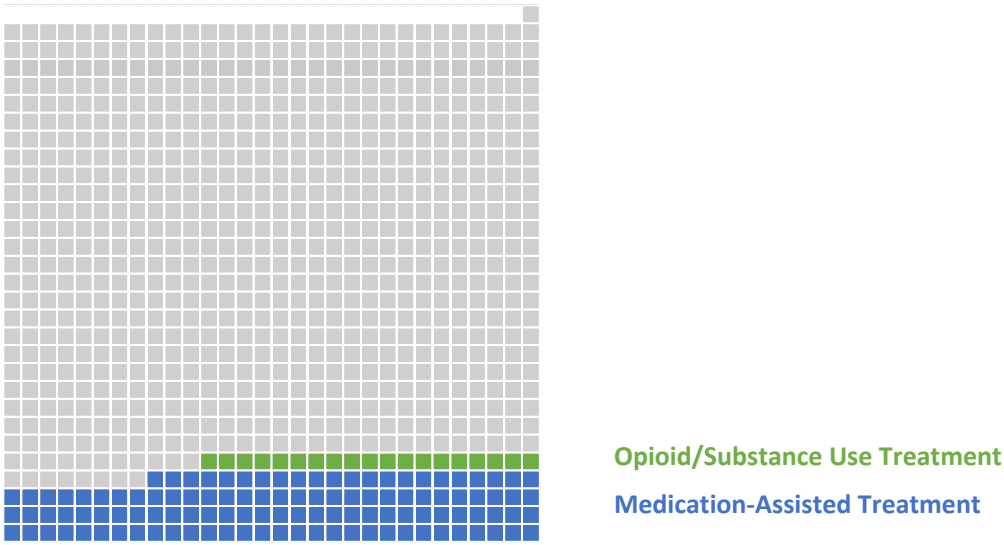
Table 7. Rate of Self-Reported Opiate Use While Pregnant, 2012-2016

County	Heroin	Opiates
Carson City/Douglas	2.0	0.7
Churchill/Humboldt/Lander/Pershing	0.3	0.8
Clark	0.7	1.7
Elko/Eureka/White Pine	0.3	2.4
Esmeralda/Lincoln/Nye	5.2	2.1
Lyon/Mineral/Storey	1.9	1.3
Washoe	1.0	1.1
Statewide	0.8	1.6

*Rates are per 1,000 live births
**Data are preliminary and subject to change.

From April 2017 to March 2018, 871 pregnant women on Medicaid were diagnosed with an opioid use disorder. Of these women, only 112 were on medication-assisted treatment and 19 submitted substance use treatment claims.

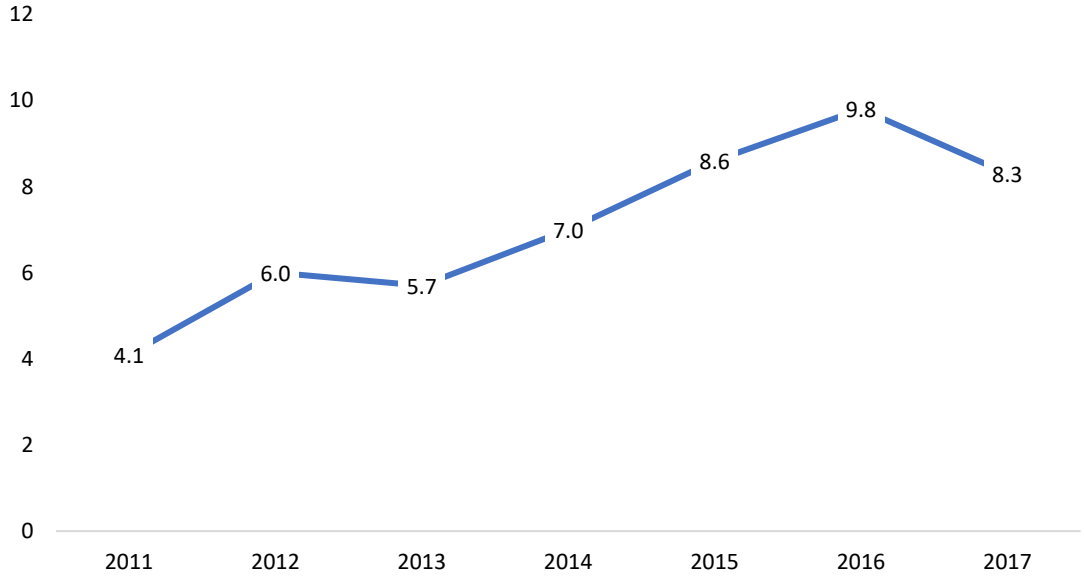
Figure 11. Number of Pregnant Women Receiving Treatment, Medicaid, April 2017-March 2018



(Source: DHHS Office of Analytics; Division of Health Care Financing and Policy)
*Opioid use disorder defined with diagnosis code F11.x.
**Buprenorphine and Methadone were identified with a set of 399 NCD codes.

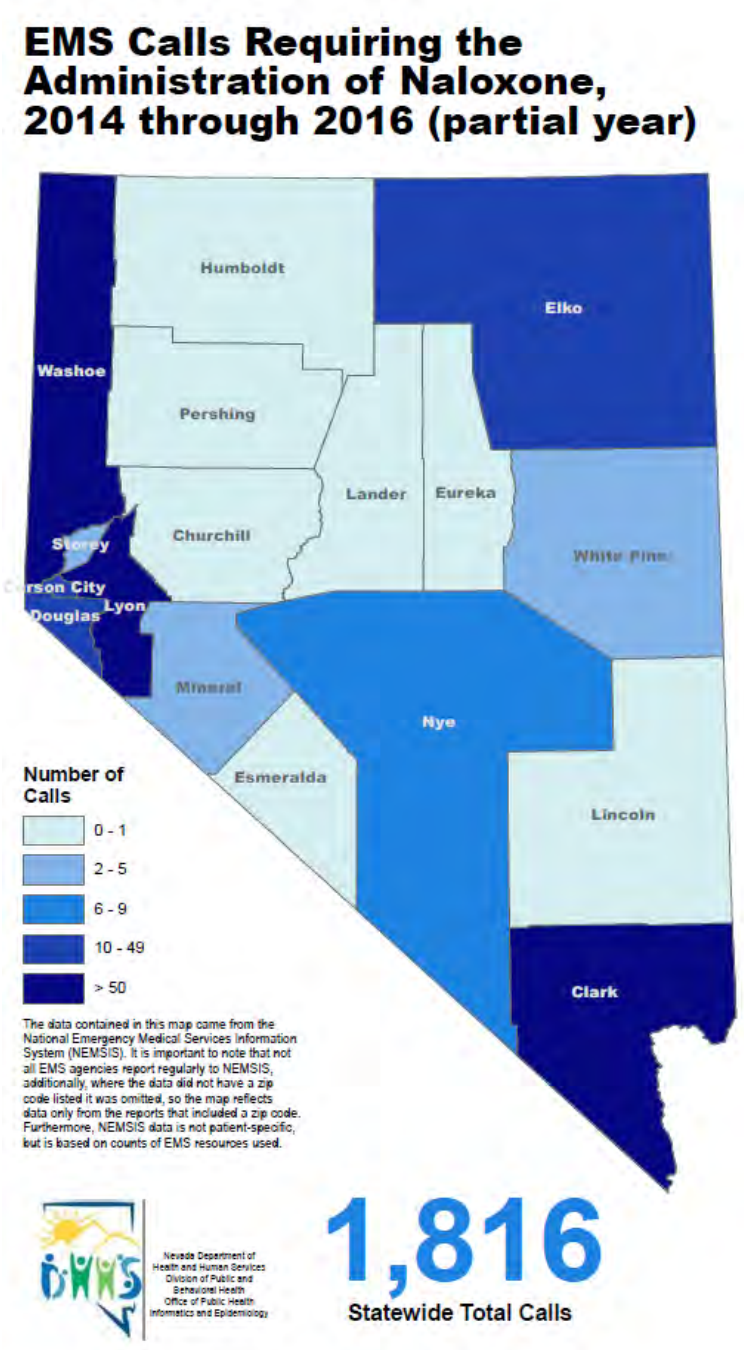
The rate of neonatal abstinence syndrome increased from 2012 to 2016, then decreased 15% in 2017.

Figure 12. Neonatal Abstinence Syndrome, 2010-2017



(Source: Hospital Inpatient Department Billing and Nevada Electronic Birth Registry System)
*ICD-10 codes replaced ICD-9 codes in last quarter of 2015, therefore data prior to that may not be directly comparable.

Medical Interventions



The rate of EMS calls requiring administration of naloxone is higher for Lyon County. Of the seven counties listed in the 0-1 calls category, five counties had zero EMS calls requiring naloxone administration: Esmeralda, Humboldt, Lander, Lincoln, and Pershing. Lincoln County EMS was part of the NROOR funding and had naloxone on the ambulances. It is unknown if naloxone is carried by EMS in the other counties with no administration.

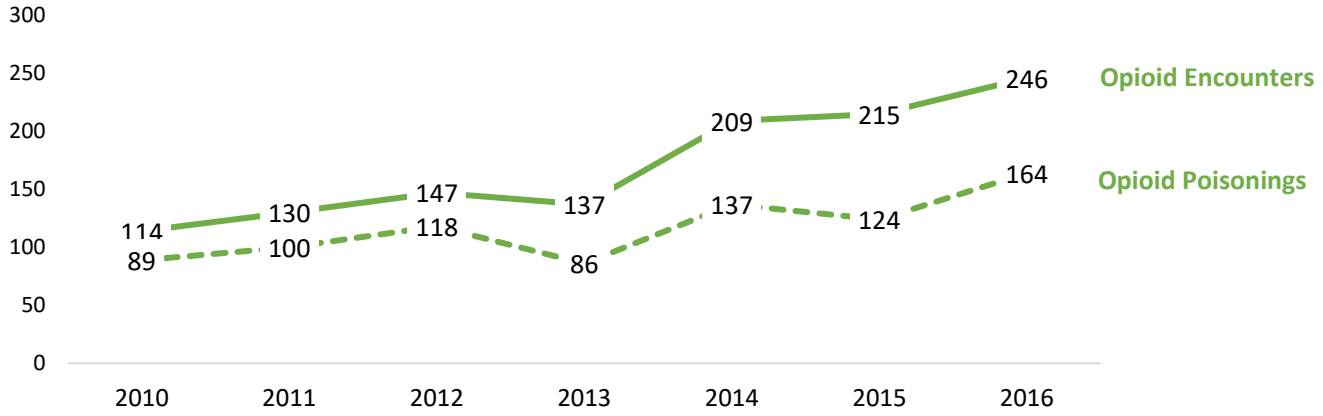
Table 8. Rate of EMS Calls Requiring Naloxone by County, 2014-2016

County	Number	Crude Rate
Carson City	49	30.1 (21.7 - 38.5)
Churchill	1	1.3 (0.0 - 3.9)
Clark	1,089	17.3 (16.3 - 18.4)
Douglas	14	9.6 (4.6 - 14.6)
Elko	47	29.6 (21.1 - 38.0)
Esmeralda	0	0.0
Eureka	1	17.3 (0.0 - 51.1)
Humboldt	0	0.0
Lander	0	0.0
Lincoln	0	0.0
Lyon	86	53.1 (41.8 - 64.3)
Mineral	3	21.7 (0.0 - 46.2)
Nye	6	4.4 (0.9 - 8.0)
Pershing	0	0.0
Storey	3	24.7 (0.0 - 52.7)
Washoe	513	38.7 (35.4 - 42.1)
White Pine	4	13.2 (0.3 - 26.1)

(Source: NEMSIS)

Naloxone administration in emergency departments increased from 2013-2016. Naloxone was only used for a small percentage of total opioid poisonings (15.2%) and opioid encounters (3.8%).

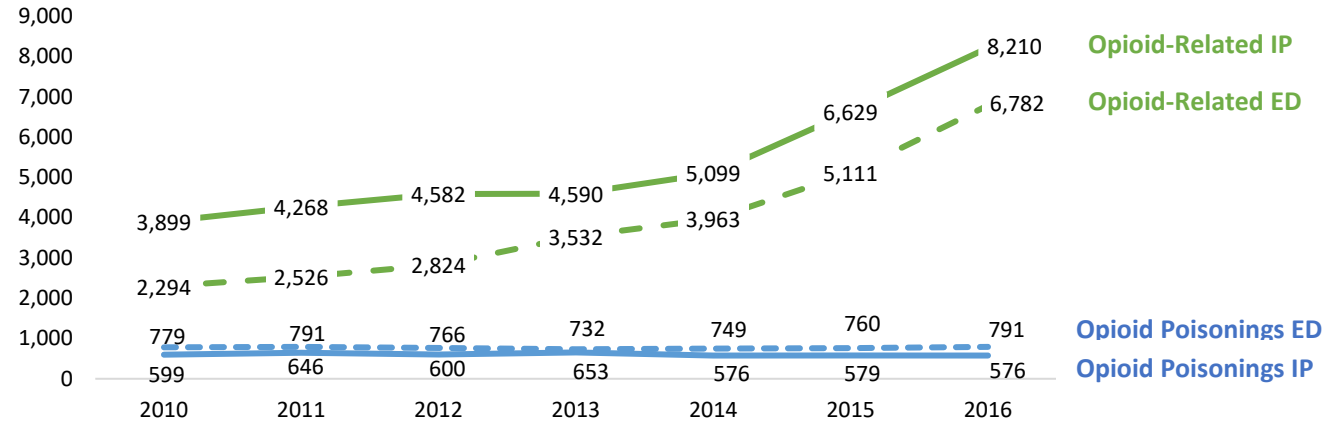
Figure 13. Emergency Department Naloxone Administrations, 2010-2016



(Source: OPHIE, Emergency Department Billing Data)
*Includes ICD-9 Codes of 965.0, 304.0, 304.7, 305.5, E850.0, E850.1, E850.2 and ICD-10 Codes of T40.0-T40.4, and T40.6, F11, and J23.10.
**Opioid poisonings are a subset of opioid encounters.

Both ED and IP admissions for opiates increased from 2010-2016. Opioid poisonings, a subset of opioid-related admissions, remained steady during those same years among ED and IP admissions. In 2014, the highest rate of opioid-related IP stays was among individuals aged 45-64 years, while opioid-related ED visits were highest among individuals 25-44 years old. ED visits were highest in this age group in all 30 states for which ED data were available. There was variation among highest age group for IP admissions, with rates highest among individuals 45-64 years in only nine states. Females had a higher rate of IP stays, while men had a higher rate of ED visits (Weiss et al., 2017).

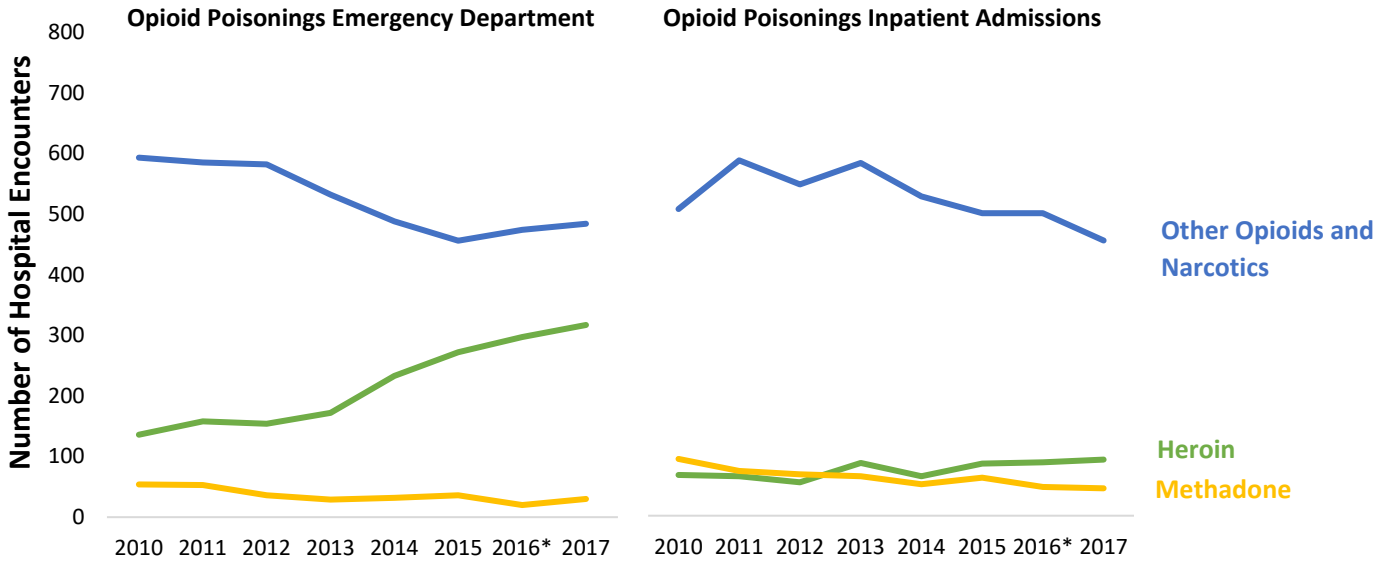
Figure 14. Opiate-Related Hospital Admissions, 2010-2016



(Source: Center for Health Information Analysis, Hospital Inpatient and Emergency Department Billing Data)
*A person can be included in more than one drug group, therefore the counts above are not mutually exclusive.
**In October 2015, ICD-10-CM codes were implemented. Previous to October 2015, ICD-9-CM codes were used for medical billing. Therefore, 2015 data consists of two distinct coding schemes, ICD-9-CM and ICD-10-CM respectively. Due to this change in coding schemes, hospital billing data from October 2015 forward may not be directly comparable to previous data.

While Figure 14 shows the number of opioid poisonings has remained stable, Figure 15 displays that the type of opioid drug causing opioid poisonings has changed. Opioid poisonings from heroin have increased in the ED and IP. Methadone and other opioid and narcotics have increased in ED encounters, while decreasing in IP admissions.

Figure 15. Opioid-Related Poisoning Hospital Admissions by Drug Category, 2010-2017



*A person can be included in more than one drug group, and therefore counts are not mutually exclusive. In 2016, the use of E-codes was eliminated, and counts are now mutually exclusive.

State of Current Services and Funding

Availability of Medication-Assisted Treatment

There are 15 Opioid Treatment Programs (OTPs) in Nevada across Clark County, Washoe County, and Carson City (see Table 10). Only one OTP location, Life Change Center Sparks, is at capacity. To address this, they are planning to open another facility in Reno. The two Mission Treatment Center locations and the four Center for Behavioral Health locations said they would add more staff as client levels increased, stating that there was no limit to their capacity. One OTP does not provide maintenance therapy, as it is only using MAT to detox and then refer the client to another provider. The 14 rural counties in Nevada have no OTPs. Capacity to provide MAT services among the 12 clinics responding to inquiry is 4,693 clients. No information was available on the remaining three facilities.

Three OTPs, Adelson Clinic in Clark County and Life Change Center (one location in Washoe County and one in Carson City), receive funding from SAPTA through the Federal Block Grant. At those facilities, the majority of clientele seeking MAT are publicly funded. Requests for number served who are publicly funded or privately funded were not returned by 12 OTPs, but most clients should be privately funded at those facilities. See Table 9 for more information on county served, program capacity, and psychosocial interventions offered.

Table 9. Nevada Opioid Treatment Program Location, Capacity, and Services

Program	County	Program Capacity	Current Number Served	Number served - publicly funded		Number served - privately funded	Psychosocial interventions offered
Adelson Clinic	Clark	300	183	Medicaid 69	SAPTA 75	21	Counseling and refer/coordination of care for other services needed by clients
Center for Behavioral Health							
• Center for Behavioral Health – Cheyenne	Clark	200	200	--		--	Counseling (variety of groups, including gender specific), family counseling, case management, coordinate care when mental health services are needed, physician available everyday
• Center for Behavioral Health – Desert Inn	Clark	450	450	--		--	Counseling (variety of groups, including gender-specific), family counseling, case management, coordinate care when mental health services are needed, physician available everyday
• Center for Behavioral Health – McDaniel	Clark	400	400	--		--	Counseling (variety of groups, including gender-specific), family counseling, case management, coordinate care when mental health services are needed, physician available everyday
• Center for Behavioral Health – Reno	Washoe	300	300	--		--	Counseling (variety of groups, including gender-specific), Family Counseling, case management, coordinate care when mental health services are needed, Physician available 2 days per week
Desert Treatment Clinic	Clark	--	--	--		--	--
Eastern Treatment Clinic	Clark	--	--	--		--	--

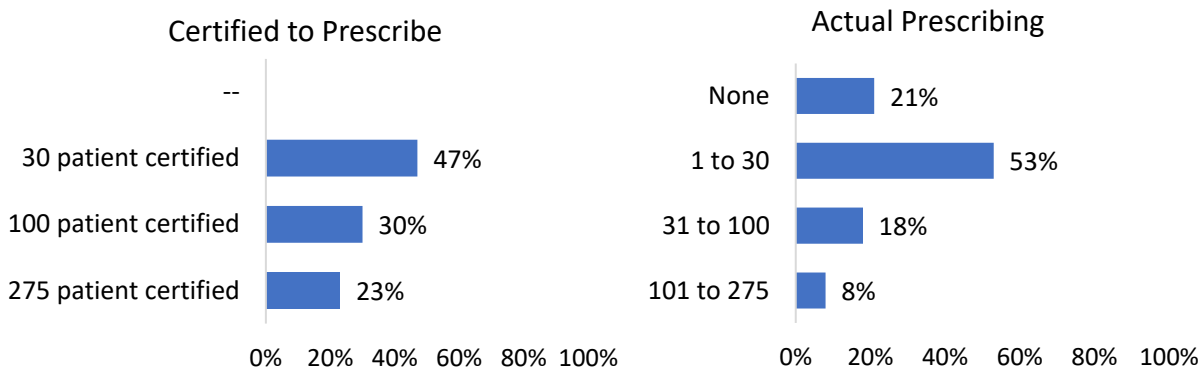
Program	County	Program Capacity	Current Number Served	Number served - publicly funded		Number served - privately funded	Psychosocial interventions offered
Mission Treatment Centers							
• Mission Treatment Centers Henderson	Clark	258	258	--		--	Counseling, coordinate care with other agencies for the client's needs (medical, mental health)
• Mission Treatment Centers Las Vegas	Clark	260	260	--		--	Counseling, coordinate care with other agencies for the client's needs (Medical, Mental Health)
Nevada Treatment Center (Nevada Integrated Behavioral Services Inc.)	Clark	300	125	--		--	Counseling (L1, 2.1 and 2.5), case management, COD services, coordination of care for client's needs.
New Beginnings Counseling Center Eastern	Clark	800	490	--		--	Counseling, domestic violence, DUI class and the victim impact panel
New Beginnings Counseling Center Lake Mead	Clark	500	180	--		--	Counseling, domestic violence, DUI class and the victim impact panel
Life Change Center				Medicaid 435	SAPTA 107	241	
• Life Change Center – Carson City	Carson	275	275				Counseling; case management by dedicated CM staff; family programming: for women: parenting and prevention program, co-occurring capable program so can screen and then assist with referral and coordination of care; medication management; assessment for initial clients for proper placement; gardening program; social recreation program

Program	County	Program Capacity	Current Number Served	Number served - publicly funded	Number served - privately funded	Psychosocial interventions offered
• Life Change Center – Sparks	Washoe	450	450			Counseling; case management by dedicated CM staff; family programming: for women: parenting and prevention program, co-occurring capable program so can screen and then assist with referral and coordination of care; medication management; assessment for initial clients for proper placement; gardening program; social recreation program
Seven Hills Hospital, Inc.	Clark	--	--	--	--	None

In August 2017, all 192 Data 2000 waivered providers were emailed a brief survey inquiring about their buprenorphine prescribing limit, current caseload of MAT patients, reasons for not prescribing at capacity, resources that could increase their MAT prescribing, counties prescribing in, use of opioid and naloxone co-prescribing, psychosocial interventions offered and interventions provided through contract arrangements. Ten email addresses were "undeliverable," reducing the sample to 182. The survey received 84 responses, with eight indicating they did not want to participate and five not completing the survey, leaving 71 responses for analysis. Survey results presented below should be interpreted with caution, as only 39% of Data 2000 waivered providers completed the survey.

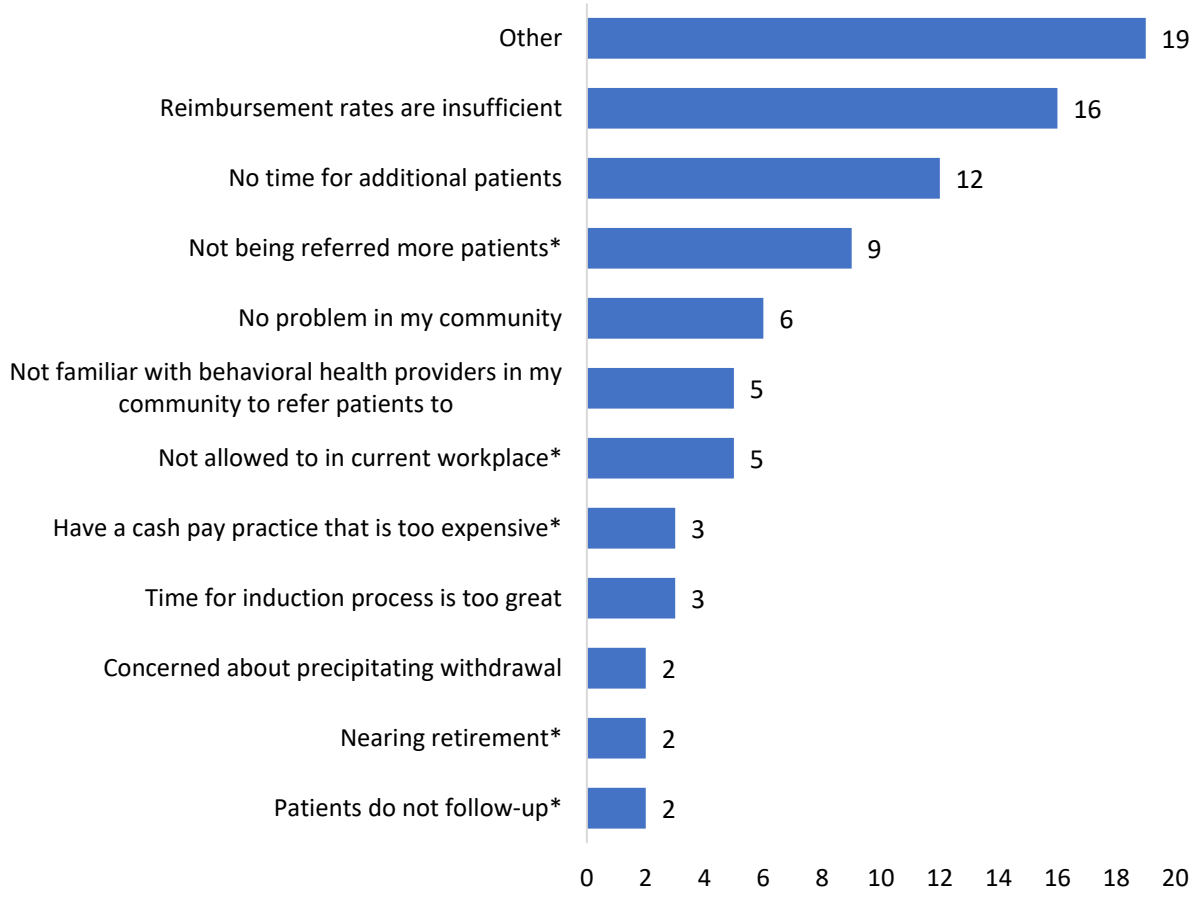
OBOTs prescribe in 10 counties: Carson City (5), Churchill (2), Clark (147), Elko (3), Humboldt (1), Lincoln (1), Lyon (1), Nye (1), Pershing (2), and Washoe (30). Of the OBOTs who responded to our electronic survey, none were prescribing at their capacity, although one had just increased their limit, so they were prescribing to their prior capacity. Three-quarters (75%) of respondents work in private practice. Nearly all (97%) of respondents said their practice/agency was accepting new clients. The number of patients the providers were certified to prescribe to ranged, with 47% *30 patient certified*, 30% *100 patient certified*, and 23% *275 patient certified*. While less than half (47%) of providers were certified to prescribe to only 30 patients, 74% of respondents were prescribing in this range. Almost one-third (30%) were allowed to prescribe buprenorphine to up to 100 patients, but only 18% of respondents actually were. Finally, while nearly one-quarter (23%) had increased their prescribing limit to 275 patients, 8% were utilizing this ability (see Figure 16).

Figure 16. Comparison of Provider Capacity and Actual Prescribing



Respondents were asked to select all of the reasons that they were not prescribing at their Buprenorphine capacity and given the opportunity to write in other reasons that were not listed. As shown in Figure 17, the most often cited reasons for not prescribing at capacity were *no time for reimbursement rates insufficient*, *additional patients*, and *not being referred more patients*.

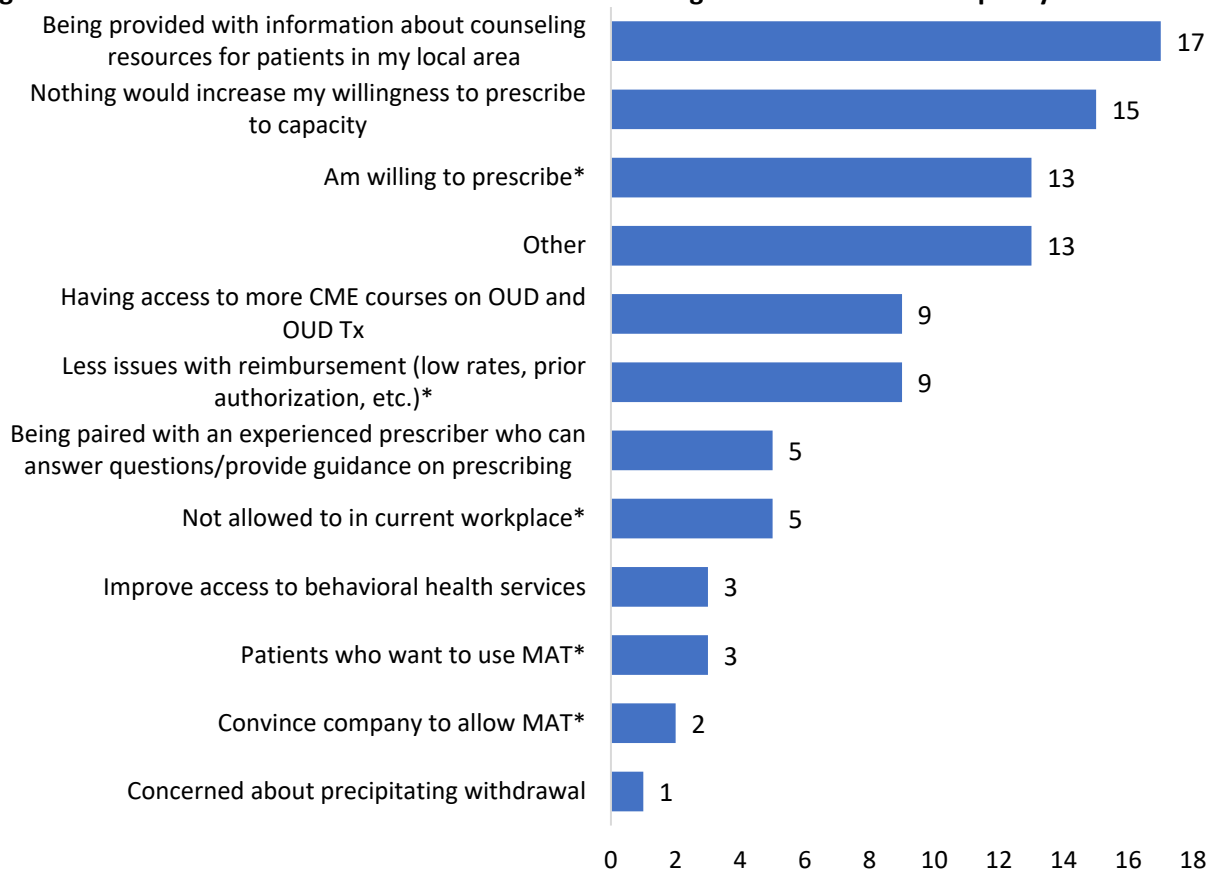
Figure 17. Reasons for Not Prescribing at Capacity



*represents aggregated responses written into Other
**Question was a select all that apply so the number of answers is more than the number of respondents

As a follow-up, participants were then asked what resources would increase their willingness to prescribe to capacity. The most common response was that the prescriber would like "*being provided with information about counseling resources for patients in my local area,"* followed by that "*nothing would increase my willingness to prescribe to capacity."*

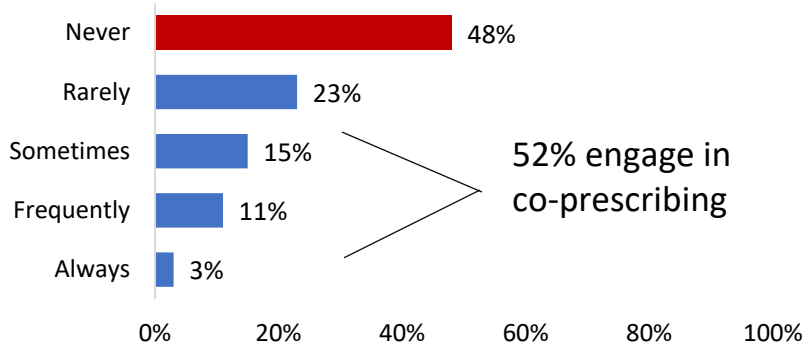
Figure 18. Resources that Would Increase Providers' Willingness to Prescribe at Capacity



*represents aggregated responses written into "Other"
**Question was a select all that apply so the number of answers is more than the number of respondents.

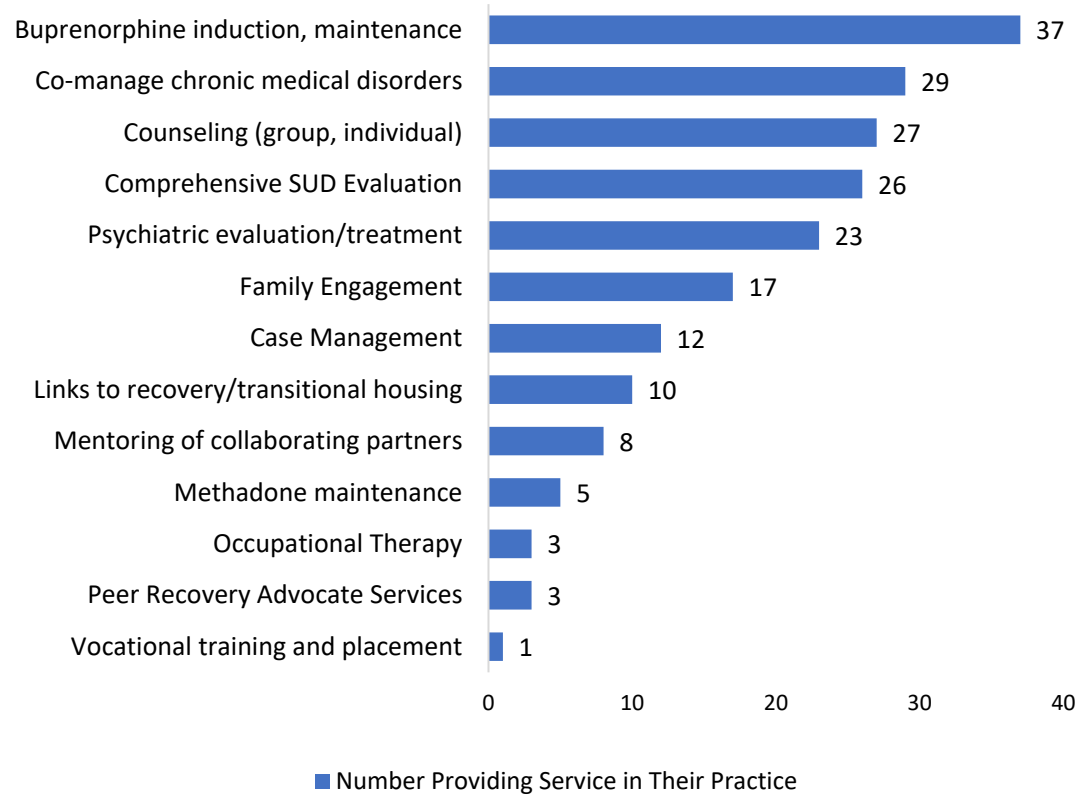
Over half (52%) of survey respondents indicated that they co-prescribed naloxone with opioid painkillers for high-risk patients, with 11% of those citing doing so "*frequently"* and 3% "*always*."

Figure 19. Frequency of Opioid Painkiller and Naloxone Co-prescribing



The majority of survey respondents (69%) were employed in a practice that offered psychosocial services or interventions and 48% provided psychosocial interventions through contract arrangements with qualified behavioral health providers. The most common service offered was buprenorphine induction and maintenance. Counseling and Substance Use Disorder Evaluation were also common responses.

Figure 20. Types of Psychosocial Services/Interventions Offered by Provider Practices



Socio-Political Environment

Policy/legislation passed in Nevada related to the opioid overdose crisis supportive of MAT is summarized below.

The Good Samaritan Drug Overdose Act of 2015 (SB 459) provides for immunity from prosecution for personal use and possession of controlled substances from individuals seeking medical attention for themselves or others during a drug overdose. Immunity does not extend to large quantities for sale or trafficking.

SB 459 requires that prescribing physicians obtain a patient utilization report on the Prescription Monitoring Program before the initiation of a schedule II, III, or IV prescription drug for a new patient, or for a course of treatment lasting longer than seven days that is part of a new course of treatment for an existing patient. SB 459 also requires the pharmacists to update the system within the next business day of filling a prescription. Participation in the PMP has increased from 16% to 98% since the legislation passed.

With the passage of SB 459, a physician can prescribe an opioid antagonist (i.e. naloxone) directly or by standing order to a person who is at risk of overdose or to a family member, friend, or other person in a position to assist a person who is at risk of experiencing an overdose. Additionally, SB 459 allows a pharmacist to dispense an opioid antagonist without a prescription. Finally, an unlicensed person may store and/or dispense an opioid antagonist under a standing order from a properly authorized prescriber, as long as the medication is dispensed without charge or compensation.

In 2016, Nevada Gov. Sandoval established a Drug Abuse Prevention Task Force led by First Lady Kathleen Sandoval. The governor convened and chaired a statewide drug summit in the summer of 2016. The summit assembled over 500 stakeholders, including legislators, healthcare professionals, law enforcement, judges, and individuals in recovery from a substance use disorder. Based on their recommendations, Gov. Sandoval announced in his 2017 State of the State Address that he was introducing the Controlled Substance Abuse Prevention Act, which will provide more training and reporting, and heightened protocols for healthcare professionals with prescribing controlled substances. Additionally, the Nevada Attorney General chairs a Substance Abuse Working Group consisting of nine members. The Working Group submitted recommendations for combating the opioid crisis to the Nevada Legislature. The Office of the Attorney General proposed SB 59, utilizing the recommendations of the Working Group. SB 59 requires reporting of controlled-substance violations, prescription drug-related overdoses or deaths, and stolen prescription drugs to the PMP. The bill went into effect on July 1, 2017.

The Controlled Substances Abuse Prevention Act (AB 474), which went into effect on Jan. 1, 2018, requires doctors and hospitals to report any drug overdoses to the state. Additionally, licensing boards can access PMP data to investigate inappropriate prescribing, dispensing, or use of a controlled substance. Prescribers will now need to perform a risk assessment before prescribing a controlled substance. For prescriptions over 30 days in length, a prescription medical agreement with the patient must be created. The prescriber must also complete a risk of abuse assessment and obtain a patient utilization report every 90 days for the duration of the prescription. Numerous trainings have been held and materials distributed to educate healthcare providers on AB 474.

Any physician or physician's assistant who is registered to prescribe controlled substances must complete at least two hours of training specifically addressing the prescribing of opioids or addiction every licensing period.

There is no dedicated state funding for MAT. All funding is allocated from the Block Grant. Dedicated state funding does not exist for naloxone either. The Commission on Behavioral Health has approved new criteria so programs will no longer be able to deny clients residential treatment who are stabilized on MAT. The new criteria went into effect April 1, 2018.

All opioid dependence and overdose reversal medications are covered by three managed care organizations (MCOs)—Amerigroup, Health Plan of Nevada, and Silver Summit Health Plan—but prior authorization and quantity limits differ. Table 10 displays prior authorization and quantity limits required by each plan.

Table 10. Health Care Plan Prior Authorization and Quantity Limits by Medication

Medication	Amerigroup		Health Plan of Nevada		Silver Summit Health Plan		Fee for Service	
	PA	Quantity Limits	PA	Quantity Limits	PA	Quantity Limits	PA	Quantity Limits
Overdose Medications								
Narcan (naloxone)		•				•		
Narcan Nasal Spray (naloxone)	•	•	•	•				
Evzio (naloxone)			•		•			
Opioid Dependence Medications								
Vivitrol (naltrexone)	•		•		•		•	•
ReVia (naltrexone)					•			
Suboxone (buprenorphine/ naloxone [bup/nal])	•	•	•	•	•	•	•	•
Zubsolv (bup/nal)	•	•	•	•	•	•	•	•
Bunavil (bup/nal)	•	•	•	•	•	•	•	•
Subutex (buprenorphine)		•	•	•	•	•	•	•
Detoxification/Withdrawal Medications								
Dolphine (methadone)	•	•			•	•		
Methadose (methadone)	•	•			•	•		

(Announcement 0921, 2017)

**Prior Authorization (PA)

Naloxone Prevention Initiatives

When this needs assessment was first conducted in July 2017, naloxone distribution was limited to pharmacies and a few hospitals. Naloxone is available without a prescription through standing orders at Walgreens and CVS Pharmacies and Smith's Food and Drug Stores. Naloxone is distributed at five (5) Nevada Rural Opioid Overdose Reversal Program (NROOR) funded hospitals in Lincoln, Lyon, Mineral, Nye, and White Pine counties to patients discharging from the hospital following an overdose.

Overdose education and naloxone distribution (OEND) expanded in 2018 through Opioid STR funding and activities. Overdose education includes training on how to recognize an overdose, the Good Samaritan law, and how to administer naloxone. Community-based organizations (CBO) can apply to serve as naloxone distribution sites. Eligible CBO types include:

- Needle exchange programs,
- SAPTA-certified or Medicaid eligible providers providing treatment services,
- Federally Qualified Health Centers (FQHC),
- Jails,
- Peer recovery communities,
- Health districts,

- Other STR funded treatment and recovery support entities.

**Exemptions to these criteria may be applied in rural and frontier high need areas or in cases of Public Health Emergency.*

To extend naloxone availability, upon request from partnering community coalitions, the Opioid STR grant will hold educational events to offer OEND to their constituents. A statewide tour of community coalitions began in June 2018, training and distributing naloxone 773 individuals.

Beginning in April 2017, Trac-B Exchange in Las Vegas opened the state's first permanent needle exchange, which also now delivers OEND free of charge. In Northern Nevada, Change Point Harm Reduction Center, provides OEND, along with syringe services and rapid HIV and hepatitis C testing. The three Integrated Opioid Treatment and Recovery Centers (IOTRC) are offering OEND to clients that are at risk of overdose, client family members, transitional living facilities, homeless shelters, community-based organizations, and weekly motels. IOTRCs have distributed 852 kids and reported 15 reversals through March – October 2018. Southern Nevada Health District is a SAMHSA First Responders – Comprehensive Addiction and Recovery Act grantee, delivering OEND services throughout Clark County. Southern Nevada Health District provided OEND to 2,798 individuals through March – October.

NROOR has trained 117 EMTs on overdose education and naloxone administration. Although not specifically education on naloxone, 46 healthcare providers, 37 mental health professionals, drug court professionals, and attendees of a community college library committee event received training on overdose education. Presentations on integrating naloxone and overdose prevention into clinical practice were given at the annual meeting of the Nevada Academy of Family Physicians and at the annual Orvis Nursing School healthcare symposium. The Nevada Rural Preparedness Summit provided a presentation on expanding naloxone access. The Carson City Law Enforcement Summit and the Las Vegas Opioid Crisis Summit included naloxone training. One coalition, covering the three rural counties of Humboldt, Pershing, and Lander counties, is training first responders on naloxone (Stein-Seroussi, Grabarek, & Hanley, 2016).

Prevention Efforts

A description of Nevada's current prevention efforts, which are primarily completed SAMHSA Strategic Prevention Framework – Partnership for Success-funded community coalitions, are summarized below.

Social marketing/media campaigns are a strategy being implemented by 11 community coalitions, including nearly 10,000 paid ads and 14,000 public service announcements (Stein-Seroussi et al., 2016). Coalitions had a media presence with the release of 'Women of Childbearing Years,' an opioid prevention TV ad; and students from Pershing County High School produced prescription drug abuse ads. An associated website was also created (www.healthiernv.org) to provide information to prescribers, families and policymakers.

Eight (8) community coalitions coordinate semi-annual Take Back events and utilize drop boxes in law enforcement facilities in between Take Back events (Stein-Seroussi et al., 2016). Funded by the Federal Office of Rural Health Policy, NROOR is providing naloxone to EMTs and paramedics and training them on its use in seven counties: Esmeralda, Eureka, Lincoln, Lyon, Mineral, Nye and White Pine.

Eleven coalitions have reported coordinating continuing education opportunities for physicians (Stein-Seroussi, Grabarek, & Hanley, 2016). Additionally, presentations to educate parents, youth, seniors, real estate agents, and veterans are conducted statewide to help them understand issues.

Over the past year, four new websites have been created. Three Nevada websites target educating the public and providers on the opioids. Prescribe365, run by the State of Nevada Division of Public and Behavioral Health is a hub of information for patients and providers. Healthcare provider information includes educational materials surrounding AB 474 and naloxone co-prescribing. Consumer materials for patients, friends and family contain information on how to use naloxone and links to treatment locators. Know your Pain Meds is operated by the Nevada State Board of Examiners, Nevada State Board of Pharmacy, and Nevada State Board of Nursing. The website contains information on the PMP, naloxone, alternatives to opioids for managing pain, and filing a concern about a medical provider. The Nevada STR website has information on funding opportunities, training opportunities, naloxone education and SBIRT materials, and STR publications. The fourth website is designed to make local data available to the public. The Nevada Opioid Overdose Surveillance Dashboard contains death rates, opioid-related emergency department visits and inpatient admissions, and opioid prescriptions at the county- and zip-code level.

Recovery Support Initiatives

At this time, Nevada has one peer-run recovery community organization, Foundations for Recovery, which is in Las Vegas. Foundations for Recovery offers a peer-recovery community center; peer recovery coaching; mutual aid support groups; life skills classes; high school equivalency (HSE) tutoring and testing; parenting classes; mental health first aid; suicide prevention trainings; houses the Southern Nevada NAMI affiliate and hosts the annual Rally for Recovery. All services are available to the public, including women with children, and pregnant women. Foundations for Recovery staff was trained in Medication Assisted Recovery Services (MARS), which is a peer-initiated and peer-based recovery support project sponsored by the National Alliance of Medication-Assisted (NAMA) Recovery.

The state of Nevada, through the Nevada Behavioral Health Association, offers a voluntary certification process for peer-support specialists. In-person and online training opportunities are available for individuals seeking peer-support specialist training.

In 2015, Nevada was one of 24 states to be awarded a Certified Community Behavioral Health Clinic (CCBHC) demonstration grant through SAMSHA, under the Excellence in Mental Health Act. In 2016, the state became one of eight selected to carry out the formal implementation of CCBHCs. Phase 1 of the project offered states one-year planning grants to develop their CCBHC program and Phase 2 enabled the selected states to move forward with the development of CCBHCs. Nevada has two CCBHCs located throughout the state (currently in rural areas) that provide a comprehensive range of mental health and substance use disorder services, particularly to vulnerable individuals with complex needs. 7 more agencies have been selected to build CCBHC services moving forward to further address coverage across the state. Peer support and family support services are included in the array of services CCBHCs are required to offer and provide.

No efforts targeting clients related to re-integration following incarceration existed when this needs assessment was completed in July 2017. Opioid STR funds are now beginning to be used to address this. Case managers have been placed strategically for screening and referral of pre-arrest individuals, warm handoff from detention centers to treatment facilities, and in post-release care following prison. Assessment of how these positions are reducing recidivism and impacting other outcomes is occurring and conversations of where other sustainable programming can be implemented is occurring.

Other Opioid Funding Sources

All other funding to address the opioid crisis is described in Table 11.

Table 11. Nevada Funding to Address the Opioid Crisis

Funding Stream	*Strategies/Activities*	*Funding Period*
CDC Prevention for States (PFS)	• Expand and improve proactive reporting • Conduct public health surveillance with PMP data and disseminate quarterly reports • Identify and provide technical assistance to high-burden communities and counties to address problematic prescribing • Create an opioid data dashboard • Link deaths, hospitalizations, and prescriptions of individuals • Create mapping of funded activities to find gaps • Administer CDC's statewide media campaign • Link health data sets and law enforcement data sets	8/16-7/19
CDC Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality (ESOOS)	• Increase timeliness of aggregate nonfatal opioid overdose reporting • Increase the timeliness of fatal opioid overdose and associated risk factor reporting • Disseminate surveillance findings to key stakeholders working to prevent or respond to opioid overdoses	9/17-8/19
CDC Opioid Overdose Crisis	• PDMP and HealthHIE Nevada Integration • Development of a BadBatch notification system • Implementation of OpenBeds	9/18-8/19
SAMHSA Strategic Framework Partnership for Success (PFS)	• Reduce the nonmedical use of prescription drugs among persons 12 and older and the consequences that result from such use, with a focus on persons ages 12-25 • Implement a comprehensive prevention strategy through community education, social marketing/media, physician training, and drop boxes/Take Back events through 13 funded coalitions	9/13-9/18
SAPG Block Grant: Funding Opportunity 003	• Target efforts to encourage the use of Prescription Drug Monitoring System by prescribers • Provide education on the use of naloxone and education on the Good Samaritan Law	4/17-9/19
Nevada Rural Opioid Overdose Reversal Program (NROOR)	• Provide naloxone administration training to EMS personnel • Provide initial stock of naloxone to EMS services that did not have it in their formulary • Provide patient education, substance abuse treatment referrals, and intranasal naloxone to opioid overdose patients upon discharge	9/15-8/17
FQHC Incubator Project	• Implement system design models that will most rapidly address the gaps in their systems of care • Deliver evidence-based treatment interventions including medication and psychosocial interventions • Report progress toward increasing availability of treatment for OUD and reducing opioid-related overdose deaths based upon measures developed in collaboration with the Department of Health and Human Services	Upon Receipt – 4/18

	• Improve retention in care, using a chronic care model	
Harold Rogers Prescription Drug Monitoring Program Grant (Reno Police Department)	• Analyze PDMP data in order to identify high-risk populations, geographic hotspots, and the relationship between heroin arrests and opioid prescriptions	10/15-9/18
Attorney General Volkswagen Settlement Money	• Design and implement a program that promotes awareness and understanding of the dangers and consequences of prescription drug misuse • Connect those at risk of developing prescription drug dependency or abuse to preventive services • Provide education on the dangers of prescription misuse, neonatal exposure, youth accidental overdose • Provide resources for chronic pain management and preventive service programs to avert prescription drug misuse and dependency • Provide the locations of where unused prescription drugs can be taken for disposal and destruction • Promote awareness of proper storage of prescription drugs • Distribute naloxone to law enforcement	10/17-6/19
First Responders – Comprehensive Addiction and Recovery Act Cooperative Agreement (Southern Nevada Health District)	• Train individuals on using naloxone in a suspected overdose • Establish referral protocols • Join advisory council • Educate on Good Samaritan Law	10/17-10/21

Gaps in Services and Policies

Only three of Nevada's 17 counties are considered urban (Clark, Washoe, and Carson City), accounting for 91% of the state's population. The remaining counties are considered rural or frontier (meaning less than 1 person per 7 square miles). The average distance between acute care hospitals in rural Nevada and the next level of care or tertiary care hospital is 114.7 miles and the average distance to the nearest incorporated town is 46.5 miles (Griswold et al., 2017).

Nevada's rurality presents issues with access to care in all types of medical and behavioral health. MAT services are limited in rural areas, with OTPs only existing in the three urban counties. Access to OBOTs is better, with access in 10 counties: Washoe, Clark, Carson, Churchill, Elko, Humboldt, Lyon, Lincoln, Pershing, and Nye. There is still a gap in MAT when considering Mineral and Storey counties lack access to an OBOT and are counties with some of the highest percentages of individuals in treatment for opiates.

There is a gap in the availability of naloxone among individuals who are legally prescribed painkillers by their doctor, with the co-prescribing of naloxone and opioids currently being underutilized by healthcare providers. With naloxone distribution following hospitalization for an overdose only available at five rural hospitals in Mineral, Nye, Lyon, and Lincoln counties, patients in the remaining counties are still at greater risk of overdose leaving the hospital. IOTRC Mobile Recovery Outreach Team services have

begun in emergency rooms, reducing this gap in some hospitals and efforts are underway to expand to more hospitals. Some towns do not have any of the three pharmacies with standing orders for naloxone and naloxone distribution events thus far have been held on only one occasion in many rural towns.

Recovery supports are limited in many regions to 12-step meetings and in some frontier communities such meetings are rare or non-existent.

With coordinated care management, not currently reimbursable by Medicaid, the connections between varying levels of care and necessary supports is lacking.

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Appendix A

Definitions

Office-based Opioid Treatment (OBOT) *ASAM*

Physicians and soon Physician Assistants and Nurse Practitioners in private practices or a number of types of public or private sector clinics can be authorized through a waiver to prescribe the partial opioid agonist buprenorphine or buprenorphine/naloxone (though OTPs can administer or dispense buprenorphine products as well through the waiver). There is no regulation per se of the clinic sites where buprenorphine-prescribers practice. It is the practice of the individual prescriber, which is regulated by FDA addressing office-based treatment.

Opioid Treatment Program (OTP) *ASAM*

Opioid treatment programs using methadone and/or buprenorphine are presented in The ASAM Criteria as a Level 1 outpatient service because opioid agonist medications are most commonly used for opioid use disorders and an outpatient setting is the context in which it is most commonly offered.

Previous terms for OTP are methadone maintenance treatment (MMT) or opioid maintenance therapy (OMT) as was used in the ASAM PPC-2R.

Opioid Treatment Services (OTS) *ASAM*
An umbrella term that encompasses a variety of pharmacological and non-pharmacological treatment modalities. This term broadens understanding of opioid treatments to include all medications used to treat opioid use disorders and the psychosocial services that are offered concurrently with these pharmacotherapies. Pharmacological agents include opioid agonist medications such as methadone and buprenorphine, and opioid antagonist medications such as naltrexone.

Medication Assisted Treatment (MAT) *SAMHSA*
The use of medications with counseling and behavioral therapies to treat substance use disorders and prevent opioid overdose.

Agonist
An opioid/drug that acts like another substance and activates certain receptors in the brain. It is the opposite of an antagonist medication. An example of an agonist medication is methadone.

Partial Opioid Agonist
An opioid that produces less effect than a full agonist when it binds to opioid receptors in the brain. An example of a partial agonist is buprenorphine (Subutex) and buprenorphine/naloxone (Suboxone).

Antagonist
A non-opioid that acts against and blocks an action. It binds to opioid receptors in the brain preventing the usual feelings of the opioid. It is the opposite of an agonist medication. An example of an antagonist is naltrexone and naloxone.

Point-of-contact:
Stephanie Woodard, PsyD
DHHS Senior Advisor on Behavioral Health
Opioid State Targeted Response Project Director
opioidstrgrant@health.nv.gov

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EXHIBIT I

EXHIBIT I

reno gazette journal

NEWS

Over-prescribing doctors can escape scrutiny in Nevada

Anjeanette Damon and Jason Hidalgo, Reno Gazette-Journal

Updated May 14, 2016, 6:42 p.m. PT

Nevada has a pill problem.

From the number of people dying from prescription pain pill overdoses to the sheer amount of narcotics that doctors prescribe, Nevada tops national lists.

At the same time, Nevada lawmakers — pushed by a strong lobby of doctors — have resisted instituting programs used in other states that could flag practitioners who may need intervention for their prescribing practices.

That regulatory gap is exacerbated by professional licensing boards that say it's not within their purview to initiate investigations against members outside of the formal complaint process.

But the arrest this month of a Reno family practice physician charged with illegally distributing controlled substances brought into sharp focus the community-wide turmoil created by a doctor who grew a practice on prescribing habits a federal prosecutor has described as criminal.

Among other charges, Dr. Robert Rand is accused of illegally distributing a controlled substance that resulted in the death of 33-year-old Michael Yenick.

"This case has definitely highlighted that a focus should be on the providers," Reno police Deputy Chief Tom Robinson said last week. "The users, they're often just a symptom of the problem."

As with many states, Nevada has a robust prescription drug monitoring program, a database of every prescription for a controlled substance filled in the state, including the dosage, the number of pills and both the patient's and prescriber's identification.

Unlike many states, however, Nevada relies on the program primarily to red flag the patients who may be "doctor shopping" or filling enough prescriptions to identify them as a potential pill abuser. The database, it is hoped, can be used to get those addicted to pills the treatment they need, regulators said.

Similar criteria that could red flag a doctor's prescribing practices, however, haven't been developed and are actively opposed by professional licensing boards such as the Board of Medical Examiners.

"It would be inappropriate, and it's not the intent of the (prescription monitoring program), to find cases to investigate," said Edward Cousineau, executive director of the Board of Medical Examiners, which licenses medical doctors and investigates malpractice complaints in the state.

In fact, Las Vegas police had to request special legislation last session to give local law enforcement investigators explicit access to the database after the pharmacy board stopped allowing them access, according to testimony at the Legislature.

The community is just starting to learn of the ripple effect created by Rand's arrest as part of a months-long investigation into a pill mill that federal investigators believe was operating out of the Jones West Ford car dealership.

Rand was one of nine people arrested, including the dealership's manager Richard "Richie" West II and seven of his present and past co-workers. West, and many of his co-defendants, were Rand patients, according to Assistant U.S. Attorney James Keller.

Yenick, who died in October from alcohol and oxycodone intoxication, also was Rand's patient.

All are pleading not guilty to the charges.

In West's detention hearing, Keller argued Rand ran a special "family and friends" program that allowed his patients to escape routine examinations and access prescriptions for a high number of pills. Keller said Rand prescribed West as many as 800 pills in one day.

Federal agents confiscated a list of names enrolled in that program during a search of the doctor's office, Keller said.

Even before the bust, Drug Enforcement Administration and FBI agents worried the fallout would have a significant effect on the medical community, the substance abuse treatment community and the patients who would no longer have access to Rand's prescriptions. Agents began to put together a task force of various agencies to address the fallout days before the bust.

On Thursday, scores of doctors, emergency medical responders, public health workers, addiction counselors, social workers and law enforcement met for the first time to discuss what was described as an opioid addiction crisis in Nevada.

The discussion, however, quickly turned to Rand.

Dr. Annemarie Campione said her family practice has taken on many of Rand's patients. Rand remains incarcerated pending a detention hearing to decide whether he should be released on his own recognizance to face the charges.

Campione said many of his patients use no pain medication and saw him for unrelated health issues. Some of those who sought pain treatment from him, however, came to Campione's practice severely dependent, unable to get new prescriptions and in a state of detoxification, she said.

"They are on boatloads of drugs," Campione said. "I can't believe they're still even breathing."

In a raw display of candor, Campione said the number of people was so overwhelming she wished the city could "set up a tent" to address their needs quickly.

The Crisis Call Center has also fielded calls from patients who can't find a new doctor, are in need of pain medication or who are having non-pain medication prescriptions being rejected by pharmacists.

Statistics show that Nevada ranks in the top five states when it comes to prescribing certain pain pills.

Overall, Nevada doctors wrote 94 prescriptions per 100 people in 2012, the latest data available.

"That scared the hell out of me," said Mike Willden, Gov. Brian Sandoval's chief of staff. "That means every man, woman and child in Nevada had access to a prescription."

Stephanie Woodard, a clinical psychologist with the Nevada Division of Public and Behavioral Health, said 94 prescriptions per 100 people puts Nevada just above average with other states overall.

But a Reno Gazette-Journal analysis of DEA data showed that for certain drugs, Nevada ranks among the highest in the country.

Take oxycodone, Nevada's most widely prescribed opioid. In 2012, nearly 1.04 million grams was distributed via retail in the state. That's more than double what doctors prescribed in 2006. Nevada's distribution rate is third highest in the country.

Nevada also ranks third for its hydrocodone distribution rate. In 2012, doctors prescribed more than 799,000 grams of hydrocodone -- nearly three times the rate of New Jersey, which has triple Nevada's population.

Woodard said the reasons for the high prescription rates aren't totally clear, but could be attributed to the fact that in 1999, medical professionals listed pain as the fifth vital sign to assess for a patient's well-being. Some doctors are advocating for that practice to stop.

While a high distribution rate isn't necessarily an indication that doctors are acting criminally, some states are using their prescription drug monitoring programs as both an investigatory tool to flag bad actors and educate doctors about their prescribing habits.

That's not necessarily happening in Nevada.

Federal agents involved in the investigation into Rand won't comment on the case, saying the investigation is continuing and more indictments may be coming.

But a Reno police source said it wasn't the prescription monitoring program that initially flagged Rand as a suspect. That happened after evidence was uncovered of illicit drug use and the investigation intensified in the wake of Yenick's death. The monitoring program, which is used when investigating complaints or criminal activity, then showed the extent of Rand's prescribing habits.

Rand's indictment alleges the doctor began illegally distributing controlled substances in 2012.

Robinson admitted that most of his department's investigations are targeted on the users and the peddlers of pain pills, not the prescribers. He said there could be a stronger role for licensing boards to play, but added they typically don't have the resources to mine data for problem prescribers.

The Board of Medical Examiners won't comment on complaints against its doctors until the complaint been through an investigation and results in a formal complaint filing. No public documents on complaints against Rand exist.

According to a Reno Gazette-Journal review of publicly available complaint documents, the Board of Medical Examiners has launched about 20 formal investigations into doctors accused of some sort of prescription irregularity involving pain medication since 2013.

Fifteen resulted in some disciplinary action, including a public reprimand, probation or license suspension.

Attacking Nevada's prescription drug program was one of Sandoval's top five priorities in last year's legislative session, Willden said.

He introduced an omnibus bill that included legal protections for those who seek help for someone who has overdosed and allows for expanded distribution of naloxone, which can reverse the effects of an opioid and stop an overdose from killing, to first responders and friends and family members of addicts. The local task force is now conducting public outreach on the Good Samaritan Law that can protect those who seek medical help for an overdose victim.

But when it came to implementing more reporting and education requirements on doctors, Sandoval had a fight on his hands.

The bill initially required that doctors receive two hours of continuing education on opioid addiction every year. The bill that passed allows licensing boards to recommend doctors take one hour of training a year.

The legislation also included a new requirement that doctors check the prescription drug monitoring database before prescribing a narcotic to a new patient in certain cases, a

measure that was also resisted by doctors but ultimately passed.

Another requirement: the prescription drug monitoring program now must send copies of the reports generated on a potential doctor-shopping patient to the prescriber's licensing board.

According to the minutes of the legislative hearings on the bill, the medical community fought against the additional requirements for doctors. In the bill's first hearing before the Assembly Healthcare Committee, only doctors testified against it.

They cited concerns that doctors would be afraid to make legitimate use of pain pill prescriptions for patients they've known and cared for. And they said doctors shouldn't have to worry about Big Brother looking over their shoulders.

"It makes me pause every time I start to write a script for any controlled substance; I should not have to feel like that," Dr. Ivan Goldsmith of Las Vegas told lawmakers during the hearing. "At the end of the day, the doctor and the patient have the relationship, not the government in the middle. Doctors should be the ones who decide what is best for their patients. This bill has a chilling effect on that."

What resulted was a compromise on how the prescription drug monitoring program should be used to flag problem prescribers.

Willden said the state needs to strike a balance in over-regulating doctors to the point they don't want to practice here. Nevada suffers from a severe doctor shortage in many disciplines as it is.

"We don't want to look like a state that's holding a 10-pound hammer and have doctors thinking we're looking over their shoulder every second," Willden said.

He said the new law should be given time to work before asking for stricter legislation.

The Pharmacy Board, which runs the prescription drug monitoring program, is responsible for sending reports on potential pill abusers to the boards that license prescribers such as doctors, nurses and dentists. But it's up to the different licensing boards to decide how to use those reports.

According to interviews, each board treats the reports differently.

First, the pharmacy board doesn't believe it has a role in flagging prescribers that show a troubling pattern.

The board sets criteria for flagging a patient, such as how many different doctors a patient is getting prescriptions from, and how many prescriptions they are filling in a certain time period.

But executive director Larry Pinson said it would be inappropriate for the board to set similar criteria to flag a doctor.

"Who's to say what's normal or what's OK," Pinson said. "It might be appropriate for a physician to be prescribing a ton of narcotics according to his specialty."

Pinson said that's not meant to minimize the problem with opioid addiction or the program's role in combating it.

"The governor's office has a real legitimate concern," he said. "There are people who are just simply dying because they are taking too many narcotics. They are dying and we need to do something about that.

"The goal is not to get people arrested and put in jail, but get them the treatment they need and get them fixed."

So, the reports on individual patients go to the various licensing boards. Then what?

The Board of Medical Examiners, which licenses the bulk of the state's doctors, said they use the reports to remind doctors to check that their patients aren't suffering from an addiction. It would be inappropriate to use them to initiate an investigation, Cousineau said.

"I've talked to many doctors over the years and they've implored me, they don't want constraints, whether through statute or regulation, that limits their subjective ability to treat patients," Cousineau said. "Ninety-nine percent of doctors are doing the right thing."

The Nursing Board goes a little further, asking their practitioner to send a letter back to the board describing why the opioids being prescribed to a patient who has been red flagged is appropriate, said executive director Cathy Dinauer.

Barbara Longo, executive director of the Board of Osteopathic Medicine, said they have been monitoring the reports from the pharmacy board and so far haven't seen any of their licensees prescribing large amounts repeatedly to red-flagged patients.

Longo said the board uses the database to investigate a complaint received on a doctor, but doesn't use it to initiate investigations.

"We don't just randomly run our providers, no way," she said. "But if we have a complaint that alleges that is happening, that is part of the investigation to (run the provider through the database.)"

While Nevada has resisted using the database to find problem prescribers, other states have found success in reducing distribution and overdose rates by making broader use of the prescription drug monitoring program.

A 2014 study by the Prescription Drug Monitoring Program Center of Excellence at Brandeis University found the programs "are uniquely positioned to help identify prescribers at risk of over-prescribing or prescribing inappropriately."

The data can be used to find prescribers who deviate from accepted medical practices and allow licensing boards to intervene, the study found. Intervention can include better education or a more formal investigation process.

Other states have deployed the program in a variety of ways to do just that.

In Arizona, the pharmacy board created prescriber report cards that identify doctors prescribing at a statistically higher rate than their peers. The practice has raised awareness among prescribers, and the state has seen a reduction in the amount of pain medication prescribed in some counties.

Other states, such as Tennessee, Texas and Kentucky, report abnormal prescribing data to licensing boards and law enforcement. Still others conduct outreach to physicians with a high number of doctor-shoppers at their practice.

"Identifying and intervening where appropriate with at-risk prescribers is a key strategy in efforts to control prescription drug misuse and diversion," the report said. "The CDC has recently recommended focusing efforts on prescribers not following accepted medical practice."

A local law enforcement officer also suggested the state could better track drug overdose deaths, looking up the deceased's prescription history in the database to see if any related doctors have troubling prescription practices.

EXHIBIT J

EXHIBIT J

Prescription Drug Monitoring Program

The Florida Prescription Drug Monitoring Program, known as E-FORCSE® (Electronic-Florida Online Reporting of Controlled Substance Evaluation Program), was created by the 2009 Florida Legislature in an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the state of Florida. Controlled substance dispensing information is submitted to the database by dispensers and made available for consultation by prescribers.

Important Information for Data Submitters (Pharmacies and Dispensing Health Care Practitioners)

Dispensers of controlled substances are required to report to the PDMP each time a controlled substance in schedules II, III, IV, and V are dispensed to a patient, as soon thereafter as possible but no later than close of business the day after the prescription is dispensed.

Important Information for Data Requestors (Prescribers and Pharmacists)

Each prescriber and dispenser or his or her designee has a duty to consult the PDMP system to review a patient's controlled substance dispensing history each time a controlled substance is prescribed or dispensed to a patient age 16 or older unless a statutory exemption applies.

Statutory exemptions include:

- If the patient is less than 16 years of age
- Drug being prescribed is a nonopioid schedule V
- System is not operational
- Requestor has technological or electrical failure

Failure to consult in the PDMP may result in a non-disciplinary citation by the regulatory board.

You may register for the PDMP at https://florida.pmpaware.net

For more information, go to www.e-forcse.com

Frequently Asked Questions

I am a prescriber with a Drug Enforcement Administration (DEA) registration, however I do not prescribe controlled substances. Am I required to register for E-FORCSE?

If you do not prescribe any controlled substances you are not required to register with or consult E-FORCSE.

You are still authorized to register. You can view your patient's-controlled substance dispensing histories.

How do I register with the PDMP?

Prescribers, dispensers and their designees may register for access at https://florida.pmpaware.net.

Is there penalty for failing to consult the PDMP?

Yes.

What is the penalty for the initial offense?

The DOH will issue a non-disciplinary citation for the initial offense.

What is the penalty for any subsequent offense?

Any subsequent offense will result in disciplinary action against the prescribing/dispensing practitioner's license. Disciplinary guidelines are individually established by the appropriate licensing board.

Does the PDMP purge information from its database?

Yes. Information that is more than 4 years old.

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Data Requesters

Prescriber Consultation

When must a prescriber or his or her designee consult the PDMP?

A prescriber or his or her designee must consult the PDMP to review their patient's controlled substance dispensing history prior to prescribing a controlled substance in Schedules II-V, as defined in section 893.03, F.S., for patients age 16 and older.

When is a prescriber not required to consult the PDMP?

- If the PDMP system is not operational as determined by DOH, or
- The PDMP cannot be accessed by the prescriber practitioner due to a temporary technological or electrical failure or
- When prescribing a nonopioid Schedule V drug or
- The patient is less than 16 years of age

What must the prescriber do if they are unable to consult the PDMP due to operational, (determined by the PDMP program), or temporary technology/electrical failure?

The prescriber must document in the patient's record the reason the PDMP was not consulted and may prescribe no more than a 3-day supply of a controlled substance.

If a prescription has refills, must the prescriber consult the PDMP before each refill?

The prescriber is not required to consult the PDMP before each refill, however, the prescriber must consult the PDMP prior to writing a new prescription for a controlled substance listed in Schedule II through V. A prescription for a controlled substance listed in Schedule II may not be refilled.

How far in advance can I consult the PDMP? (i.e. 1 day? 1 week?)

The statute does not provide any guidance on how far in advance the PDMP may be consulted. Please refer to your Board's website for further guidance.

Do I have to consult the PDMP each time I write a prescription, or only at the initial appointment?

The PDMP must be consulted each time a prescription for a controlled substance is written.

Dispenser Consultation

Does a dispenser always have to consult the PDMP?

A dispenser or a designee of a dispenser must consult the PDMP to review a patient's-controlled substance dispensing history prior to dispensing a controlled substance in schedules II-V, as defined in section 893.03, F.S., for patients age 16 or older for each new and refill prescription.

When may a dispenser not consult the PDMP?

A dispenser or a designee of a dispenser does not have to consult the PDMP when dispensing a nonopioid controlled substance listed in Schedule V of s. 893.03, F.S. or 21 U.S.C. 812.

The duty to consult the system does not apply when the system:

- Is determined by the department to be nonoperational; or
- Cannot be accessed by the dispenser or a designee of the dispenser because of a temporary technological or electrical failure

What should a dispenser do if he or she cannot consult the system?

A dispenser or designee of a dispenser who does not consult the PDMP shall document the reason he or she did not consult the system in the patient's medical record or prescription record and shall not dispense greater than a 3-day supply of a controlled substance to the patient.

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Is a dispenser required to consult the PDMP on refills for schedules III, IV, and V controlled substances?

A dispenser must consult the PDMP on the new prescription and on each subsequent refill.

Data Submitters

What is a dispenser?

A dispenser is a dispensing health care practitioner, pharmacy, or pharmacist licensed to dispense controlled substances to the ultimate consumer or his or her agent in or into this state.

What is a dispensing practitioner?

A dispensing practitioner is a practitioner authorized by law to prescribe drugs who may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with s. 465.0276, F.S. Dispensing practitioners may include: physicians, dentists, certified optometrists, podiatrists, advanced registered nurse practitioners and physician assistants.

Is a dispenser required to report controlled substances dispensed to a patient?

Dispensers are required to report to the PDMP each time a controlled substance is dispensed to a patient, as soon thereafter as possible, but no later than close of business the day after the prescription is dispensed unless an extension or exemption is approved by the Department of Health.

Which controlled substances must be reported to the PDMP?

All controlled substances in schedules II through V must be reported to the system by the close of the next business day. If the dispenser does not dispense any controlled substances for that day, then a zero report must be submitted.

Are there exemptions to reporting to the PDMP?

Yes, there are two exemptions from reporting:

- Controlled substances administered to patients;
- Controlled substances dispensed in the health care system of the Department of Corrections; and
- Controlled substances dispensed to patients under the age of 16 are exempt from reporting to E-FORCSE.

What new reporting requirements must the dispenser submit to the PDMP?

- The telephone number of the person for whom the prescription was written, in addition to the name, address, and date of birth the prescriber currently inputs;
- Whether the prescription is an initial prescription or a refill, and the number of refills prescribed;
- The name of the individual picking up the controlled substance prescription and the type and issuer of the identification provided; and
- The pharmacy's DOH-issued permit number or the dispensing practitioner's DOH-issued license number

When will dispensers be required to submit controlled substance data using the new ASAP 2009 version 4.2a format?

The Department has published a notice of rule development and will be amending Rule 64K-1.002, FAC . The PDMP will continue to accept submissions in the ASAP 2009 version 4.2 and the new 4.2a standard for one year from the effective date of the rule.

What are the new fields that are required to be reported in ASAP 2009 version 4.2a?

- The pharmacy permit number or the dispensing health care practitioner's license number.
- The name of the individual picking up the controlled substance prescription and type and issuer of the identification provided.

What will happen if a dispenser fails to report the dispensing of a controlled substance?

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A person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this law commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, F.S. Further, the department shall issue a non-disciplinary citation to any prescriber or dispenser who fails to consult the system as required by this subsection for an initial offense. Each subsequent offense is subject to disciplinary action pursuant to s. 456.073, F.S.

No comments to show.

Archives

- November 2021

Categories

- Uncategorized

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EXHIBIT K

EXHIBIT K

Cureus

Open Access
Editorial

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Nevada’s Healthcare Crisis: A Severe Shortage of Physicians and Residency Positions

Kenny Do [1], Jenifer Do [2], Eric Kawana [1], Ren Zhang [3]

1. Kirk Kerkorian School of Medicine at UNLV (University of Nevada, Las Vegas), University of Nevada, Las Vegas, Las Vegas, USA 2. School of Life Sciences, University of Nevada, Las Vegas, Las Vegas, USA 3. Colorectal Surgery, Nevada Surgery and Cancer Care, Las Vegas, USA

Corresponding author: Kenny Do, dok3@unlv.nevada.edu

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Abstract

The state of Nevada is home to millions of people and a prominent entertainment industry. However, the state ranks among the lowest in terms of available primary care doctors and general surgeons per capita, resulting in limited access to essential healthcare services and an increased reliance on emergency departments and hospitals. Nevada also faces the challenges posed by an aging physician workforce and a significant proportion of inactive providers. The scarcity of residency positions in Nevada's medical schools drives many graduates to seek residency training opportunities elsewhere, leading to a reduced likelihood of their return to practice within the state. We propose potential solutions, including increased funding for residency positions, prioritizing the retention of medical school graduates through local residency training, and the establishment of interdisciplinary comprehensive academic health centers. These measures are essential to meet the escalating healthcare demands of Nevada's rapidly growing population and to ultimately enhance patient outcomes.

Categories: Preventive Medicine, Public Health, Health Policy
Keywords: specialty treatment, prevention in primary care, medical residency, physician shortage, global healthcare systems

Editorial

With a population of over 3 million people and with one of the biggest entertainment capitals in the world, Las Vegas, the state of Nevada still faces a healthcare crisis [1]. Out of the 50 states in America, Nevada is currently ranked forty-eighth for the number of primary care doctors available for 100,000 Nevadans and ranked forty-ninth for the number of general surgeons available for 100,000 Nevadans [2]. The state needs an additional 2,561 physicians in its healthcare workforce just to meet the country’s standards. Recent reports have suggested that the state needs 540 additional surgeons, 1,038 physicians in medical specialties, and many more physicians from other fields [3].

Current research has shown that there is a higher probability of a healthy community when there are more primary care physicians available for the general population. Concurrently, an increase in the number of primary care physicians has also been shown to lower the frequency of patients presenting to the emergency department or hospital [4]. One study assessed the association between the severity of cardiovascular disease and access to primary care. It concluded that the readmission rate for cardiovascular patients was 33.3% for those who had challenges receiving preventative care, which is significantly higher than the 17.9% readmission rate for patients who had access to primary care [5]. For patients in Nevada, many may wait up to or even longer than one month just to see their primary care physicians. For specialty care, the wait time may even be more extended, and this is assuming that the specialty exists in the state.

The state also has a problem with an aging physician workforce and a high number of inactive providers. Close to 17% of the licensed doctors in Nevada are inactive, and these are providers who are retired or are not currently practicing medicine [3]. The growing age of the providers in Nevada poses another problem to the physician shortage in the state. In some of Nevada’s counties, the average age of allopathic doctors is 61.2 and the average age of osteopathic doctors is 57.7. These numbers are higher than the national averages of 52.9 for allopathic and 49.7 for osteopathic physicians, respectively [3].

One of the reasons for the shortage of medical specialties and care in the state is the lack of residency spots in its academic health systems. Currently, there are two allopathic and one osteopathic medical school in Nevada. The Kirk Kerkorian School of Medicine at UNLV (University of Nevada, Las Vegas) has a class size of 66, the University of Nevada Reno (UNR) School of Medicine has a class size of 70, and Touro University has a class size of 180. Ideally, these three schools should generate more than 300 physicians each year. However, this is not the case because of the limited residency spots in Nevada. This means that eventually, most of these graduates end up leaving the state and completing residency elsewhere [6]. To make matters worse, studies have shown that the number of physicians who eventually reside within a 100-mile radius of where they completed residency can be up to 50%, meaning that many of the Nevada medical school

graduates may not even come back to practice in the state [6].

As of now, there are around 404 residency positions that are funded by the Center for Medicare and Medicaid Services (CMS) in the state [6]. In the past two residency match cycles, only 14.6% and 36.2% of the residency positions in Nevada were filled by UNR and UNLV medical students, respectively [6]. It is likely that these students have to leave the state for residency training because many specialties and subspecialties are missing from Nevada's graduate medical education. There are no residency or fellowship programs for dermatology, ophthalmology, neurosurgery, urology, hematology/oncology, and rheumatology [6]. To keep physicians in Nevada, it is not enough just to recruit medical students who have close ties to the state. Although there is a 30% chance that these students will practice in Nevada, this number increases to more than 70% if the same students complete their residency in the state as well [7]. With Nevada being the fifth fastest-growing state in the country, it is crucial that the state gets more funding for residency and fellowship positions to address the increasing healthcare needs of its growing and aging populations [8].

Nevada is currently in the works of building major academic health centers. Currently, it has UNLV Health, which was first founded in 2017 and is growing to become a major academic health system that provides care to the state's southern populations [9]. Studies have shown that academic teaching hospitals and their affiliated medical schools are at the forefront of conducting research to find novel treatments for diseases and improving methods to yield the best patient outcomes. In fact, the National Institutes of Health (NIH) funds over half of its external medical research for these academic health centers [10]. Other studies have found that patients who are treated at these academic health centers have better outcomes than if they are seen at nonteaching hospitals [10]. Not only should the state build a major academic health center that possesses all major medical specialties, but it should also work concurrently with other disciplines such as dentistry, nursing, occupational therapy, and physical therapy [9]. This creates an interconnected health network that ensures patients receive comprehensive and convenient care.

Conclusion

Nevada's shortage of physicians should be addressed immediately, considering that the state's population is growing at a rapid rate. One of the ways to address this issue is to increase residency positions and specialties because physicians who train in the state are more likely to stay and serve the local communities, especially if they completed medical school here as well. Increasing the number of physicians in the state would not only yield better patient outcomes, but it would also diversify Nevada's economy by creating more jobs in its healthcare field.

Additional Information

Disclosures

Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **QUI THAI, MD,** **Certificate of Registration No. CS13843,** **Respondent.**	**Case No. 22-476-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Respondent Qui Thai, M.D., ("Respondent"), by and through counsel, Eric K. Stryker, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that he has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein. The parties agree that Count One and Count Two of the Accusation are duplicative in certain respects. Therefore, in the interest of compromise, Counts One and Two shall be combined upon approval of this Stipulation by the Board, and the Amended Count One will allege, to wit:

A. Respondent's Prescription Monitoring Program (PMP) account was opened on February 21, 2017;

B. Between January 1, 2018 through December 31, 2024, Respondent never accessed the PMP database to review his own prescribing activity;

C. Between January 1, 2018 and November 15, 2022, Respondent never accessed the PMP database to evaluate the prescription histories of the patients for whom he prescribed controlled substances;

D. Between January 1, 2018, and December 31, 2024, Respondent wrote 14,051 prescriptions for controlled substances for 1,295 unique patients.

E. Respondent's noncompliance with the PMP constitutes conduct contrary to the public interest under NAC 639.945(1)(i), which is grounds for action pursuant to NRS 639.210(4) and (12); NRS 639.255(3), NRS 453.236(1)(d) and (e), and NRS 453.241(1).

7. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agrees to the imposition of the following penalties:

A. Respondent accepts the Stipulation as a **public reprimand** imposed pursuant to NRS 639.255(1)(e).

B. Respondent agrees to **continue to comply with all PMP-related laws and regulations**, including but not limited to, NRS 453.164(7) and NRS 639.23507, and to contact the Board of Pharmacy in the future if he has any problems or questions;

C. Respondent agrees to **participate in training with Board staff on use of the PMP system** within sixty (60) days of the effective date of this order and will participate in follow-up training six (6) months after the initial training;

D. Respondent shall pay a fine of **Five Thousand Dollars and Zero Cents ($5,000.00)** for the alleged violations, payable by *cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within ninety (90) days of the effective date of this Order;

E. Respondent shall pay **One Thousand Dollars and Zero Cents ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check* or *certified check* or *money order* made payable to **"Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within ninety (90) days of the effective date of this Order;

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 22-476-CS-S. However, Respondent understands and acknowledges that his failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 3, 2025, in Reno, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of August, 2025

QUI THAI, MD,
Certificate of Registration No. CS13843

Signed this ___ day of August, 2025

LAURA M. TUCKER
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of August, 2025

ERIC K. STRYKER, ESQ.
Partner – Freeman Mathis & Gary, LLP

DECISION AND ORDER

As to Qui Thai, in Case No. 22-476-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of September 2025.

_____
Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9981,** **Pharmacy License No. PH01300,** **and** **JOSEPH DELALLO, RPH,** **Certificate of Registration No. 18429,** **Respondents.**	**CASE NOS. 25-034-PH-N** **25-034-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Joseph Delallo, RPh (Delallo), Certificate of Registration No. 18429, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #9981, Pharmacy License No. PH01300, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Delallo was employed as managing pharmacist of CVS Pharmacy #9981, located at 3240 Hwy. 50 in Carson City, at the time of the events alleged herein.

3. On January 21, 2025, CVS Pharmacy #9981 received a prescription for 5ml Amoxicillin-Pot Clavulanate from prescriber S.E. for 18-month-old patient C.S. The CVS pharmacy computer system designated this prescription no. 1054115.

4. On January 21, 2025, Catherine Torres (Torres), a pharmaceutical technician, prepared prescription no. 1054115.

5. After preparing the prescription, Torres gave prescription no. 1054115 to Delallo for verification. Delallo inspected the medication visually and by scanning a QR code on the bottle.

6. The bottle containing prescription no. 1054115 included a QR code, a lot number, and an expiration date. The QR code contains information about the medication contained within the bottle, including the expiration date.

7. Delallo confirmed through a visual inspection that the medication inside the bottle was correct. However, the QR code did not scan properly, and Delallo was unable to confirm any of the information about the medication from the QR code.

8. The expiration date printed on the bottle for prescription no. 1054115 was May 2024.

9. Although the expiration date was printed on the bottle along with the lot number, Delallo overlooked it during his verification.

10. On January 22, 2025, CVS #9981 dispensed prescription no. 1054115.

11. Beginning on January 22, 2025, Patient C.S.'s parents gave him the medication twice a day for five days, as directed by prescriber S.E.

12. On or about January 27, 2025, Patient C.S.'s father discovered from looking at the bottle that prescription no. 1054115 expired in May 2024.

13. On or about January 27, 2025, Patient C.S.'s mother called CVS #9981 to report that prescription no. 1054115 had expired. Pharmacy staff told C.S.'s mother that, although the bottle said the prescription was expired, it was still good.

14. Patient C.S. ingested the medication for prescription no. 1054115 twice per day for five days as directed. Patient C.S. did not appear to have any negative symptoms.

15. In 2023, the Board disciplined Respondent Delallo for (a) unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest for failing to verify the contents of and dispensing a prescription drug in strict conformance with the instructions of a prescribing practitioner, and (b) violations of law as the responsible managing pharmacist. In the 2023 case, the Board ordered Respondent Delallo to pay a total fine of $3,000.

16. In 2022, the Board issued a citation and fine in the amount of $500 against Respondent Delallo for erroneously dispensing a prescription to a patient with the incorrect instructions.

17. In 2014, the Board disciplined Respondent Delallo for (a) unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest for failing to verify the contents of and dispensing a prescription drug in strict conformance with the instructions of a prescribing practitioner; (b) failing to provide adequate counseling; and (c) removing the original fill record in violation of NAC 639.910(1) and (2). In the 2014 case, the Board and Respondent Delallo stipulated that, among other things, Respondent Delallo should pay a total fine of $1,500 and take a continuing education credit.

APPLICABLE LAW

18. Unprofessional conduct includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i). The Board may suspend or revoke any certificate, license, registration or permit if the holder is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

19. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702.

20. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license

by the Board. NRS 639.230(5); NAC 639.702. Furthermore, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

21. The sale or delivery or holding or offering for sale any drug that is adulterated is prohibited under Nevada law. NRS 585.520(1). A drug shall be deemed adulterated if it is a drug recognized in an official compendium and its quality or purity falls below the standard set forth in the compendium. NRS 585.380.

22. Any licensee who violates or attempts to violate any law or regulation relating to drugs or the practice of pharmacy is cause for the suspension or revocation of the license of pharmacy by the Board. NRS 639.210(12).

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Delallo)

23. Delallo engaged in unprofessional conduct as defined in NAC 639.945(1)(i) when, as the managing pharmacist at CVS #9981, he performed final verification for prescription no. 1054115 and failed to observe that the medication was expired.

24. Having performed his duties in incompetent, unskillful, or negligent manner, as described above, Delallo is subject to discipline pursuant to NRS 639.210(4) and NRS 639.230(5).

COUNT TWO

Unprofessional Conduct – Violation of Law Relating to Drugs

(Respondent Delallo)

25. As alleged above, Delallo violated or attempted to violate NRS 585.520(1) when, as the managing pharmacist at CVS #9981, he sold prescription no. 1054115, an adulterated drug, to a patient.

26. Having violated or attempting to violate NRS 585.520(1), Delallo is subject to discipline pursuant to NRS 639.210(4) and NRS 639.230(5).

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COUNT THREE

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS #9981)

27. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent CVS #9981 is responsible for those violations, including all errors and omissions of Respondent Delallo and any other pharmacy personnel in the course of erroneously filling and dispensing prescription no. 1054115, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificates of registration of these Respondents.

Signed this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9981,** **Pharmacy License No. PH01300,** **Respondent.**	**Case No. 25-034-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9981,** **Pharmacy License No. PH01300,** **Respondent.**	**Case No. 25-034-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

AUTHORIZED REPRESENTATIVE FOR
CVS Pharmacy #9981

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

CVS Pharmacy #9981
3240 US Hwy 50 E
Carson City, NV 89701

CVS Pharmacy #9981
c/o Brian J. Convery, Esq.
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895

Joseph Delallo, RPh
[redacted]
Reno, NV [redacted]

CVS Pharmacy #9981
c/o Joseph Delallo, RPh
3240 US Hwy 50 E
Carson City, NV 89701

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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FILED
JUL 2 4 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9981,** **Pharmacy License No. PH01300,** **and** **JOSEPH DELALLO, RPH,** **Certificate of Registration No. 18429,** **Respondents.**	**CASE NOS. 25-034-PH-N** **25-034-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Joseph Delallo, RPh (Delallo), Certificate of Registration No. 18429, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #9981, Pharmacy License No. PH01300, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Delallo was employed as managing pharmacist of CVS Pharmacy #9981, located at 3240 Hwy. 50 in Carson City, at the time of the events alleged herein.

3. On January 21, 2025, CVS Pharmacy #9981 received a prescription for 5ml Amoxicillin-Pot Clavulanate from prescriber S.E. for 18-month-old patient C.S. The CVS pharmacy computer system designated this prescription no. 1054115.

4. On January 21, 2025, Catherine Torres (Torres), a pharmaceutical technician, prepared prescription no. 1054115.

5. After preparing the prescription, Torres gave prescription no. 1054115 to Delallo for verification. Delallo inspected the medication visually and by scanning a QR code on the bottle.

6. The bottle containing prescription no. 1054115 included a QR code, a lot number, and an expiration date. The QR code contains information about the medication contained within the bottle, including the expiration date.

7. Delallo confirmed through a visual inspection that the medication inside the bottle was correct. However, the QR code did not scan properly, and Delallo was unable to confirm any of the information about the medication from the QR code.

8. The expiration date printed on the bottle for prescription no. 1054115 was May 2024.

9. Although the expiration date was printed on the bottle along with the lot number, Delallo overlooked it during his verification.

10. On January 22, 2025, CVS #9981 dispensed prescription no. 1054115.

11. Beginning on January 22, 2025, Patient C.S.'s parents gave him the medication twice a day for five days, as directed by prescriber S.E.

12. On or about January 27, 2025, Patient C.S.'s father discovered from looking at the bottle that prescription no. 1054115 expired in May 2024.

13. On or about January 27, 2025, Patient C.S.'s mother called CVS #9981 to report that prescription no. 1054115 had expired. Pharmacy staff told C.S.'s mother that, although the bottle said the prescription was expired, it was still good.

14. Patient C.S. ingested the medication for prescription no. 1054115 twice per day for five days as directed. Patient C.S. did not appear to have any negative symptoms.

15. In 2023, the Board disciplined Respondent Delallo for (a) unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest for failing to verify the contents of and dispensing a prescription drug in strict conformance with the instructions of a prescribing practitioner, and (b) violations of law as the responsible managing pharmacist. In the 2023 case, the Board ordered Respondent Delallo to pay a total fine of $3,000.

16. In 2022, the Board issued a citation and fine in the amount of $500 against Respondent Delallo for erroneously dispensing a prescription to a patient with the incorrect instructions.

17. In 2014, the Board disciplined Respondent Delallo for (a) unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest for failing to verify the contents of and dispensing a prescription drug in strict conformance with the instructions of a prescribing practitioner; (b) failing to provide adequate counseling; and (c) removing the original fill record in violation of NAC 639.910(1) and (2). In the 2014 case, the Board and Respondent Delallo stipulated that, among other things, Respondent Delallo should pay a total fine of $1,500 and take a continuing education credit.

APPLICABLE LAW

18. Unprofessional conduct includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i). The Board may suspend or revoke any certificate, license, registration or permit if the holder is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

19. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702.

20. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license

by the Board. NRS 639.230(5); NAC 639.702. Furthermore, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

21. The sale or delivery or holding or offering for sale any drug that is adulterated is prohibited under Nevada law. NRS 585.520(1). A drug shall be deemed adulterated if it is a drug recognized in an official compendium and its quality or purity falls below the standard set forth in the compendium. NRS 585.380.

22. Any licensee who violates or attempts to violate any law or regulation relating to drugs or the practice of pharmacy is cause for the suspension or revocation of the license of pharmacy by the Board. NRS 639.210(12).

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Delallo)

23. Delallo engaged in unprofessional conduct as defined in NAC 639.945(1)(i) when, as the managing pharmacist at CVS #9981, he performed final verification for prescription no. 1054115 and failed to observe that the medication was expired.

24. Having performed his duties in incompetent, unskillful, or negligent manner, as described above, Delallo is subject to discipline pursuant to NRS 639.210(4) and NRS 639.230(5).

COUNT TWO

Unprofessional Conduct – Violation of Law Relating to Drugs

(Respondent Delallo)

25. As alleged above, Delallo violated or attempted to violate NRS 585.520(1) when, as the managing pharmacist at CVS #9981, he sold prescription no. 1054115, an adulterated drug, to a patient.

26. Having violated or attempting to violate NRS 585.520(1), Delallo is subject to discipline pursuant to NRS 639.210(4) and NRS 639.230(5).

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COUNT THREE

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS #9981)

27. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent CVS #9981 is responsible for those violations, including all errors and omissions of Respondent Delallo and any other pharmacy personnel in the course of erroneously filling and dispensing prescription no. 1054115, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificates of registration of these Respondents.

Signed this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOSEPH DELALLO, RPH,** **Certificate of Registration No. 18429,** **Respondent.**	**Case No. 25-034-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOSEPH DELALLO, RPH,** **Certificate of Registration No. 18429,** **Respondent.**	**Case No. 25-034-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Joseph Delallo, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

CVS Pharmacy #9981
3240 US Hwy 50 E
Carson City, NV 89701

CVS Pharmacy #9981
c/o Brian J. Convery, Esq.
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895

Joseph Delallo, RPh
[redacted]
Reno, NV [redacted]

CVS Pharmacy #9981
c/o Joseph Delallo, RPh
3240 US Hwy 50 E
Carson City, NV 89701

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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6A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☒ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☒ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☒ Location Change*	M P00545	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Advanced Prosthetics and Orthotics, Inc.

MDEG Physical Address: 1701-5 N. Green Valley Parkway, Suite C

City: Henderson State: NV Zip: 89074

Mailing Address (if different from physical address): 7455 Washington Ave. #215

City: Las Vegas State: NV Zip: 89128

Telephone: 702-256-5265 Website: www.APONV.com

Email: Vikram@quantmpo.com

Name of MDEG Administrator (NAC 639.694): Nathan Gorgun

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☒ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.9S4):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:00a-5:00p	■ Tue: 8:00a-5:00p	■ Wed: 8:00a-5:00p	■ Thurs: 8:00a-5:00p	■ Fri: 8:00a-5:00p
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare PTAN 1151210003
Medicaid 10051882

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Illinois

Parent Company (if any): _____

Corporation/Organization Name: Quantum Clinics, Inc.

Mailing Address: 440 N. McClurg Ct. #113

City: Chicago State: IL Zip: 60611-4352

Telephone: 312-300-4472 Email: Vikram@quantumpo.com

Contact Person Name: Vikram Choudhary

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Viviram Choudhary

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6-23-25

Date

Board Use Only	Date Received: _____ Amount: _____

ADVAPRO-10 PLATESSA

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 5/2/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER World Insurance Associates, LLC 4610 Market Street P.O. Box 3989 Youngstown, OH 44513-3989	CONTACT NAME: Shellene Wilkinson PHONE (A/C, No, Ext): (330) 782-8068 FAX (A/C, No): (330) 782-0458 E-MAIL ADDRESS: shellenewilkinson@worldinsurance.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : United Specialty Insurance Company	12537
INSURED Advanced Prosthetics & Orthotics, Inc. 7455 West Washington Avenue, Suite 215 Las Vegas, NV 89128	INSURER B : American Casualty Company of Reading, Pennsylvania	20427
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			VGM11812352924-5	4/12/2025	4/12/2026	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
	X Professional Liab						MED EXP (Any one person)	$ 10,000
	X Hired/Non-Owned Auto						PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			7092354698	3/19/2025	3/19/2026	X PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N N/A						E.L. EACH ACCIDENT	$ 500,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 500,000
							E.L. DISEASE - POLICY LIMIT	$ 500,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
*Locations Covered: 1) 7455 West Washington Avenue, Suite 215, Las Vegas NV 89128; 2) 2281 E. Postal Drive, Suite 5, Pahrump NV 89048; 1701 N. Green Valley Parkway, Building 5, Suite C, Henderson NV 89074.

CERTIFICATE HOLDER

For Insurance Verification Only

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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File Number 7438-662-8

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

QUANTUM CLINICS INC., A DOMESTIC CORPORATION, INCORPORATED UNDER THE LAWS OF THIS STATE ON SEPTEMBER 20, 2023, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS IN GOOD STANDING AS A DOMESTIC CORPORATION IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 30TH *day of* MAY *A.D.* 2025 .

Authentication #: 2515003768 verifiable until 05/30/2026
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

2024

Agent Information
VIKRAM CHOUDHARY
[redacted]

Agent Change Date
09-20-2023

Services and More Information

Choose a tab below to view services available to this business and more information about this business.

Available Services	Officers	Assumed Name	Old Corp Name	File History

Officer	Name and Address	
President	VIKRAM CHOUDHARY [redacted]	60611
Secretary	VIKRAM CHOUDHARY [redacted]	60611

Business Entity Search

Entity Information

Entity Name
QUANTUM CLINICS INC.

File Number
74386628
Status
ACTIVE

Entity Type
CORPORATION
Type of Corp
DOMESTIC BCA

Incorporation Date (Domestic)
09-20-2023
State
ILLINOIS

Duration Date
PERPETUAL

Annual Report Filing Date

09-23-2024
Annual Report Year

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Advanced Prosthetics & Orthotics, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 7455 W Washington Ave # 215

City Las Vegas State NV Zip 89128

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email vikram@quantumpo.com

Section 2: Personal Information

First Vikram Middle _____ Last Choudhary

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip 60458

Telephone [redacted] Email vikram@quantumpo.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.179)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		NA

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ALL INDIA INSTITUTE OF PHYSICAL MEDICINE AND REHAB		04/92- 05/95	
Address	**City**	**State**	**Zip**
Haji Ali Dargah, Keshavrao Khadye Marg,	Bombay	Maharashtra	400034
Diploma/Degree obtained, if any			
Bachelors in Prosthetics & Orthotics			

School Name		From - To (MM/YY – MM/YY)	
INSTITUTE OF PUBLIC HEALTH & HYGIENE			
Address	**City**	**State**	**Zip**
Block B, 164/1 164/1 Mahipalpur Bypass Block B Mahipalpur	New Delhi	Delhi	110037
Diploma/Degree obtained, if any			
Masters in Hospital Management and Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/14/2014- Current	[redacted]	[redacted]	[redacted]	60611
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
SV Real Estate LLC			10/12- Current	
Business Address	**City**		**State**	**Zip**
440 N Mcclurg Ct,	Chicago		IL	60611
Phone	**Title**			
	President			
Description of Duties				
As a principal manager and owner of real estate buildings				

Business Name			From - To (MM/YY – MM/YY)	
Quantum Prosthetics & Orthotics			01/21-current	
Business Address	**City**		**State**	**Zip**
9050 81st St Suite 300	Justice		IL	60458
Phone	**Title**			
312-300-4472	President			
Description of Duties				
Manage the practice in Prosthetics & Orthotics				

Business Name			From - To (MM/YY – MM/YY)	
Northern Prosthetics & Orthopedic Inc			11/23- current	
Business Address	**City**		**State**	**Zip**
2629 Charles St	Rockford		IL	61108
Phone	**Title**			
8152260444	President			
Description of Duties				
Manage the practice in Prosthetics & Orthotics				

Business Name			From - To (MM/YY – MM/YY)	
Advanced Prosthetics & Orthotics, Inc.				
Business Address	**City**		**State**	**Zip**
7455 W Washington Ave # 215	Las Vegas		NV	89128
Phone	**Title**			
702-256-5265	President			
Description of Duties				
Manage the practice in Prosthetics & Orthotics				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		N A
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		NA
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		N A
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		N A
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		NA
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		N A
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		NA
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		N A
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		NA
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		N A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6.17.25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vikram Choudhary

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/12/2025

Date

Please have this section completed in the presence of a Notary Public.

State of IL, ss. County of COOK

I, Vikram Choudhary, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-17-25

Date

Subscribed and Sworn to before me this 17 day of June 2025

Notary Public Signature

Official Seal
DIANA Y DE LA SANCHA
Notary Public, State of Illinois
Commission No. 1004491
My Commission Expires February 13, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Advanced Prosthetics and Orthotics — MDEG License # (if applicable): MP00545

Physical Address: 1701 N Green Valley Parkway, Building 5 - Suite C

City: Henderson — State: NV — Zip: 89074

Mailing Address (if different from physical address): 7455 W Washington Ave, Ste 215

City: Las Vegas — State: NV — Zip: 89128

Telephone: 702-256-5265 — Website: www.aponv.com

Licensing Company Email: KiveliW@aponv.com

Section 2: Personal Information

First: Nathan — Middle: Kenan — Last: Gorgun

Alias(es, nicknames, name changes, etc.): Nate

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] — State: [redacted] — Zip: 89147

Telephone: [redacted] — Email: NateG@aponv.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Spring Valley High School		08/04 - 05/08	
Address	**City**	**State**	**Zip**
3750 S Buffalo Dr, Las Vegas, NV 89147	Las Vegas	NV	89147
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/96 - 06/25	[redacted]	[redacted]	[redacted]	89147
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Advanced Prosthetics and Orthotics			01/08 - 10/24
Business Address	**City**	**State**	**Zip**
7455 W Washington Ave, Suite 215	Las vegas	NV	89128
Phone	**Title**		**Number of Employed Hours**
702-256-5265	Office Administrator, Orthotic Fitter, Inventory Intake Admin		32,960
Description of Duties			
Verifying Insurance Benefits, scheduling, Intake Check In/Check Out, Inventory Management, Patient Care, Orthotic Fitter, Lab Technician			

Business Name			From - To (MM/YY – MM/YY)
Advanced Prosthetics and Orthotics			03/25 - 06/25
Business Address	**City**	**State**	**Zip**
7455 W Washington Ave, Suite 215	Las Vegas	NV	89128
Phone	**Title**		**Number of Employed Hours**
702-256-5265	Office Administrator, Inventory Intake Admin, Technician		600
Description of Duties			
Verifying Insurance Benefits, scheduling, Intake Check In/Check Out, Inventory Management, Patient Care, Lab Technician			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Nathan Gagen
Original Signature (electronic, copies or stamps not accepted)

06/18/2025
Date

I, Nathan Kenan Gorgun, **certify that as the MDEG Administrator for**

Advanced Prosthetics and Orthotics,

that I (initial that you have read and meet the following requirements):

1. NKG Have a high school diploma or its equivalent;
2. NKG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. NKG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. NKG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Gorgun

Print Name (First, Last)

Nathan Gorgun

Original Signature (electronic, copies or stamps not accepted)

06/18/2025

Date

Board Use Only	Date Received:

6B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (0S/12/2022)

Where is the facility located?	☒ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☒ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M P00076	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Advanced Prosthetics and Orthotics, Inc.

MDEG Physical Address: 7455 Washington Ave. #215

City: Las Vegas State: NV Zip: 89128

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-256-5265 Website: www.APONV.com

Email: Vikram@quantmpo.com

Name of MDEG Administrator (NAC 639.694): Kiveli Williams

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☒ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

4251

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:00a-5:00p	■ Tue: 8:00a-5:00p	■ Wed: 8:00a-5:00p	■ Thurs: 8:00a-5:00p	■ Fri: 8:00a-5:00p
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare PTAN 1151210001
Medicaid 003302056

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Illinois

Parent Company (if any): n/a

Corporation/Organization Name: Quantum Clinics, Inc.

Mailing Address: 440 N. McClurg Ct. #113

City: Chicago State: IL Zip: 60611-4352

Telephone: 312-300-4472 Email: Vikram@quantumpo.com

Contact Person Name: Vikram Choudhary

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vikram Choudhary

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6-23-25

Date

Board Use Only	Date Received: 7/3/25	Amount: $500 ck# 10353

ADVAPRO-10 PLATESSA

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 5/2/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Shellene Wilkinson	
World Insurance Associates, LLC 4610 Market Street P.O. Box 3989 Youngstown, OH 44513-3989	PHONE (A/C, No, Ext): (330) 782-8068	FAX (A/C, No): (330) 782-0458
	E-MAIL ADDRESS: shellenewilkinson@worldinsurance.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : United Specialty Insurance Company	12537
INSURED	INSURER B : American Casualty Company of Reading, Pennsylvania	20427
Advanced Prosthetics & Orthotics, Inc. 7455 West Washington Avenue, Suite 215 Las Vegas, NV 89128	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY							
	CLAIMS-MADE X OCCUR			VGM11812352924-5	4/12/2025	4/12/2026	EACH OCCURRENCE	$ 1,000,000
	X Professional Liab						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
	X Hired/Non-Owned Auto						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						X PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N	N/A		7092354698	3/19/2025	3/19/2026	E.L. EACH ACCIDENT	$ 500,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 500,000
							E.L. DISEASE - POLICY LIMIT	$ 500,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
*Locations Covered: 1) 7455 West Washington Avenue, Suite 215, Las Vegas NV 89128; 2) 2281 E. Postal Drive, Suite 5, Pahrump NV 89048; 1701 N. Green Valley Parkway, Building 5, Suite C, Henderson NV 89074.

CERTIFICATE HOLDER

For Insurance Verification Only

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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File Number 7438-662-8

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

QUANTUM CLINICS INC., A DOMESTIC CORPORATION, INCORPORATED UNDER THE LAWS OF THIS STATE ON SEPTEMBER 20, 2023, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS IN GOOD STANDING AS A DOMESTIC CORPORATION IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 30TH *day of* MAY *A.D.* 2025 .

Authentication #: 2515003768 verifiable until 05/30/2026
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

2024

Agent Information
VIKRAM CHOUDHARY
[redacted]

Agent Change Date
09-20-2023

Services and More Information

Choose a tab below to view services available to this business and more information about this business.

Available Services | Officers | Assumed Name | Old Corp Name | File History

Officer	Name and Address	
President	VIKRAM CHOUDHARY [redacted]	60611
Secretary	VIKRAM CHOUDHARY [redacted]	60611

Business Entity Search

Entity Information

Entity Name
QUANTUM CLINICS INC.

File Number
74386628
Status
ACTIVE

Entity Type
CORPORATION
Type of Corp
DOMESTIC BCA

Incorporation Date (Domestic)
09-20-2023
State
ILLINOIS

Duration Date
PERPETUAL

Annual Report Filing Date

09-23-2024
Annual Report Year

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Advanced Prosthetics & Orthotics, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 7455 W Washington Ave # 215

City Las Vegas State NV Zip 89128

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email vikram@quantumpo.com

Section 2: Personal Information

First Vikram Middle _____ Last Choudhary

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip 60458

Telephone [redacted] Email vikram@quantumpo.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		NA

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ALL INDIA INSTITUTE OF PHYSICAL MEDICINE AND REHAB		04/92- 05/95	
Address	**City**	**State**	**Zip**
Haji Ali Dargah, Keshavrao Khadye Marg,	Bombay	Maharashtra	400034
Diploma/Degree obtained, if any			
Bachelors in Prosthetics & Orthotics			
School Name		From - To (MM/YY – MM/YY)	
INSTITUTE OF PUBLIC HEALTH & HYGIENE			
Address	**City**	**State**	**Zip**
Block B, 164/1 164/1 Mahipalpur Bypass Block B Mahipalpur	New Delhi	Delhi	110037
Diploma/Degree obtained, if any			
Masters in Hospital Management and Administration			
School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/14/2014- Current	[redacted]	[redacted]	[redacted]	60611
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SV Real Estate LLC			10/12- Current
Business Address	**City**	**State**	**Zip**
440 N Mcclurg Ct,	Chicago	IL	60611
Phone	**Title**		
	President		

Description of Duties

As a principal manager and owner of real estate buildings

Business Name			From - To (MM/YY – MM/YY)
Quantum Prosthetics & Orthotics			01/21-current
Business Address	**City**	**State**	**Zip**
9050 81st St Suite 300	Justice	IL	60458
Phone	**Title**		
312-300-4472	President		

Description of Duties

Manage the practice in Prosthetics & Orthotics

Business Name			From - To (MM/YY – MM/YY)
Northern Prosthetics & Orthopedic Inc			11/23- current
Business Address	**City**	**State**	**Zip**
2629 Charles St	Rockford	IL	61108
Phone	**Title**		
8152260444	President		

Description of Duties

Manage the practice in Prosthetics & Orthotics

Business Name			From - To (MM/YY – MM/YY)
Advanced Prosthetics & Orthotics, Inc.			
Business Address	**City**	**State**	**Zip**
7455 W Washington Ave # 215	Las Vegas	NV	89128
Phone	**Title**		
702-256-5265	President		

Description of Duties

Manage the practice in Prosthetics & Orthotics

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		N A
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		NA
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		N A
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		N A
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		NA
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		N A
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		NA
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		N A
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		NA
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		N A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6-12-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vikram Choudhary

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/12/2025

Date

Please have this section completed in the presence of a Notary Public.

State of IL, ss. County of Cook

I, Vikram Choudhary, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-17-25

Date

Subscribed and Sworn to before me this 17 day of June 2025

Notary Public Signature

Official Seal
DIANA Y DE LA SANCHA
Notary Public, State of Illinois
Commission No. 1004491
My Commission Expires February 13, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Advanced Prosthetics & Orthotics, Inc — MDEG License # (if applicable): MP00076

Physical Address: 7455 Washington Ave #215

City: Las Vegas — State: NV — Zip: 89228

Mailing Address (if different from physical address):

City: — State: — Zip:

Telephone: 702-256-5265 — Website: www.APONV.com

Licensing Company Email: Vikram@Quantumop.com

Section 2: Personal Information

First: Kiveli — Middle: — Last: Williams

Alias(es, nicknames, name changes, etc.): Kiveli Bolden

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] — State: [redacted] — Zip: 89128

Telephone: [redacted] — Email: [redacted] KiveliW@aponv.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pacific High School		09/1977 - 06/1981	
Address	**City**	**State**	**Zip**
1020 Pacific Ave	San Bernardino	CA	92404
Diploma/Degree obtained, if any			
General Education Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2020 - current	[redacted]	[redacted]	[redacted]	89128
From - To (MM/YY – MM/YY)				Zip
09/2016-11/2020				89128
From - To (MM/YY – MM/YY)				Zip
-08/2012 - 09/2016				89147
From - To (MM/YY – MM/YY)				Zip
10-2004 - 08/2012				89147
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Advanced Prosthetics & Orthotics, Inc.			11/2006 - Current	
Business Address	**City**		**State**	**Zip**
7455 Washington Ave. #215	Las Vegas		NV	89128
Phone	**Title**		**Number of Employed Hours**	
702-256-5265 x102	Practice Manager		37,440 / 40hrs p/week	
Description of Duties				
Operations management, credentialing, contracting, licensing & all general office management duties.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6.19.2025
Date

I, Kiveli Williams, **certify that as the MDEG Administrator for**

Advanced Prosthetics & Orthotics, Inc.,

that I (initial that you have read and meet the following requirements):

1. KW Have a high school diploma or its equivalent;
2. KW Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KW Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KW Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kiveli Williams
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4.19.2025
Date

Board Use Only	Date Received:

6C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☒ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☒ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M P00184	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Advanced Prosthetics and Orthotics, Inc.

MDEG Physical Address: 2281 Postal Drive #4 & 5

City: Pahrump State: NV Zip: 89048

Mailing Address (if different from physical address): 7455 Washington Ave. #215

City: Las Vegas State: NV Zip: 89128

Telephone: 775-751-2030 Website: www.APONV.com

Email: Vikram@quantmpo.com

Name of MDEG Administrator (NAC 639.694): Marissa McCoy

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☒ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____ Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:00a-5:00p	■ Tue: 8:00a-5:00p	■ Wed: 8:00a-5:00p	■ Thurs: 8:00a-5:00p	■ Fri: 8:00a-5:00p
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare PTAN 1151210002
Medicaid 100518448

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Illinois

Parent Company (if any): _____

Corporation/Organization Name: Quantum Clinics, Inc.

Mailing Address: 440 N. McClurg Ct. #113

City: Chicago State: IL Zip: 60611-4352

Telephone: 312-300-4472 Email: Vikram@quantumpo.com

Contact Person Name: Vikram Choudhary

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vikram Choudhary

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6-23-25

Date

Board Use Only	Date Received: _____ Amount: _____

ADVAPRO-10 PLATESSA

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 5/2/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Shellene Wilkinson
World Insurance Associates, LLC 4610 Market Street P.O. Box 3989 Youngstown, OH 44513-3989	PHONE (A/C, No, Ext): (330) 782-8068 FAX (A/C, No): (330) 782-0458 E-MAIL ADDRESS: shellenewilkinson@worldinsurance.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : United Specialty Insurance Company	12537
INSURER B : American Casualty Company of Reading, Pennsylvania	20427
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED

Advanced Prosthetics & Orthotics, Inc.
7455 West Washington Avenue, Suite 215
Las Vegas, NV 89128

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY							
	☐ CLAIMS-MADE ☒ OCCUR			VGM11812352924-5	4/12/2025	4/12/2026	EACH OCCURRENCE	$ 1,000,000
	X Professional Liab						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
	X Hired/Non-Owned Auto						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						X PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N ☐ N/A			7092354698	3/19/2025	3/19/2026	E.L. EACH ACCIDENT	$ 500,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 500,000
							E.L. DISEASE - POLICY LIMIT	$ 500,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
*Locations Covered: 1) 7455 West Washington Avenue, Suite 215, Las Vegas NV 89128; 2) 2281 E. Postal Drive, Suite 5, Pahrump NV 89048; 1701 N. Green Valley Parkway, Building 5, Suite C, Henderson NV 89074.

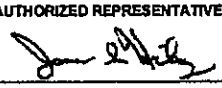
CERTIFICATE HOLDER

For Insurance Verification Only

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE



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File Number 7438-662-8

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

QUANTUM CLINICS INC., A DOMESTIC CORPORATION, INCORPORATED UNDER THE LAWS OF THIS STATE ON SEPTEMBER 20, 2023, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS IN GOOD STANDING AS A DOMESTIC CORPORATION IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 30TH *day of* MAY *A.D.* 2025 .

Authentication #: 2515003768 verifiable until 05/30/2026
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

2024

Agent Information
VIKRAM CHOUDHARY
[redacted]

Agent Change Date
09-20-2023

Services and More Information

Choose a tab below to view services available to this business and more information about this business.

Available Services | Officers | Assumed Name | Old Corp Name | File History

Officer	Name and Address
President	VIKRAM CHOUDHARY [redacted]
Secretary	VIKRAM CHOUDHARY [redacted]

Business Entity Search

Entity Information

Entity Name
QUANTUM CLINICS INC.

File Number
74386628
Status
ACTIVE

Entity Type
CORPORATION
Type of Corp
DOMESTIC BCA

Incorporation Date (Domestic)
09-20-2023
State
ILLINOIS

Duration Date
PERPETUAL

Annual Report Filing Date

09-23-2024
Annual Report Year

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Advanced Prosthetics & Orthotics, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 7455 W Washington Ave # 215

City Las Vegas State NV Zip 89128

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email vikram@quantumpo.com

Section 2: Personal Information

First Vikram Middle _____ Last Choudhary

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip 60458

Telephone [redacted] Email vikram@quantumpo.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		NA

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ALL INDIA INSTITUTE OF PHYSICAL MEDICINE AND REHAB		04/92- 05/95	
Address	**City**	**State**	**Zip**
Haji Ali Dargah, Keshavrao Khadye Marg,	Bombay	Maharashtra	400034
Diploma/Degree obtained, if any			
Bachelors in Prosthetics & Orthotics			

School Name		From - To (MM/YY – MM/YY)	
INSTITUTE OF PUBLIC HEALTH & HYGIENE			
Address	**City**	**State**	**Zip**
Block B, 164/1 164/1 Mahipalpur Bypass Block B Mahipalpur	New Delhi	Delhi	110037
Diploma/Degree obtained, if any			
Masters in Hospital Management and Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/14/2014- Current	[redacted]	[redacted]	[redacted]	60611
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SV Real Estate LLC			10/12- Current
Business Address	**City**	**State**	**Zip**
440 N Mcclurg Ct,	Chicago	IL	60611
Phone	**Title**		
	President		

Description of Duties

As a principal manager and owner of real estate buildings

Business Name			From - To (MM/YY – MM/YY)
Quantum Prosthetics & Orthotics			01/21-current
Business Address	**City**	**State**	**Zip**
9050 81st St Suite 300	Justice	IL	60458
Phone	**Title**		
312-300-4472	President		

Description of Duties

Manage the practice in Prosthetics & Orthotics

Business Name			From - To (MM/YY – MM/YY)
Northern Prosthetics & Orthopedic Inc			11/23- current
Business Address	**City**	**State**	**Zip**
2629 Charles St	Rockford	IL	61108
Phone	**Title**		
8152260444	President		

Description of Duties

Manage the practice in Prosthetics & Orthotics

Business Name			From - To (MM/YY – MM/YY)
Advanced Prosthetics & Orthotics, Inc.			
Business Address	**City**	**State**	**Zip**
7455 W Washington Ave # 215	Las Vegas	NV	89128
Phone	**Title**		
702-256-5265	President		

Description of Duties

Manage the practice in Prosthetics & Orthotics

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		N A
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		NA
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		N A
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		N A
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		NA
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		N A
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		NA
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		N A
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		NA
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		N A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6·17·25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vikram Choudhary
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/12/2025
Date

Please have this section completed in the presence of a Notary Public.

State of IL, ss. County of COOK

I, Vikram Choudhary, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-17-25
Date

Subscribed and Sworn to before me this 17 day of June 2025

Notary Public Signature

Official Seal
DIANA Y DE LA SANCHA
Notary Public, State of Illinois
Commission No. 1004491
My Commission Expires February 13, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Advanced Prosthetics and Orthotics, Inc. MDEG License # (if applicable) MP00184

Physical Address 7455 W Washington Ave Ste 215

City Las Vegas State Nevada Zip 89128

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email aponv@aol.com

Section 2: Personal Information

First Marissa Middle _____ Last Mccoy

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip 89048

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNLV		08/05- 05/06	
Address	**City**	**State**	**Zip**
4505 S Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
N/A			
School Name		**From - To (MM/YY – MM/YY)**	
Death Valley Academy		08/03-05/05	
Address	**City**	**State**	**Zip**
217 Old State Hwy 127	Shoshone	CA	92384
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Messmer High School		08/01-05/03	
Address	**City**	**State**	**Zip**
742 W Capitol Dr	Milwaukee	WI	53206
Diploma/Degree obtained, if any			
N/A			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/20- Current	[redacted]	[redacted]	[redacted]	89048
From - To (MM/YY – MM/YY)				Zip
10/11- 08/20				89060
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Advanced Prosthetics and Orthotics			08/2022	
Business Address		**City**	**State**	**Zip**
2281 E Postal Rd		Pahrump	NV	89048
Phone	**Title**		**Number of Employed Hours**	
775-751-2999	Office Admin		6560	
Description of Duties				
Schedule appointments/ answer incoming calls/ make outgoing insurance calls/ verify benifits and eligibility/ assist with billing/ order products/ oversee inventory control/ collect financial responsibility and copays				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.	✔	

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/16/2022	5/29/2024	NV	Pahrump	USA
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
22-053-PT-S		Nevada State Board of Pharmacy		
Reason/Charge				
Diversion				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
NV Board of Pharmacy		None		
Name of Business/Industry/Entity				
Desert View Hospital				

Provide explanation below:

Board citation and administrative action due to drug diversion. Criminal charges dismissed. Board of pharmacy tech license was revoked for 10 years and $1,500 in attorney's fees if reapplication is filed. Stipulation and board meeting minutes attached for reference.

Original Signature (electronic, copies or stamps not accepted)

6.18.25
Date

I, Marissa McCoy, **certify that as the MDEG Administrator for** ADVANCED PROSTHETICS & ORTHOTICS,

that I (initial that you have read and meet the following requirements):

1. ___ Have a high school diploma or its equivalent;
2. ___ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ___ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ___ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Marissa McCoy
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-18-25
Date

Board Use Only	Date Received: 7/3/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206, Reno, NV 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

MINUTES

May 29-30, 2024

BOARD MEETING

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, May 29, 2024, at 9:00 am. The meeting will continue Thursday, May 30, 2024, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hilton Garden Inn
7830 S Las Vegas Blvd.
Las Vegas, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

Board Members Present:

Helen Park	Krystal Freitas	Wayne Mitchell	Richard Tomasso
Adam Porath	Gener Tejero	Jade Jacobo	

Board Staff Present:

David Wuest	Yenh Long	Gregory Zunino	Gustaf Vanderdonck
Brett Kandt	Darlene Nases	Erin Miller	Jessette Phaynarikone
Joe Dodge	Leo Basch	Dena McClish	John Castaldo
Ken Scheuber	Todd Weiss		

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

Lyn Beggs made a comment on the case and shared what has been implemented since.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to approve the Stipulation and Order for Joshua Hamilton as presented by Mr. Vanderdonck.

Second: Adam Porath

Action: Passed unanimously.

S. Marissa Crain (22-053-PT-S)

Marissa Crain appeared and was sworn in by President Park prior to answering questions and offering testimony.

Krystal Freitas recused herself from this item due to her employment.

Gregory Zunino, Senior General Counsel for the Nevada State Board of Pharmacy, prosecuted the case against Ms. Crain alleging diversion of controlled substances.

Mr. Zunino presented a proposed Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for Marissa Crain are the following: 1) revocation of Certificate of Registration No. PT14524 for a period of ten (10) years.

Board discussion ensued.

Jacobo wants the attorney's fees to be assessed if she reapplies with the Board in ten (10) years.

The Board took a recess for the amended stipulation to be discussed with Ms. Crain.

Ms. Crain agreed to amend the stipulation to add $1,500 in attorney's fees if she reapplies in ten (10) years.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Marissa Crain as presented by Mr. Zunino with the amendment for Ms. Crain to

pay $1,500 in attorney's fees and costs if she reapplies with the Board after a period of ten (10) years.

Second: Adam Porath

Action: Passed unanimously. (Freitas recused).

R. George James Maiorano (21-207-PT-S)

Trevor Wade appeared as counsel on behalf of Mr. Maiorano.

Gregory Zunino, Senior General Counsel for the Nevada State Board of Pharmacy, prosecuted the case against Mr. Maiorano and gave an overview of the case and reviewed the allegations.

Mr. Zunino stated that the parties have agreed for respondent to plead guilty to Count One, and that Count Two would be dismissed upon approval of the proposed Stipulation and Order by the Board.

The proposed stipulated penalties for Mr. Maiorano are the following: 1) pay a $2,000 fine for the violations; and 2) pay $1,000 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order for Mr. Maiorano as presented by Mr. Zunino.

Second: Jade Jacobo

Board discussion ensued.

Action: Passed unanimously.

F. William Alvear (20-162-CS-S)

Donald Green appeared as counsel on behalf of Dr. Alvear.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Dr. Alvear based upon his federal conviction on eight felony counts of distribution of a controlled substance.

Mr. Kandt requested that the voluntary surrender of Dr. Alvear's Certificate of Registration No. CS08254 be admitted into the record as Exhibit 1 and that the

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARISSA CRAIN, PT,** **Certificate of Registration No. PT14524,** **Respondent.**	**Case Nos. 22-053-PT-S** **ORDER ON AMENDED AND RESTATED STIPULATION**

The above-captioned matter came before the Nevada State Board of Pharmacy ("Board") at its regularly scheduled meeting on Wednesday May 29, 2024. Gregory Zunino, Senior General Counsel, appeared on behalf of the Board's staff, and Respondent Marissa Crain ("Respondent") appeared on her own behalf. The parties presented a stipulation and proposed order for the Board's consideration and possible approval. At the suggestion of Board Member Jade Jacobo, the parties reached an agreement to amend the stipulation. The parties verbally agreed on the record to the amendment, at which point the Board approved the stipulation as amended. The terms of the stipulation are hereby amended, restated, and memorialized as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that she understands the terms of this stipulation and has agreed to it knowingly and voluntarily.

4. Respondent acknowledges that she is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which

governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Excluding the right to challenge any determination that Respondent has failed to comply with the terms set forth herein, Respondent hereby freely and voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent denies that she diverted injectable controlled substances as alleged in paragraph 8 of the Accusation, but she admits that she diverted controlled substances in tablet form. Respondent further maintains that she diverted these controlled substances for personal use and not for purposes of sale or distribution.

7. Notwithstanding her representations as set forth in paragraph 6 above, Respondent admits that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violation alleged against Respondent in Count One of the Accusation.

8. To settle the disputed issues described in paragraph 6 above, and to resolve this matter without incurring any further costs or the expenses associated with a hearing, the parties agree that as of the effective date of this Order, Respondent's Certificate of Registration No. PT14524 shall be **REVOKED** for a period of ten (10) years. Upon the expiration of this 10-year period, if Respondent petitions the Board to reinstate her certificate of registration as a pharmacy technician, Respondent shall as a condition of reinstatement partially reimburse the Board for its costs of investigation and prosecution in the amount of One Thousand Five Hundred and No/100 Dollars ($1,500.00).

9. The parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation.

[Remainder of this Page Intentionally Left Blank]

NOW, THERFORE, as to Respondent Marissa Crain, the Nevada State Board of Pharmacy hereby adopts the foregoing Amended and Restated Stipulation as its final decision in Case No. 23-053-PT-S, and hereby orders that its terms be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 29th day of May 2024.

Helen Park, President
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. MARISSA CRAIN, PT, Certificate of Registration No. PT14524, Respondent.	Case Nos. 22-053-PT-S STIPULATION AND ORDER

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Marissa Crain ("Respondent"), hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that she understands the terms of this Stipulation and has executed it knowingly and voluntarily.

4. Respondent acknowledges that she is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with its provisions, Respondent hereby freely and voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent denies that she diverted injectable controlled substances as alleged in paragraph 8 of the Accusation, but she admits that she diverted controlled substances in tablet form. Respondent further maintains that she diverted these controlled substances for personal use and not for purposes of sale or distribution.

7. Notwithstanding her representations as set forth in paragraph 6 above, Respondent admits that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violation alleged against Respondent in Count One of the Accusation.

8. To settle the disputed issues described in paragraph 6 above, and to resolve this matter without incurring any further costs or the expenses associated with a hearing, the parties agree that as of the effective date of this Order, Respondent's Certificate of Registration No. PT14524 shall be **REVOKED** for a period of ten (10) years.

9. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting at 9 a.m. on **May 29, 2024, at the Hilton Garden Inn, 7830 S. Las Vegas Boulevard, Las Vegas, Nevada.** Respondent understands and acknowledges that she is expected to make a personal appearance at this hearing.

10. Respondent understands and acknowledges that if she fails to make a personal appearance at the Board's meeting on May 29, 2024, the Board may enter a default order against her and impose such discipline, including fines and fees, as may be authorized by Nevada law.

11. Respondent understands and acknowledges that the Board is not obligated to accept this Stipulation. Assuming the Board accepts this Stipulation, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the parties agree to release each

other from any or all additional claims arising from the facts set forth in the Accusation.

AGREED:

Signed this 14 day of March 2024.

MARISSA CRAIN, PT

Certificate of Registration No. PT14524

Signed this 14th day of March 2024.

NEVADA STATE BOARD OF PHARMACY

By

GREGORY L. ZUNINO

Senior General Counsel

Nevada Bar No. 4805

DECISION AND ORDER

As to Respondent Marissa Crain, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in Case No. 23-053-PT-S, and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 29th day of May 2024.

Helen Park, President

Nevada State Board of Pharmacy

6D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☒ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☒ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Fix My Oxygen LLC

MDEG Physical Address: 3909 Maryland Pkwy unit 400

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 702-807-8474 Website: fixmyoxygen.com

Email: fixmyoxygen@gmail.com

Name of MDEG Administrator (NAC 639.694): Kenneth Wayne Beasley Jr

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☒ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 10am-5pm	■ Tue: 10am-5pm	■ Wed: 10am-5pm	■ Thurs: 10am-5pm	■ Fri: 10am-5pm
☐ Sat: 10am-2pm	☐ Sun: Closed	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))

none

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: Karapet Ayvazyan Not a health professional / N/A Credentials: owner N/A %: 100

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Karapet Ayvazyan

Business Name: Fix My Oxygen LLC

Business Address: 3909 S Maryland Pkwy suit 400

City: Las Vegas State: NV Zip: 89119

Telephone: 702-807-8474 Email: fixmyoxygen@gmail.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List of all Officers and Directors.	✓	✓		
• List of all general and limited partner names and their percent ownership (NAC 639.6942).			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last 6 months.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• "**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Karapet Ayvazyan

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

01/19/2025

Date

Board Use Only	Date Received: _____	Amount: _____

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/24/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER

MG Insurance Agency, LLC
8440 W. Lake Mead Blvd
Suite 102
Las Vegas, NV 89128

CONTACT NAME: Marine Ghykasian
PHONE (A/C, No, Ext): 818 281-3917 FAX (A/C, No):
E-MAIL ADDRESS: mg.insurancellc@gmail.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A: Kinsale Insurance Company	38920
INSURER B:	
INSURER C:	
INSURER D:	
INSURER E:	
INSURER F:	

INSURED

Fix My Oxygen LLC
3909 S Maryland Pkwy Ste 400
Las Vegas, NV 89119

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE / OCCUR	X		05809651	06/16/2025	06/16/2026	EACH OCCURRENCE	$ 1,000,000.
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000.
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
	GEN'L AGGREGATE LIMIT APPLIES PER: POLICY / PRO-JECT / LOC						GENERAL AGGREGATE	$ 2,000,000.
							PRODUCTS - COMP/OP AGG	$
	OTHER:							$
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY / SCHEDULED AUTOS HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB / OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB / CLAIMS-MADE						AGGREGATE	$
	DED / RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE / OTH-ER	
							E.L. EACH ACCIDENT	$
							E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Nevada State Board of Pharmacy
is added as additional insured.

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, # 206
Reno, NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marine Ghykasian

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SECRETARY OF STATE



STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

Fix My Oxygen LLC

Organizational Documents on File	Filing Date
Articles of Organization	12/17/2024

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence Fix My Oxygen LLC, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 12/17/2024, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/14/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507145899632
You may verify this certificate online at
https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Fix my Oxygen

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 3909 S Maryland pkwy Unit 400

City Las Vegas State NV Zip 89119

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 702-807-8474 Website fixmyoxygen.com

Licensing Company Email fixmyoxygen@gmail.com

Section 2: Personal Information

First Karapet Middle _____ Last Ayvazyan

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip 89119

Telephone [redacted] Email fixmyoxygen@gmail.com

Are you a citizen of the United States? ☐ Yes ☑ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Lycee Francais Anatole France		06-81 . 09-86	
Address	City	State	Zip
37 Burnazian st	Yerevan	AM	.0005
Diploma/Degree obtained, if any			
Engineering (BSE)			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03-24 - now	[redacted]	[redacted]	[redacted]	89119
- 03-24				Yerevan
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
None	

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
Meditech	02-17 - 09-24

Business Address	City	State	Zip
2213 Admiral Isakov ave	Yerevan	AM	

Phone	Title
+37410560146	repair of medical equipment

Description of Duties
Accepting and repairing oxygen machines and cpap machine also wheelchairs

Business Name	From - To (MM/YY – MM/YY)
None	

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
None	

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
None	

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

01/14/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Karapet Ayvazyan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07-01-2025
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Karapet Ayvazyan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/2/2025
Date

Subscribed and Sworn to before me this 2nd day of July, 2025.

Notary Public Signature

SAAM NAGHDI
Notary Public, State of Nevada
No. 10-1715-1
My Appt. Exp. Jan. 21, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG ~~Kenneth Wayne Beasley Jr~~ Fix My Oxygen MDEG License # (if applicable) _____

Physical Address 6300 W. Lake Mead Blvd #1111

City Las Vegas State NV Zip 89108

Mailing Address (if different from physical address) 3909 Maryland Parkway #400

City Las vegas State NV Zip 89119

Telephone 702-807-8474 Website Fixmyoxygen.com

Licensing Company Email Fixmyoxygen@gmail.com

Section 2: Personal Information

First Kenneth Middle wayne Last Beasley jr

Alias(es, nicknames, name changes, etc.) Ken

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip 89108

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✔	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✔	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Carrington College		04-2012 04-2014	
Address	**City**	**State**	**Zip**
5740 S. Eastern Ave #140	las vegas	Nv	89119
Diploma/Degree obtained, if any			
Associates in Applied Science			

School Name		From - To (MM/YY – MM/YY)	
AB Miller High School		09-1995 06-1999	
Address	**City**	**State**	**Zip**
6821 Oleander Ave	Fontana	Ca	92336
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	[redacted]	[redacted]	Zip
01-2023 current				89108
From - To (MM/YY – MM/YY)				Zip
01-2018- 01-2023				89149
From - To (MM/YY – MM/YY)				Zip
01-2015 01-2018				89123
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Centennial Hills Hospital			01-2012 current	
Business Address		**City**	**State**	**Zip**
6900 N. Durango		Las Vegas	NV	89149
Phone	**Title**		**Number of Employed Hours**	
702-835-7900	RCP Respiratory Therapist		40 weekly	
Description of Duties				
Respiratory. Modalities, Equipment setup, services and management. Education of respiratory health and equipment				

Business Name			From - To (MM/YY – MM/YY)	
Optigen Medical DME			06-2017 current	
Business Address		**City**	**State**	**Zip**
1351 13th Ave S Suite 100		Jacksonville	FL	32250
Phone	**Title**		**Number of Employed Hours**	
800-273-9114	Respiratory Therapist		Contract	
Description of Duties				
Respiratory. Modalities, Equipment setup, services and management. Education of respiratory health and home visit equipment management, inventory.				

Business Name			From - To (MM/YY – MM/YY)	
Apria Healthcare			01-2001-06-2009	
Business Address		**City**	**State**	**Zip**
7370 Eastgate RD		Las Vegas	NV	89011
Phone	**Title**		**Number of Employed Hours**	
702-736-4466	Respiratory Therapist		60	
Description of Duties				
Respiratory. Modalities, Equipment setup, services and management. Education of respiratory health and equipment Home visits, setup and education				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03/12/2025
Date

I, Kenneth W.Beasley Jr., **certify that as the MDEG Administrator for**

Fixmyoxygen.com,

that I (initial that you have read and meet the following requirements):

1. KB Have a high school diploma or its equivalent;
2. KB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kenneth Beasley
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/12/2025
Date

Board Use Only	Date Received:

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Fix My Oxygen LLC

Nevada Business Identification # NV20243257053
Expiration Date: 12/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 12/17/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202412175274677
You may verify this certificate online at https://www.nvsilverflume.gov/home

7

7A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: BBP9296749 NewPendinf
	■ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: National Health RX

Physical Address: 5835 S. Eastern Avenue Ste 101

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-791-3800 Toll Free # (NAC 639.708, NRS 639.23286): 888-490-5534

Fax: 702-791-3800 Contact Email: info@nationalhealthrx.com

Website: nationalhealthrx.com (pending)

Nevada Business License # (if applicable) NV20253361354

Supervising/Managing Pharmacist Name (NRS 639.220): Jerry Depa

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 12508 Exp 10/31/2025

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Depa, Jerry	NV Pharmacist Registration #: 12508
Name: Barbose, Marc	NV Pharmacist Registration #: 14251
Name: Cybulska, Magdalena	NV Pharmacist Registration #: 22437
Name: Angeles, Tammy	NV Pharmacist Registration #: 19070
Name: Peters, Christopher	NV Pharmacist Registration #: 19870
Name: Ngo, Paulina	NV Pharmacist Registration #: 18970
Name: Li, Kenny	NV Pharmacist Registration #: 16325
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Vitel Path LLC

Corporation/Organization Name: National Health RX LLC

Mailing Address: 5835 S. Eastern Avenue Ste 101

City: Las Vegas State: NV Zip: 89119

Telephone: 702-791-3800 Email: info@partellpharmacy.com

Contact Person Name: Massimo Cavallaro

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: NA

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Member (title) for National Health RX (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Massimo Cavallaro

Print Name of Authorized Person

Massimo Cavallaro

Original signature of Authorized Person (copies or stamps not accepted)

8-5-2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Massimo Cavallaro hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Member (title) for National Health RX (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 5TH day of AUGUST, 2025

Notary Public

MARLON RIVERA
Notary Public, State of Nevada
Appointment No. 24-6431-01
My Appt. Expires May 25, 2028

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Jerry Depa Pharmacist Registration #: 12508

Pharmacy Name: National Health RX

Initial each statement below to indicate you have read and agree with the following:

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

8/5/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Massimo Cavallaro

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Massimo Cavallaro

Original signature of Authorized Person (copies or stamps not accepted)

6/2/2025

Date

Board Use Only	Date Received: 6/5/25	Amount: $500 CC

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **National Health Rx LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 05/27/2025, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 05/27/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202505275749755
You may verify this certificate online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

National Health Rx LLC

Nevada Business Identification # NV20253361354
Expiration Date: 05/31/2026

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/27/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202505275749720
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Partell Pharmacy

Pharmacy/Wholesaler License # (if applicable) Current PHO2828 Requesting New

Physical Address 5835 S. Eastern Avenue STE 101

City Las Vegas State NV Zip 89119

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 408.805.0300 Website partellpharmacy.com

Licensing Company Email info@partellpharmacy.com

Section 2: Personal Information

First Mitchell Middle Dean Last Whitaker

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Prairiland High School		9/98 - 5/02	
Address	**City**	**State**	**Zip**
466 FM 196	Pattonville	TX	75468
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/20 - present	[redacted]			
7/19-9/20				
12/14-7/19				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Partell Pharmacy			12/14 - Present	
Business Address		**City**	**State**	**Zip**
5835 S. Eastern Ave ste 101		Las Vegas	NV	89119
Phone	**Title**		**Number of Employed Hours**	
928-451-6299	Operations Manager		20,800	
Description of Duties				
Manages day to day operation of the pharmacy.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Mitchell Whitaker, **certify that as the designated representative for**

Partell Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MW I am at least 21 years of age;
3. MW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Mitchell Whitaker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/2/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mitchell Whitaker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, MITCHELL WHITAKER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/2/2025

Date

Subscribed and Sworn to before me this 02 day of June, 2025. By: Mitchell Whitaker

Lolita Heer

Notary Public Signature

LOLITA HEER
Notary Public, State of Nevada
Appointment No. 20-9962-01
My Appt. Expires Feb 13, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Partell Pharmacy

Pharmacy/Wholesaler License # (if applicable) current PHO2828 requesting new

Physical Address 5835 S. Eastern Avenue ste 101

City Las Vegas State NV Zip 89119

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 408.805.0300 Website partellpharmacy.com

Licensing Company Email info@partellpharmacy.com

Section 2: Personal Information

First Jerry Middle David Last Depa

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Lane Technical High School		9/1970 - 6/1974	
Address	**City**	**State**	**Zip**
2501 W Addison St	Chicago	IL	60618
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Wilbur Wright College		8/1974 - 5/1976	
Address	**City**	**State**	**Zip**
4300 N Narragansett Ave	Chicago	IL	60634
Diploma/Degree obtained, if any			
Pre-Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Illinois at Chicago		8/1976 - 5/1977	
Address	**City**	**State**	**Zip**
1200 W Harrison St	Chicago	IL	60607
Diploma/Degree obtained, if any			
Pre-Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Iowa College of Pharmacy		8/1980 - 5/1983	
Address	**City**	**State**	**Zip**
2700 UCC	Iowa City	IA	52242
Diploma/Degree obtained, if any			
BS in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/2015 - Present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Partell Pharmacy			10/24 - Present	
Business Address		**City**	**State**	**Zip**
5835 S Eastern Ave Ste 101		Las Vegas	NV	89119
Phone	**Title**		**Number of Employed Hours**	
702-791-3800	Pharmacist		640	
Description of Duties				
Review math for compounding formulas, review prescriptions for accuracy, dosing, and allergies. Patient counseling. Accepting and discussing therapy with practitioners.				

Business Name			From - To (MM/YY – MM/YY)	
Atlas Pharmaceuticals			3/17 - 1/21	
Business Address		**City**	**State**	**Zip**
711 E Carefree Hwy		Phoenix	AZ	85085
Phone	**Title**		**Number of Employed Hours**	
844-661-1829	Pharmacist		7800	
Description of Duties				
Fulfilling office orders for sterile and non-sterile compounds. Work with the chemistry lab to process sterility, stability, and endotoxin testing. Supervise techs in compounding and clean rooms. Review formulations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Jerry Depa, **certify that as the designated representative for**

Partell Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JD I am at least 21 years of age;
3. JD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jerry Depa

Print Name (First, Last)

Jerry Depa

Original Signature (electronic, copies or stamps not accepted)

6/2/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JERRY DEPA

Print Name (First, Last)

Jerry Depa

Original Signature (electronic, copies or stamps not accepted)

6/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, JERRY DEPA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jerry Depa

Original Signature

6/2/2025

Date

Subscribed and Sworn to before me this 02 day of June, 2025 By: Jerry Depa

Lolita Heer

Notary Public Signature

LOLITA HEER
Notary Public, State of Nevada
Appointment No. 20-9962-01
My Appt. Expires Feb 13, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Partell Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Current: PHO2828 - requesting new

Physical Address: 5835 S. Eastern Avenue Ste 101

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-791-3800 Website: partellpharmacy.com

Licensing Company Email: info@partellpharmacy.com

Section 2: Personal Information

First: Massimo Middle: Luigi Last: Cavallaro

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UA Local 393		1987-1991	
Address	City	State	Zip
6299 San Ignacio Avenue	San Jose	CA	95119
Diploma/Degree obtained, if any			
Journeyman HVAC Supervisor			

School Name		From - To (MM/YY – MM/YY)	
Menlo Atherton		1971 - 1975	
Address	City	State	Zip
555 Middlefield Road	Atherton	CA	94027
Diploma/Degree obtained, if any			
High School Dipolma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/21 -current	[redacted]			
02/18-12/21				
01/71-02/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Cavallaro Investments			9/1/2021 - present	
Business Address		**City**	**State**	**Zip**
1309 Coffeen Avenue Ste 1200		Sheridan	WY	82801
Phone	**Title**			
408-805-0300	Managing Partner			
Description of Duties				
Operational management of family Investments.				

Business Name			From - To (MM/YY – MM/YY)	
Envia Systems			1/2010 - 2/2022	
Business Address		**City**	**State**	**Zip**
7979 Gateway Blvd. Ste 101		Newark	CA	94560
Phone	**Title**			
866-258-3217	Director of Operations			
Description of Duties				
Fully responsible for all aspects of new construction, renovations, modernization, maintenance, and oversight of R&D laboratories, office space, support infrastructure, and grounds.				

Business Name			From - To (MM/YY – MM/YY)	
Professional RX Pharmacy			4/17-6/19	
Business Address		**City**	**State**	**Zip**
2650 Sunset Road Ste 120		Las Vegas	NV	89120
Phone	**Title**			
NA	President/Owner			
Description of Duties				
Owned and operated retail pharmacy sold to Walgreens in 2019.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Massimo L. Cavallaro

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Manatee

I, Massimo Cavallaro, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/2/2025

Date

Subscribed and Sworn to before me this 2nd day of June 2025.

Notary Public Signature

CHRISTOPHER DAME
Notary Public-State of Florida
Commission # HH 508457
My Commission Expires
March 26, 2028

(Seal)

7B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH PH04348	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday ☒ Tuesday ☒ Wednesday ☒ Thursday	☒ Friday ☐ Saturday ☐ Sunday ☐ Holidays	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: BH Endeavors NV LLC dba Prosource Pharmacy

Physical Address: 6530 S Buffalo Dr, Ste 110

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-444-2021 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-444-2053 Contact Email: BHEndeavorsNV@gmail.com

Website: www.prosourcepharmacy.com

Nevada Business License # (if applicable) NV20243260312

Supervising/Managing Pharmacist Name (NRS 639.220): Victor Beraja

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 12967

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Victor Beraja	NV Pharmacist Registration #: 12967
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✔	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: BH Endeavors NV, LLC dba Prosource Pharmacy

Mailing Address: 6115 Keswick Ct

City: Fort Collins State: CO Zip: 80525

Telephone: 605-641-2119 Email: BHEndeavorsNV@gmail.com

Contact Person Name: Tate Berger

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Member (title) for Prosource Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Tate Berger

Print Name of Authorized Person

Tate Berger

Original signature of Authorized Person (copies or stamps not accepted)

7-25-2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Tate Berger hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Member (title) for Prosource Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Tate Berger
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25th day of JULY, 2025

Keith Leah
Notary Public

KEITH LEAH
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 08-05-27
Certificate No: 11-5485-5

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Victor Beraja Pharmacist Registration #: 12967

Pharmacy Name: Prosource Pharmacy

Initial each statement below to indicate you have read and agree with the following:

VAB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

VAB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

VAB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

VAB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

VAB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

7-25-25
Date

Section 3, Question 1

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/15/2006	4/20/2006	SD	Deadwood	Lawrence
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
40399M0600825		Lawrence County		
Reason/Charge				
vandalism				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of South Dakota				
Name of Business/Industry/Entity				

Provide explanation below:

I was leaving a restaurant with a friend and he broke a picture hanging on the wall. The police were called, and we were both charged with vandalism. My friend admitted it was him and I had nothing to do with it. The charge was dismissed.

DISMISSED - MOTION BY PROSECUTOR

Tate Berger
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

Section 3, Question 1

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/20/2001	9/12/2001	SD	Spearfish	Lawrence
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
40C01000656AO		Lawrence County		
Reason/Charge				
Driving Under the Influence/ Reckless Driving/ Obstruct Police/ Impersonation to Deceive Law Enforcement Officer				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of South Dakota				
Name of Business/Industry/Entity				

Provide explanation below:

I drove home from a night out with friends. Police officers arrived as I was walking to my apartment. I initially ran towards my apartment before stopping and talking with the police. As a result of running initially, I was charged with obstruction. When asked for ID, I inadvertently gave police my older brother's ID and was charged with impersonation. The police stated that it sounded like I was driving too fast and charged me with reckless driving. My blood alcohol was within the legal limits so DUI charges were dismissed.

Disposition: DUI - DISMISSAL - REDUCTION

Disposition: Reckless Driving - Guilty Plea - Fines Paid

Disposition: Obstruct Police - Guilty Plea - Fines Paid

Disposition: Impersonation to Deceive Law Enforcement Officer - DISMISSED - MOTION BY PROSECUTOR

Tate Berger
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

Section 3, Question 1

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/12	9/12/2001	SD	Spearfish	Lawrence
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
40C01000656AO		Lawrence County		
Reason/Charge				
Driving Under the Influence/ Reckless Driving/ Obstruct Police/ Impersonation to Deceive Law Enforcement Officer				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
State of South Dakota				
Name of Business/Industry/Entity				

Provide explanation below:

I was walking home from a night out with some friends and decided to stop at a friend's apartment on the way. I went to the wrong apartment and the police were called and I was charged with disorderly conduct.

Disposition: Guilty Plea - Fines Paid

Tate Berger
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

Section 3, Question 1

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/18/2008	06/06/2008	WY	Laramie	Albany
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
08-03760		Albany County		
Reason/Charge				
Urination in public				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of Wyoming				
Name of Business/Industry/Entity				

Provide explanation below:

Tate Bergen
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

Section 3, Question 1

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/17/2007	01/23/2008	SD	Deadwood	Lawrence
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
40C07001347AO		Lawrence County		
Reason/Charge				
Entering Property- after notice				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of South Dakota				
Name of Business/Industry/Entity				

Provide explanation below:

- I was out celebrating with friends in a nearby town and we got a hotel. I went back to the hotel early and had a room key but didn't remember the room number. My friend had booked the hotel, so my name was not on the reservation. They would not tell me the room number and asked me to leave the property. I didn't have anywhere else to go so I said I would remain until my friend arrived. They called the police and I was charged with entering and remaining after notice to leave.

Disposition: Guilty Plea - Fines Paid

Tyte Berger
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tate Berger

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Tate Berger

Original signature of Authorized Person (copies or stamps not accepted)

7-25-2025

Date

Board Use Only	Date Received: 7/28/25	Amount: $500.00

BH Endeavors NV, LLC dba Prosource Pharmacy

This Non-Publicly traded company has 2 managing members:

Tate Berger, Managing member, 50% ownership

Jessica Hopper, Managing Member, 50% ownership

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **BH Endeavors NV, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 12/21/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/21/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507215921187
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler BH Endeavors NV LLC dba Prosource Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 6530 S Buffalo Dr, Ste 110

City Las Vegas State NV Zip 89113

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-444-2021 Website www.prosourcepharmacy.com

Licensing Company Email BHEndeavorsNV@gmail.com

Section 2: Personal Information

First VICTOR Middle ALBERTO Last BERAJA

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
UNIVERSIDAD NACIONAL DE CORDOBA			03/86 – 07/91
Address	**City**	**State**	**Zip**
ARGENTINA	CORDOBA		
Diploma/Degree obtained, if any			
PHD PHARMACY-BIOCHEMISTRY			

School Name			From - To (MM/YY – MM/YY)
HIPOLITO VIEYTES			03/80 – 11/85
Address	**City**	**State**	**Zip**
ARGENTINA	BUENOS AIRES		
Diploma/Degree obtained, if any			
COMMERCIAL HIGH SCHOOL ASSOCIATE			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/97 – NOW				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
PROSOURCE PHARMACY			07/21 - 07/25
Business Address	**City**	**State**	**Zip**
6530 S. BUFFALO DR #110	LAS VEGAS	NV	89113
Phone	**Title**		**Number of Employed Hours**
702-444-2021	PHARMACY MANAGER		8,000
Description of Duties			
PIC - PHARMACY MANAGER DUTIES			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, VICTOR ALBERTO BERAJA, **certify that as the designated representative for**

BH ENDEAVORS NV LLC DBA PROSOURCE PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VAB I am at least 21 years of age;
3. VAB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VAB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VAB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VAB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VAB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

VICTOR BERAJA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-24-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

VICTOR BERAJA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-25-25

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, VICTOR BERAJA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-25-25

Date

Subscribed and Sworn to before me this 25th day of JULY, 2025

Keith Leah

Notary Public Signature

KEITH LEAH
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 08-05-27
Certificate No: 11-5485-5

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: BH Endeavors NV LLC dba Prosource Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 6530 S Buffalo Dr, Ste 110

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-444-2021 Website: www.prosourcepharmacy.com

Licensing Company Email: BHEndeavorsNV@gmail.com

Section 2: Personal Information

First: Jessica Middle: _____ Last: Hopper

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.179)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Laramie Senior High School			08/96-05/00	
Address		City	State	Zip
		Fort Collins	CO	80525
Diploma/Degree obtained, if any				
Diploma				
School Name			From - To (MM/YY – MM/YY)	
University of Wyoming			08/00-05/04	
Address		City	State	Zip
1000 E University Ave				
Diploma/Degree obtained, if any				
Bachelors Secondary Education, Bachelors Math				
School Name			From - To (MM/YY – MM/YY)	
University of Wyoming			08/08-05/12	
Address		City	State	Zip
1000 E University Ave				
Diploma/Degree obtained, if any				
Doctor of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/24-3/25	[redacted]			
7/16-1/24				
8/15-7/16				
6/14-8/15				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
BH Endeavors OKC LLC			06/23-present
Business Address	**City**	**State**	**Zip**
10717 E May Ave, Ste T	The Village	OK	73120
Phone	**Title**		
405-451-0777	Managing Member		
Description of Duties			
Financial oversight			

Business Name			From - To (MM/YY – MM/YY)
Cheyenne VA Medical Center			11/23-06/2025
Business Address	**City**	**State**	**Zip**
2360 E Pershing Blvd	Cheyenne	WY	82001
Phone	**Title**		
307-778-7550	Mental Health Clinical Pharmacy Practitioner		
Description of Duties			
Direct patient care in mental health outpatient services			

Business Name			From - To (MM/YY – MM/YY)
Phoenix VA Healthcare System			08/15-11/23
Business Address	**City**	**State**	**Zip**
650 E Indian School Rd	Phoenix	AZ	85021
Phone	**Title**		
602-277-5551	Mental Health Clinical Pharmacy Specialist		
Description of Duties			
Direct patient care in Mental health inpatient services			

Business Name			From - To (MM/YY – MM/YY)
Black Hills VA Medical Center			06/14-08/15
Business Address	**City**	**State**	**Zip**
500 N 5th st	Hot Springs	SD	57747
Phone	**Title**		
605-745-2000	Mental Health Clinical Pharmacist		
Description of Duties			
Direct patient care in Residential treatment program			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Hopper

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-25-2025

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, Jessica Hopper, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-25-2025

Date

Subscribed and Sworn to before me this 25th day of JULY, 2025

Notary Public Signature

KEITH LEAH
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 08-05-27
Certificate No: 11-5485-5

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: BH Endeavors NV LLC dba Prosource Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 6530 S Buffalo Dr, Ste 110

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-444-2021 Website: www.ProsourcePharmacy.com

Licensing Company Email: BHEndeavorsNV@gmail.com

Section 2: Personal Information

First: Tate Middle: _____ Last: Berger

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
University of Wyoming			08/07-05/12
Address	**City**	**State**	**Zip**
1000 E University Ave	Laramie	WY	82071
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name			From - To (MM/YY – MM/YY)
Black Hills State University			08/00-05/04
Address	**City**	**State**	**Zip**
1200 University St	Spearfish	SD	57799
Diploma/Degree obtained, if any			
Bachelors of Science Chemistry			

School Name			From - To (MM/YY – MM/YY)
Newcastle Highschool			08/96-05/00
Address	**City**	**State**	**Zip**
111 Casper Ave	Newcastle	WY	82701
Diploma/Degree obtained, if any			
Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/24-3/25	[redacted]			
7/16-1/24				
8/15-7/16				
6/14-8/15				
From - To (MM/YY – MM/YY)			State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: BH Endeavors OKC LLC bda Bristol Pharmacy				From - To (MM/YY – MM/YY): 06/23-present
Business Address: 10717 N May Aver, Ste D		City: The Village	State: OK	Zip: 73120
Phone: 405-451-0777	Title: Managing Member			
Description of Duties: Financial oversight				

Business Name: Safeway				From - To (MM/YY – MM/YY): 08/12-present
Business Address: 5918 Stoneridge Mall Rd		City: Pleasanton	State: CA	Zip: 94588
Phone: 925-467-3000	Title: Pharmacist			
Description of Duties: Pharmacy manager, Staff pharmacist				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✔	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/15/2006	4/20/2006	SD	Deadwood	Lawrence
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
40399M0600825		Lawrence County		
Reason/Charge				
vandalism				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
State of South Dakota				
Name of Business/Industry/Entity				

Provide explanation below:

I was leaving a restaurant with a friend and he broke a picture hanging on the wall. The police were called, and we were both charged with vandalism. My friend admitted it was him and I had nothing to do with it. The charge was dismissed.

DISMISSED - MOTION BY PROSECUTOR

Tate Berger
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/20/2001	9/12/2001	SD	Spearfish	Lawrence
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
40C01000656AO		Lawrence County		
Reason/Charge				
Driving Under the Influence/ Reckless Driving/ Obstruct Police/ Impersonation to Deceive Law Enforcement Officer				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of South Dakota				
Name of Business/Industry/Entity				

Provide explanation below:

I drove home from a night out with friends. Police officers arrived as I was walking to my apartment. I initially ran towards my apartment before stopping and talking with the police. As a result of running initially, I was charged with obstruction. When asked for ID, I inadvertently gave police my older brother's ID and was charged with impersonation. The police stated that it sounded like I was driving too fast and charged me with reckless driving. My blood alcohol was within the legal limits so DUI charges were dismissed.

Disposition: DUI - DISMISSAL - REDUCTION

Disposition: Reckless Driving - Guilty Plea - Fines Paid

Disposition: Obstruct Police - Guilty Plea - Fines Paid

Disposition: Impersonation to Deceive Law Enforcement Officer - DISMISSED - MOTION BY PROSECUTOR

Tate Berger
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/12	9/12/2001	SD	Spearfish	Lawrence
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
40C01000656AO		Lawrence County		
Reason/Charge				
Driving Under the Influence/ Reckless Driving/ Obstruct Police/ Impersonation to Deceive Law Enforcement Officer				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of South Dakota				
Name of Business/Industry/Entity				
-				

Provide explanation below:

I was walking home from a night out with some friends and decided to stop at a friend's apartment on the way. I went to the wrong apartment and the police were called and I was charged with disorderly conduct.

Disposition: Guilty Plea - Fines Paid

Tate Brogan
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/18/2008	06/06/2008	WY	Laramie	Albany
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
08-03760		Albany County		
Reason/Charge				
Urination in public				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of Wyoming				
Name of Business/Industry/Entity				

Provide explanation below:

Tate Breagen
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/17/2007	01/23/2008	SD	Deadwood	Lawrence
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
40C07001347AO		Lawrence County		
Reason/Charge				
Entering Property- after notice				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of South Dakota				
Name of Business/Industry/Entity				

Provide explanation below:

I was out celebrating with friends in a nearby town and we got a hotel. I went back to the hotel early and had a room key but didn't remember the room number. My friend had booked the hotel, so my name was not on the reservation. They would not tell me the room number and asked me to leave the property. I didn't have anywhere else to go so I said I would remain until my friend arrived. They called the police and I was charged with entering and remaining after notice to leave.

Disposition: Guilty Plea - Fines Paid

Tate Berger
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tate Berger
Print Name (First, Last)

Tate Berger
Original Signature (electronic, copies or stamps not accepted)

7-25-2025
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Tate Berger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Tate Berger
Original Signature

7-25-2025
Date

Subscribed and Sworn to before me this 25th day of JULY 2025

Keith Leah
Notary Public Signature

KEITH LEAH
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 08-05-27
Certificate No: 11-5485-5

(Seal)

8

8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Y

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH PH03822	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FA4009090 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Avrio Pharmacy

Physical Address: 9015 E Pima Center Parkway, Suite 3

City: Scottsdale State: Arizona Zip: 85258

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (480) 270-6700 Toll Free # (NAC 639.708, NRS 639.23286): (844) 310-6700

Fax: (480) 270-6701 Contact Email: info@avriorx.com

Website: www.avriorx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Hanna Johnson

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22529

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Hanna Johnson	NV Pharmacist Registration #: 22529
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	✓	

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Arizona

Parent Company (if any): _____

Corporation/Organization Name: All-Care Pharmacy LLC

Mailing Address: 9015 E Pima Center Parkway, suite 3

City: Scottsdale State: Arizona Zip: 85258

Telephone: (480) 270-6700 Email: info@avriorx.com

Contact Person Name: Keith Barron

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PIC (title) for Avrio Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Hanna Johnson

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

5/13/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Keith Barran

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6/16/2025

Date

Board Use Only	Date Received: 6/23/25	Amount: $500 - CK 1152

Avrio Pharmacy, Section 3, History of Company, Explanation regarding Affirmative Responses

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?

Avrio Pharmacy's ("Avrio's") affirmative response to this question results solely from the conviction against Avrio's prior owner, Mr. Raef Hamaed in *United States v. Abdallah*, et al., No. 20-CR-20162. The new owner, Salim Soufan, has not been charged or convicted of a felony or gross misdemeanor. Mr. Hamaed previously notified the Nevada Board of Pharmacy of his indictment and the pending charges on June 19, 2020. Mr. Hamaed was found guilty of conspiracy to commit health care fraud and wire fraud on September 5, 2024, in the United States District Court Eastern District of Michigan. This conviction results from Mr. Hamaed's ownership interest in other pharmacies, not the applicant, Avrio Pharmacy. Mr. Hamaed is in the final stages of selling his interest in Avrio and surrendering his pharmacist license in all states where he previously held a license.

Raef Hamaed

6-16-25

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?

Due to Mr. Hamaed's conviction, as explained above, the pharmacy is in the process of resolving a complaint with the Nevada Board of Pharmacy. We provide the below explanations in an abundance of caution and for transparency with the Board. Currently, the Pharmacy has not surrendered, voluntarily or otherwise, any of its licenses.

- The Nevada State Board of Pharmacy filed that certain Notice of Intended Action and Accusation against Avrio Pharmacy, Case No. 20-198-PH-S. According to communications with the Board's General Counsel, it is our understanding that the Nevada Board of Pharmacy will review this change of ownership application and, if approved, dismiss the complaint against the pharmacy.
- On April 10, 2025, the Florida State Board of Pharmacy notified Avrio that it is statutorily required to deny any renewals of entities with owners/principals who have been convicted of a felony under Fla. Stat. Ann. § 456.0635(3)(a). However, the Florida Board of Pharmacy stated that, given the change of ownership, the renewal application would be held for two weeks and that, during this time, a formal denial will not be entered, and Avrio may continue to ship to and serve patients in Florida with a permit status of "Delinquent". The pharmacy's license will remain delinquent until the change of ownership is approved. Additionally, the Board advised that while the change of ownership is being processed, Avrio may apply for a new non-resident pharmacy permit with Mr. Soufan listed as the owner. The new non-resident pharmacy permit was granted on April 22, 2025.

Furthermore, Mr. Hamaed, Avrio's prior owner, was a licensed pharmacist in numerous states. He is in the process of voluntarily surrendering his license, or having those licenses revoked. This includes:

- Arizona pharmacist license number, S016023, was revoked by the Arizona Board of Pharmacy.
- Florida pharmacist license number, PS42036, was voluntarily surrendered on March 4, 2025. The Florida Board of Pharmacy is scheduled to approve the voluntary relinquishment order on June 12, 2025.
- Michigan pharmacist license number, 5302030019, was voluntarily surrendered on March 7, 2025. The Michigan Board of Pharmacy is scheduled to approve the consent order for the surrender on June 18, 2025.
- Oregon pharmacist license number, RPH-0016422, was voluntarily surrendered on March 7, 2025. The Ohio Board of Pharmacy executed the consent order for surrender on March 26, 2025.

We provide you with these disclosures in full transparency. The pharmacy and the new owner, Salim Soufan, have not surrendered a license, permit or certificate of registration, voluntarily or otherwise.

AVRIO PHARMACY

Your Healthcare Partner

May 13th, 2025

The following is the information related to the ownership and management of All-Care Pharmacy LLC DBA Avrio Pharmacy.

Salim Soufan, RPh
Sole Member
Percent of ownership: 100%

Keith Barron, PharmD
President

Hanna Johnson, PharmD
PIC

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

All-Care Pharmacy LLC

ACC file number: L18510153

was incorporated under the laws of the State of Arizona on 06/03/2013, and that, according to the records of the Arizona Corporation Commission, said limited liability company is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **02/17/2025**

Douglas R. Clark, Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler All-Care Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable) PH03822

Physical Address 9015 E Pima Center Parkway, Suite 3

City Scottsdale State AZ Zip 85258

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 480-270-6700 Website www.avriorx.com

Licensing Company Email info@avriorx.com

Section 2: Personal Information

First Keith Middle Andrew Last Barron

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh School of Pharmacy		08/06-04/10	
Address	**City**	**State**	**Zip**
3501 Terrace Street	Pittsburgh	PA	15261
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh		08/04-04/06	
Address	**City**	**State**	**Zip**
4200 Fifth Ave	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Undergrad Pre-requisites for PharmD program - no degree			

School Name		From - To (MM/YY – MM/YY)	
Avon Grove High School		09-00-06-04	
Address	**City**	**State**	**Zip**
10 Waltman Way	West Grove	PA	19390
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/13- current	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
All-Care Pharmacy, LLC			01/18-current	
Business Address		**City**	**State**	**Zip**
9015 E Pima Center Parkway, Suite 3		Scottsdale	AZ	85258
Phone	**Title**		**Number of Employed Hours**	
480-270-6700	Pharmacist / President		>15,000	
Description of Duties				
Pharmacist and now President of operations with day to day managing of pharmacy operation.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Keith A Barron, **certify that as the designated representative for**

All-Care Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. x I am at least 21 years of age;
3. x I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. x I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. x I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. x I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. x I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Keith, Barron

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/12/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Keith, Barron

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/12/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Keith Barron, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/12/2025

Date

Subscribed and sworn to before me this 12TH day of JUNE, 2025

Notary Public Signature

SCOTT WEIRBACK
Notary Public
STATE OF THE STATE OF ARIZONA
Commission # 606452
My Comm. Expires July 09, 2025
MARICOPA COUNTY, ARIZONA
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Avrio Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH03822

Physical Address: 9015 E Pima Center Parkway , Suite 3

City: Scottsdale State: Arizona Zip: 85258

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (480) 270-6700 Website: www.avriorx.com

Licensing Company Email: info@avriorx.com

Section 2: Personal Information

First: Salim Middle: Last: Soufan

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

SS

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Ferris State University			8/1999 – 5/2002
Address	**City**	**State**	**Zip**
1201 S. State St,	Big Rapids	MI	49307
Diploma/Degree obtained, if any			
Bachelor in science (Pharmacy)			

School Name			From - To (MM/YY – MM/YY)
Henry Ford College			1/97 – 5/99
Address	**City**	**State**	**Zip**
5101 Evergreen Rd	Dearborn	MI	48128
Diploma/Degree obtained, if any			
All Pharmacy Pre-Requisite to Ferris State University School of Pharmacy.			

School Name			From - To (MM/YY – MM/YY)
Institute of Science of Beirut Highschool			10/1992 – 6/1995
Address	**City**	**State**	**Zip**
Airport Route Blvd	Beirut	Lebanon	
Diploma/Degree obtained, if any			
Highschool.			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2016 – Current	[redacted]			
1/2011 – 10/2016				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
WEST PALM PHARMACY			10/2011 – Current	
Business Address	**City**		**State**	**Zip**
5760 Okeechobee Blvd	West Palm Beach		FL	33417
Phone	**Title**			
561-249-2130	Owner / Pharmacist.			
Description of Duties				
Retail Pharmacist.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

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Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

SS

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

salim soufan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/14/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, salim soufan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/14/2025

Date

Subscribed and Sworn to before me this 14th day of June 2025.

Notary Public Signature

Langston M Childs
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 22447701
Expires June 21, 2026

State of Nevada

County of Clark

This instrument was acknowledged before me (Seal)
on 06/14/2025 by salim soufan.

Notarized remotely using audio-video communication technology via Proof.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Avrio Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): PH03822

Physical Address: 9015 E Pima Center Pkwy #3

City: Scottsdale State: AZ Zip: 85258

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 480-270-6700 Toll Free # (NAC 639.708, NRS 639.23286): 844-310-6700

Fax: 480-270-6701 Contact Email: info@avriorx.com

Website: avriorx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Hanna Johnson

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22529

Name of Designated Person(s) as defined by revised USP-797 guidelines: Hanna Johnson

Email of Designated Person(s): hanna@avriorx.com

Telephone of Designated Person(s): 480-270-6700

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ■ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 2/6/2025

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? We complete surface sampling weekly

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Tacrolimus 0.03% eye drops (veterinary)
Cyclosporine 2% eye drops (veterinary)
Idoxuridine 0.1% eye drops (veterinary)
Cidofovir 0.5% eye drops (veterinary)
Demecarium Bromide 0.125% eye drops (veterinary)
Progesterone 50mg/ml in ethyl oleat inj
Tirzepatide/Cyanocobalamin 10mg/500mcg/ml inj
Semaglutide/Methylcobalamin 5mg/1mg/ml inj

12. What laboratory performs your sterility or endotoxin testing?

Name: Pharmetric Lab

Address: 7265 Ulmerton Rd

City: Largo State: FL Zip: 33771

Telephone: 727-209-5778

13. What is your procedure for visual inspection of compounded sterile products?

Wipe the container closure system with a damp, lint-free wipe to remove any external particles.
Gently agitate and/or swirl the CSP, with a light source shining behind or under the CSP and hold in front of both a black and white background.
Observe for color, clarity, precipitate/foreign matter, phase separation, etc. Use magnifying glass if needed.
Reject CSP if any deviations are observed and document results

14. How often do you perform glove fingertip and medial fill testing?

Every 3 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Please see SOP 3.4.2 attached

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

C-PEC is cleaned with Peridox before and after compounding daily, followed by sIPA (when being used). Floors are cleaned daily after use with Peridox.
C-PEC and C-SEC are cleaned monthly using Peridox, followed by sIPA (after the proper dwell time).

17. Who performs the sterile compounding process at your facility?

Sterile technician and sterile pharmacist

18. Who is responsible and accountable for the sterile compounding process at your facility?

PIC - Hanna Johnson

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Products are shipped using priority mail (usps or fed ex) to get to patients in a timely manner. Refrigerated or cold chain products are packaged appropriately with ice and shipped overnight to get to patients.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? BSC		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

All HD drug products are labeled to alert the public that it is a hazardous drug.
Auxiliary label(s) state:
1. Hazardous Drug
2. CAUTION: Follow procedures for proper handling and disposal of hazardous drugs.
In addition, anti-neoplastic medications, the final container is placed into a yellow bag prior to packaging with alert labels.

Additional Information to the consumer:

To dispose of the hazardous medication, keep the medication inside of it's original container (remove identifiable patient information from the label) and place into a seal-able bag (like a zipper storage bag) or container and dispose of in regular trash. Follow your state or local laws if more stringent. You may also find additional information on drug take back days and other disposal options on the FDA website here:
https://www.fda.gov/consumers/consumer-updates/where-and-how-dispose-unused-medicines

In addition, if the medication is for a veterinary patient it may read "x medication" and its byproducts can be hazardous to other animals and people that come in contact with it. Therefore, all bodily waste (urine, feces, litter), blood, or vomit should only be handled while wearing disposable gloves. Seal the waste in a plastic bag and then place both the bag and gloves in with the regular trash. Contact your pharmacist for additional precautionary information.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

The initial process for training new employees for compounding sterile hazardous drugs are the same from section 2, question 15, with the addition of extra training. Extra training includes competencies and sign off of handling of hazardous drugs, receipt and storage, spills, breakages, exposure, and additional requirements for PPE.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Tacrolimus 0.03% eye drops (veterinary)
Cyclosporine 2% eye drops (veterinary)
Progesterone 50mg/ml in ethyl oleate inj
Tirzepatide/Cyanocobalamin 10mg/500mcg/ml inj
Semaglutide/Methylcobalamin 5mg/1mg/ml inj

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Every 3 months

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

Monthly

5. What is the frequency for completing surface sampling? Weekly		
6. What is the frequency for using sporicidal agents? Weekly		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?**we are in process of getting stability data and therefore will only be dispensing based on Category 2 until we have all documentation.	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hanna Johnson

Name of Person who Completed the Form

Pharmacist In charge

Title

Signature (copies or stamps not accepted)

6/16/25

Date

Board Use Only	Date Received: 6/23/25 Date Approved: _____ Approved By: _____

1. Overview and Scope

1.1 This policy serves as the written Sterile Compounding Training and Evaluation Program for Avrio pharmacy and describes the procedures for training and evaluating sterile practice knowledge and competencies of personnel involved in or having direct oversight of compounded sterile preparations (CSPs).

1.2 The Sterile Compounding Training & Competency Program equips compounding personnel with the didactic knowledge and practical training in the foundational principles of sterile compounding. Competency evaluations validate proficiency in the required skills necessary to perform related job functions and maintain the quality of the sterile environment. The Program consists of initial and ongoing training and evaluation in the following areas:

Sterile Compounding Core Competencies and Principles Knowledge - demonstrates Compounding Personnel possess the knowledge of and proficiency in the skills necessary to perform sterile manipulations and achieve and maintain appropriate environmental conditions.

Hand Hygiene and Garbing Competency (including Gloved Fingertip and Thumb Sampling) - ensures Compounding Personnel can safely and effectively complete hand hygiene, garbing, and donning of gloves without touch contamination.

Aseptic Manipulation Competency (including Media Fill) - validates Compounding Personnel aseptic technique and related manipulations within an ISO 5 compounding environment.

1.3. The USP Expert Committee has recognized an effective sterile compounding practice involves personnel, vendors, and other visitors that are not directly compounding or performing compounding related activities. Consequently, training and evaluation requirements are defined based on role and potential risk for contaminating the sterile compounding areas.

Compounding Personnel – individuals performing or directly overseeing compounding activities as well as the Designated Person(s)

Other Personnel & Visitors – individuals who have a need to enter compounding areas (under supervision) but do not participate in or support the compounding activities in any way

2. Policy

2.1. Compounding and supporting personnel successfully complete training and demonstrate knowledge of and proficiency in all of the skills and competencies necessary maintain the quality of the compounding environment and perform job-related functions *before* compounding CSPs, supervising, or performing support-related activities independently and complete refresher training and requalification as outlined below; adapted from USP <797> Tables 2 & 3.

Personnel Function	Training & Competency in Maintaining Quality of Compounding Environment	Training & Competency in Sterile Compounding Principles & Practices	Hand Hygiene & Garbing Competency* *(Including GFT)*	Aseptic Manipulation Competency* *(Including Media Fill, Post-GFT, and Surface Sample)*
Compounding Personnel: Personnel compounding or with direct oversight of compounding personnel & activities				
Compounder	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 3 months	Initially & Every 3 months
Designated Person(s)	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months
Assigned Trainer(s)	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months
Personnel with Direct Oversight of Compounding Personnel	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months

Knowledge and Core Skill Competencies:

2.2 Compounding personnel involved in or having direct oversight of compounding CSPs ("Compounding Personnel") as well as the Designated Person(s) and Assigned Trainer(s) (AT) complete training and evaluation in core competencies, skills, and sterile practice principles including, but not limited to:

Sterile core competencies and skills in maintaining the quality of the sterile compounding environment including, but not limited to:

- Hand hygiene
- Garbing
- Cleaning and disinfection
- Calculations, measuring, and mixing
- Aseptic technique
- Achieving and/or maintaining sterility (and apyrogenicity if compounding with non-sterile components)
- Use of equipment
- Documentation of the compounding process (e.g., master formulation and compounding records)
- Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
- Proper use of primary engineering controls (PECs)
- Principles of movement of materials and personnel within the compounding area

Sterile compounding principles and practices including, but not limited to:

- *USP <797> Pharmaceutical Compounding –Sterile Preparations*, other applicable standards, and relevant literature.

- Avrio Pharmacy's policies and procedures related to sterile compounding and related job duties.
- Beyond use dating, packaging, storage, and labeling of CSPs
- Quality assurance and quality control procedures (including release inspections and tests if applicable)

2.3 The Designated Person(s) assigns the role of Assigned Trainer (AT) to personnel who are responsible for or assist in training and evaluating competency of compounding personnel.

2.4 Core skills, competencies, and knowledge are assessed with hands-on demonstration of skill under direct observation by a DP or AT and sterile principles knowledge is assessed via written or electronic examination.

2.5 Successful or "passing" results for the Sterile Core Competencies and Knowledge Assessment are:

Observation	**Validation**	**Initial** Prior to Compounding Independently	**Ongoing** Every 12 Months
Competency-based checklist with 100% proficiency	USP <797> & Sterile Principles Knowledge Exam	≥ 80% cumulative score	≥ 80% cumulative score

Hand Hygiene and Garbing Competency:

2.6 Hand hygiene and garbing competencies are assessed with hands-on demonstration of skill under direct observation by a DP or AT and validated via the Gloved Fingertip and Thumb Sampling Assessment.

- **Initial Gloved Fingertip and Thumb Sampling Assessment (GFS):** successfully completed three separate times prior to compounding independently; each GFS is conducted separately after a completing the hand hygiene and garbing procedure
- **Ongoing Gloved Fingertip and Thumb Sampling Assessments:** successfully completed at least once every 3 months for Compounding Personnel requalification

2.7 Successful or "passing" results for the Hand Hygiene and Garbing Competency are:

Observation	**Validation**	**Initial** Prior to Compounding Independently	**Ongoing** Every 3 Months
Competency-based checklist with 100% proficiency	Gloved fingertip assessment	3 separate assessments • 6 total plates (1 plate per hand per assessment) 7-day incubation with zero (0) CFUs	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with zero (0) CFUs

Microbial identification of cultured CFU(s) is not required for Gloved Fingertip and Thumb Sampling.

Aseptic Manipulation Competency:

2.9 The Aseptic Manipulation Competency is administered, observed, and documented by the DP or AT and consists of four components:

- Media Fill Testing
- Direct visual observation of aseptic technique and manipulations
- Gloved Fingertip and Thumb Sampling of both hands *after* the media fill test
- Surface Sampling of the Direct Compounding Area (DCA) *after* the media fill test

2.10 The Media Fill Test(s) simulates the most difficult and challenging compounding procedure(s), compounding environments, and processing condition(s). Refer to References and Media Fill documents in Simplifi797.

2.11 Successful or "passing" results for the Initial and Ongoing Aseptic Manipulations Competency is as follows:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 3 Months
Competency-based checklist with 100% proficiency	Media Fill	1 assessment 14-day incubation with no growth or turbidity	1 assessment 14-day incubation with no growth or turbidity
	Post Media Fill Gloved fingertip assessment	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with ≤ 3 CFU combined (total)	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with ≤ 3 CFU combined (total)
	Surface sample	1 sample of direct compounding area (DCA) 7-day incubation with ≤ 3 CFU	1 sample of DCA 7-day incubation with ≤ 3 CFU

2.11 If any portion of the Hand Hygiene and Garbing or Aseptic Manipulations Competency does not meet the minimum passing result, the respective Competency is repeated in its entirety. Failures in other Core Competencies are repeated individually. Documentation of the failure, corrective actions, and the repeated competency results is retained and readily accessible.

2.12 In the event of a repeated, sequential failures of Core Competencies, Hand Hygiene and Garbing Competency, and/or Aseptic Manipulations Competency, corrective action plans are implemented that are consistent with Board of Pharmacy requirements and under the review and discretion of the DP. Patterns of competency failures over time are assessed on a case-by-case basis.

	Initial	Ongoing
1st Failure	• Coaching and retraining • Repeat failed competency ***STATUS: Independent compounding not allowed until all competencies are successfully completed.***	• Coaching • Repeat failed competency ***STATUS: Allowed to continue with compounding duties while results pending.***
2nd Failure	• Extensive skills and foundation knowledge retraining • Repeat failed competency ***STATUS: Independent compounding is not allowed. If passed, consider increased competency assessment requirements (e.g. every month for 3 months).***	• Skills and foundational knowledge retraining • Repeat failed competency ***STATUS: Independent compounding is not allowed; reassign to non-compounding duties while results pending.***
3rd Failure	• Reassign to non-compounding role; consider referral to HR. ***STATUS: Reassigned outside of sterile compounding practice.***	• Reassign to non-compounding role, consider referral to HR. ***STATUS: Future sterile training requires completion of initial training and competency requirements and increased competency assessments.***

2.13 Other personnel or visitors who do not undergo training and evaluation in core competencies, skills, or knowledge required to maintain the quality of the sterile compounding environment, are required to, at a minimum:

- Adhere to all aspects of the Hand Hygiene and Garbing policy and procedure,
  Comply with proper materials movement and cleaning procedures
- Only enter a controlled compounding area under direct supervision of the DP or designee
  Minimize movement within the controlled areas and contact with any surfaces

2.14 Compounding personnel performing specialized roles and responsibilities within the sterile practice complete initial training and knowledge assessments before performing these tasks independently. Training and evaluation are administered and documented by the DP. Ongoing reeducation and assessment in these specialized skills is conducted at least every 12 months.

3. Roles & Responsibilities

3.1 The Designated Person(s) (DP):

- Oversees the Sterile Training and Evaluation Program for Compounding Personnel and supporting personnel involved in or supporting compounding activities.
- Reviews competency results, evaluation and determination of corrective actions, and monitors for longer-term trends with Compounding Personnel Competency performance.
- Ensures non-compounding personnel and visitors who enter the sterile compounding area and/or handle CSPs understand the expectations appropriate to their role or are directly observed to ensure compliance and minimize impact to the quality of the sterile environment.

- May designate and qualify an Assigned Trainer(s) (AT) to assist with the training, evaluation, and competency administration process.
- May define additional training and competency evaluation requirements for compounding personnel performing specialized roles or responsibilities.

3.2 Compounding personnel and supporting roles:

- Successfully complete assigned training and demonstrate proficiency via competency assessment on a timely basis and before the evaluation activities are past due.
- Uphold sterile practice and quality standards to help ensure the quality of the sterile compounding area.

4. Procedures

4.1 Sterile Compounding Knowledge, Skills and Core Competency Assessment

DP or AT directly observes Compounding Personnel performing the Core Competencies and Skills (refer to Sections 2.2 and 2.3) and records results on the forms found in Simplifi797.

Core competency evaluation can be completed in a single or multiple observed sessions. If the process is completed in separate sessions, documentation reflects the date, time, and initials of the DP or AT performing and evaluating the specific competencies.

Competencies for hand hygiene, garbing, and aseptic technique can be conducted concurrently with the respective competency assessment. Observations and evaluations of each competency are clearly documented on the respective competency form.

4.2 Documentation of the Hand Hygiene and Garbing and Aseptic Manipulation Competencies includes, at a minimum:

- Name of person evaluated
- Evaluation date and time
- Media and component manufacturer, lot, and expiration date
- Incubation temperatures
- Dates of Incubation
- Competency results
- Name of competency observer and individual(s) reading and documenting results
- Corrective actions (if needed)

4.3 Garbing Competency and Gloved Fingertip and Thumb Sampling Assessment Procedure

- Remove sampling plates (or alternative sampling device) from refrigerator in manufacturer's overwrap and check expiration dates; do not use expired media.
- Collect other supplies needed including black, fine tipped permanent marker. Disinfect with sIPA, and move supplies to controlled environment.
- Allow sampling plates to come to room temperature just prior to sampling.
- Enter media lot numbers, expiration dates, and manufacturer on the GFS Competency Form.
- DP or AT labels the base (i.e. agar side) of the sampling plates legibly around the outer edge. Label each sample plate with sample type (e.g. "GFS"), hand (e.g., "L" -left or "R"

- right), sample number (e.g., 1, 2, or 3) for initial competency, date, and initials of individual.
- Complete hand hygiene and garbing under direct observation.

GFS:

- Don sterile gloves but do NOT apply sIPA to gloved hands.
- DP or AT sanitizes sterile gloves with sIPA, removes the lid of a labeled sampling plate, and holds vertically.
- Compounding personnel gently rolls the pad of each finger, one at a time, in an arch across the top of the agar surface ensuring not to overlap fingerprints. A thumb print is then gently placed in the middle of the plate.
- The lid is immediately replaced, and the sample is set to the side.
- Repeat sampling process for the second hand; ensure the correctly labeled plate is used.
- Immediately, after both hands have been sampled and without touching any surfaces, complete the garb doffing process.
- *During the Initial GFT competency assessment*, repeat the entire process two more times.
- After all samples are collected, seal plates to ensure the lid is not dislodged during transit, incubation, or results inspection.

4.3 Aseptic Manipulation Competency Procedure (including Media Fill and Post Media Fill Gloved Fingertip and Surface Sampling)

- Collect supplies needed for the media fill testing, post media fill GFS (2 plates per media fill test), and surface sampling (1 plate per media fill test). Collect all supplies necessary to complete media fill such as vials, TSA, syringes, needles, thin black permanent marker.
- Check all growth media components for expiration date. Do not use expired media. Allow sampling plates to come to room temperature just prior to sampling.
- Inspect all sterile media fill components for cracks, leaks, or other potential factors that may have compromised product's sterility. Do not use media suspected of contamination or sterile container defects.
- Disinfect all media and supplies with sIPA, and move supplies to controlled environment.
- Enter media lot numbers, expiration dates, and manufacturers on the competency form found in Simplifi797.

DP or AT labels the base (i.e. agar side) of the sampling plates legibly around the outer edge (or permanently affixed lid on slide or paddle) and the final dosage unit(s) for the media fill test. Label each sample with sample type (e.g. "MF", "PMF-GFS", or "SS"), hand (e.g., "L" -left or "R" - right), date, and initials of individual.

Stage all media and supplies within reach of Primary Engineering Control (PEC).

Disinfect gloved hands and all components with sIPA prior to being moved into the ISO Class 5 area of the PEC.

Perform media fill under direct observation per procedure.

sIPA is used throughout the media fill process to sanitize sterile gloves, critical sites, and the direct compounding area; however, do not apply sIPA to gloved hands or the DCA after the final step of the media fill procedure.

Nonsterile solutions are reconstituted and manipulated in a manner that simulates typical nonsterile-to-sterile compounding activities.

- Commercially available nonsterile soybean–casein digest powder is dissolved in non-bacteriostatic water creating a 3% nonsterile solution as part of the procedure.
- At least 1 container of non-sterile broth is compounded and incubated as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation.
- Retain sterilizing filter for bubble point testing and filter packaging displaying the lot and expiration of the filter to record on and/or affix to the media fill records.

Immediately following the final step of the media fill procedure and before sIPA is applied to gloved hands or the DCA:

- DP or AT performs the post media fill GFS (PMF-GFS) and DCA surface sample *inside* the ISO 5 PEC. GFS sampling is performed for both hands with one plate per hand. Refer to the GFS sampling procedures above.

After all samples are collected and removed from the PEC, seal plates to ensure the lid is not dislodged during transit or incubation and results inspection.

Perform a bubble point test on the sterilizing filter and record both the expected and achieved PSI on the Media Fill form.

- If the sterilizing filter does not pass the bubble point test, the media is considered non-sterile and is resterilized inside an ISO 5 PEC with a new sterilizing filter. The new filter undergoes bubble point testing and PSI results are recorded.

Remove all other trash from the PEC and clean and disinfect PEC prior to commencing compounding.

Remove and replace sterile gloves immediately without touching any other surfaces; gloves are contaminated with growth medium. Repeat hand hygiene and garbing prior to returning to compounding activities.

4.4 Selection, Incubation, & Interpretation of Media

Media Selection:

Select a general microbial growth agar (plate, paddle, or slide) supporting both bacterial and fungal growth, such as trypticase soy agar (TSA), for gloved fingertip and surface sampling. Growth medium contains additives that neutralize residual cleaning solutions, such as lecithin and polysorbate 80.

For media fill procedures, replace all CSP components with soybean–casein digest media components.

Obtain a Certificate of Analysis (COA) from the growth media supplier or manufacturer. The DP reviews and retains the COA to ensure the culture media supports growth of microorganisms (as defined in Table 1 of USP <71>). Store media per manufacturer

instructions and media is used in accordance with manufacturer instructions and before the expiration date of the media.

Media Incubation & Interpretation:

Locate calibrated incubators monitored by NIST certified temperature gauge outside of the sterile compounding area. A minimum of two incubators are available:

- Incubator 1: calibrated and maintained at 20 to 25°C
- Incubator 2: calibrated and maintained at 30 to 35°C

Invert gloved fingertip and surface sample agar plates during incubation to ensure moisture condensation does not collect and fall onto the agar surface which can contaminate and/or invalidate the results.

Incubation temperatures and timeframes:

Competency	Media	1st Incubation	2nd Incubation	Total Incubation Timeframe
Gloved fingertip and surface samples	TSA agar plate, paddle or slide with polysorbate 80 & lecithin (neutralizers)	≥ 48 hours at 30°C - 35°C	≥ 5 Days at 20°C - 25°C	≥ 7 Days
Media fill test final dose unit(s)	Soybean casein digest (all components)	7 Days at 20°C - 25°C	7 Days at 30°C - 35°C	14 Days

Only the DP who is qualified to manage, read, and interpret media places or moves media into and out of incubators.

Record date, time, incubator temperature, and person(s) moving media into and between incubators on competency form(s).

Read and record CFU counts per sampling plate and examine media fill bags/units for visible changes daily or, at a minimum, when media are moved from the first to the second incubator. Record interim results on competency form(s).

Read and record CFU counts per sampling plate at the conclusion of the full incubation; total CFU counts from all plates to determine the final CFU count results. Record results on the competency form(s).

Examine the media fill bag/units for any visible turbidity or changes indicating growth at the conclusion of the full incubation against a white and black background in a well-lit area, record either a pass or failed result on the Media Fill form.

4.5 Corrective Action for Competency Failure

Any personnel failing to demonstrate competency during a foundational knowledge exam or hands-on skills assessment is coached and reinstructed on the applicable policy, technique(s), and foundational knowledge related to the skill; and subsequently re-evaluated by the DP or AT.

Evaluation and corrective action for observed competencies is documented within the competency form. Corrective action records are used for long-term assessment of personnel competency and potential contributing factors to maintaining a state of microbial control within the sterile compounding environment.

4.6 Extended Absence or Frequency of Compounding

If personnel are not actively engaged in CSP activities for 12 months or are on extended leave during the time their observed competencies are due, initial training and competency is assigned upon their return.

Initial training and competency assessments are completed before re-entry to CSP activities and compounding independently.

4.7 Ongoing Training

The DP is responsible for assessing the training needs of personnel and the appropriate method for communication and delivery as new or updated equipment, components, recipes, or procedures are introduced.

4.8 Monitoring of Compounding Activities

The DP conducts tracer observations of CSP personnel and processes.

If deficient practices are observed, the DP discusses the following with the personnel:

- Identify the issue(s) observed.
- Review and reinstruct on the expected practice.
- Confirm understanding with a return demonstration or teach back method.

5. Definitions

5.1 Assigned Trainer (AT): One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation and/or evaluation of personnel for the preparations of CSPs.

5.2 **CSP:** compounded sterile preparation

5.3 **Designated Person (DP):** is one ore more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.

5.4 **Direct Compounding Area (DCA):** A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air

5.5 **Laminar airflow workbench (LAFW):** An LAFW is a device that provides an ISO Class 5 or better environment for sterile compounding. The LAFW provides either horizontal or vertical unidirectional HEPA-filtered airflow.

5.6 **Media-fill test:** A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.

5.7 **Primary Engineering Control (PEC)**: A device or zone that provides an ISO Class 5 air quality environment for sterile compounding. (Ex: LAFW, BSC, RABS, CAI, CACI)

5.8 **sIPA:** sterile 70% isopropyl alcohol.

5.9 **Secondary Engineering Control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

5.10 **Segregated Compounding Area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2 United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

6.3 United States Pharmacopeial Convention, Inc. <71> Sterility Tests, Culture Media, and Incubation Temperatures, Growth Promotion Test of Aerobes, Anaerobes, and Fungi. current version.

7. Approval and Review Summary

7.1 Initial version published by Wolters Kluwer 2022.

Version #	Revise Date:	Approved By:	Description of Revision
1.0	10/18/2024	Hanna Johnson	New Chapter

Approval History

Approval date	10/18/2024			
Approved by	Hanna Johnson			

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

DEMOGRAPHICS

AZ permit# : Y005679	AZ Permit Exp.Date : 10/31/2025	Business Name : All-Care Pharmacy, LLC D/B/A Avrio Pharmacy
Address : 9015 E Pima Center Parkway STE 3		
Zip : 85258	City : Scottsdale	State : AZ
Phone : (480) 270-6700	Fax : (480) 270-6701	Email : hanna@avriorx.com
Inspection Date : 10/31/2024	PIC : Hanna Johnson	Pic License Exp Date : 10/31/2026
DEA # : FA4009090	DEA # Exp. date : 06/30/2025	Inspection Reviewed With : Hanna Johnson, Keith Barron
Reviewers License# : S021380 (HJ) and S017978 (KB)	Inspection type : Routine	

Inspection Conducted By : Dennis Waggoner

Facility Data

# Rxs/Week	RPh Hours/Week	# Rxs/Hours
1300	200	6.5

PERMITS

1	Arizona	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1933(A); R4-23-606(A)
2	DEA	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 36-2522(A)(2); 21 CFR 1301.35(c)

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3	Suppliers	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1929; R4-23-601(A); R4-23-604(A); R4-23-605(A); R4-23-607(A)

LICENSES

1	Pharmacists	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1925(A); R4-23-201(A)
2	Interns / Graduate interns	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1923(B); R4-23-301(G)
3	Technicians / Trainees	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1925(A); R4-23-1101(A); R4-23-1102(D); R4-23-1103(B)(2)
4	Current renewal licenses maintained	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1933(B)

PHARMACY

1	Drug storage and security	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-609(G)(H)
2	Personnel and security procedures	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-610
3	Facilities	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-611(A)
4	Drug supply	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-611(B)
5	Quarantine expired drugs	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-611(B)(4)

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6	Equipment	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-612
7	Policies and procedures Must maintain documentation of the biennial review.	☐ S ☑ N/I ☐ V ☐ N/A	R4-23-610(A); R4-23-611(B)

TECHNICIANS

1	Training program	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1105(B)(D)
2	Training program - compounds	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1105(C)
3	Activities - trainees	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1104(A)
4	Activities - technicians	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1104(A)(B)
5	Policies and procedures	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1104(F)(G)

COUNSELING

1	Documentation	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(G)(H)
2	Oral consultation	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-402(C)(D)(E)
3	Written information	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(C)(I)

PRESCRIPTION AUDIT

1	Prescription files	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1964; ARS § 36-2525(C)(1)(2)
2	Prescription label	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968(D); ARS § 36-2525(L)
3	CII prescriptions No C2 prescriptions.	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1968; 36-2525(A) to (G); R4-23-407(A)
4	CIII - CV prescriptions	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968; 36-2525(A)(C)(2)(H)(I); R4-23-407(A)
5	Non-controlled prescriptions	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968; R4-23-407(A)
6	Transfers	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-407(D)
7	Telephone	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968(A)(5); R4-23-402(A)(1)(2)
8	Refill authorizations	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968(A)(6); R4-23-402(A)(13); R4-23-407(E)(5)
9	Facsimile	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-407(E)
10	Electronically transmitted	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-407(F); R4-23-408(H)

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11	Patient information	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(A)(3)(4)
12	Allergies / medical conditions	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(A)(3)(b)
13	Brand / generic	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1963.01
14	Foreign prescriptions	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1969
15	Prescription blank advertising prohibited Reminder - no identifying information (ie phone/fax number) on preprinted prescription forms.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-404(B); ARS § 32-1901.01(B)(25)
16	Prescription audit numbers C3-5: 460000-460999, Rx: random eRx reviewed		

COMPUTER REQUIREMENTS

1	Security	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(F)
2	Log books / printout	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(C)(4)
3	Reports	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(B)(5)(6)
4	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-408(A)

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IMMUNIZATIONS

1	Certification	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(D)(K); R4-23-411(A)
2	Recordkeeping	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(F)(3); R4-23-411(F)(I)
3	Reporting requirements	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(F); R4-23-411(F)(2)
4	Current certificate maintained	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-411(C)(2)
5	Administration without a prescription	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(A)(B); R4-23-411(A)
6	Prescription only administration	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(C)(I); R4-23-411(A)(4); (B); (I)

MECHANICAL STORAGE / COUNTING DEVICES

1	Cell identification	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(A)(1)
2	Paper / electronic log	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(A)(2)(3)
3	Training	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(C)(1)(D)
4	Maintenance	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(C)(2)(D)

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5	Accuracy validation testing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(C)(3)(D)
6	Return by approval only	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(B)(G)
7	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(E)

MECHANICAL COUNTING DEVICES

1	Training	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(A)(1)(B)
2	Maintenance	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(A)(2)(B)
3	Accuracy validation testing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(A)(3)(B)
4	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(C)

CONTROLLED SUBSTANCE RECORDS

1	CIIs purchase / sale / disposal No C@ drugs received, stocked or dispensed.	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 36-2523(A); ARS § 36-2524; R4-23-601(D);R4-23-1003(A)(4)(B)
2	CIII - CVs purchase / sale / disposal	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 36-2523(A); R4-23-601(D); R4-23-612(11); R4-23-1003(A)(4)
3	Inventory	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 36-2523(B); R4-23-1003

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4	Audit	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 36-2523
5	DEA 106 Theft/Loss reporting	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-1003(A)(2); 21 CFR 1301.76(b)

MISCELLANEOUS

1	Badges - name / title	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(K); R4-23-671(B)(4); R4-23-1104(E)
2	Sales of drugs to practitioners	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1981(7)(d); R4-23-601(D); R4-23-1003(A)(4)
3	Schedule V register	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 36-2525(J)
4	Delivery Fed Ex, USPS	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1901.01(B)(23); R4-23-402(I)
5	CQA training / Policies and procedures	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1973; R4-23-620
6	Non-controlled substances purchase / sale / disposal	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-601(D)
7	Dextromethorphan sales restrictions	☐ S ☐ N/I ☐ V ☑ N/A	ARS 32-1978
8	Federal medication guides	☑ S ☐ N/I ☐ V ☐ N/A	21 CFR part 208

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9	Pharmacy to pharmacy transfer of drugs (intracompany)	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-601(D); R4-23-1003(A)(4)

METHAMPHETAMINE PRECURSORS

1	Storage	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1977(B)
2	Documentation	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1977(C); 21 CFR 1314
3	Self-certification	☐ S ☐ N/I ☐ V ☑ N/A	21 CFR 1314.35; 21 CFR 1314.40

SHARED SERVICES

1	Current resident / nonresident permit	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(A)
2	Same owner / written contract / common electronic file	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(B)
3	Notification to patients	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(C)
4	Maintain manual / electronic records	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(D)
5	Work outside pharmacy	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(F)
6	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(E)

COMPOUNDING PRACTICES (GENERAL)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

1	Documentation product compounded	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(C)(1)(e); R4-23-410(I)(K)
2	Patient label	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(I)(4)
3	Beyond-use dates	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(I)(4)(b); R4-23-410(B)(3)(d)
4	Equipment	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(F)(G)
5	Product produced in excess	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(B)(2); R4-23-410(J)
6	Component removed from original container	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(I)(6)
7	Compounds for medical practitioners	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(B)(3); R4-23-601(D); R4-23-1003(A)(4)
8	Patient written list	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(I)(5)
9	Protective apparel	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(C)(2)(c)
10	Facility	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(E)
11	Components for compounding/storage	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(B)(H)

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12	Policies and procedures	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(D)(G)(H)(I)(K)

STERILE COMPOUNDING

1	Compounding area Previous positive pressure buffer room not classified. All compounding conducted as hazardous compounding in the negative pressure buffer room.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(A)(E)(F)
2	Equipment	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(B)
3	Sterile product reference	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(B)(6)
4	Certification hood / environment	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(D)(14)(g)
5	Documentation routine cleaning / maintenance	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(D)(14)(g)
6	Personnel protective clothing	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(E)(3)(F)(2)
7	Annual / semi-annual media fill tests	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(E)(4)(F)(3)
8	Documentation of product compounded	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(C)(1)(e); R4-23-410(I)(K)
9	Beyond-use dates	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(D)(14)(d); R4-23-410(B)(3)(d)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

10	Process / product validation testing	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(D)(14)(f)
11	Policies and procedures	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-670(C)(D)

AUDIT

Date Of Inventory : 05/01/2024

Inventory Taken : Open

Date Of Audit : 10/31/2024

Name & Strength of Drug	Initial Inventory	Total Purchased	Total Accounted For	Closing Inventory	Sales (Rx & log)	Total Can Account for	Difference	Percentage
Tramadol 50mg tab	458	1000	1458	213	1245	1458	0	0.00
Testosterone cypionate 200mg/mL 10mL vial	12	40	52	2	50	52	0	0.00
Phenobarbital 64.8mg tab	190	1500	1690	670	1020	1690	0	0.00

NOTES

Hours: M-F (8A-6P), Sat (9A-2P)

Handouts: 2022/2023 Statute/Rule Changes summary, ARS 32-1926 reminder, DEA Form 106 Reporting reminder, AzBOP Newsletter July 2024, Continuing Education Audit information, 2024 CE Requirements for Renewal, AzBOP Scam Alert, FDA advisory on insulin pen packaging and dispensing, DEA reminder on manual signature for prescribers, CSPDMP handout, Hormonal Contraceptive FAQ,.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 10/02/2023
Receipt Number: 2023159957
Receipt Amount $: 480.00

Pharmacy - Independent

Compounding – Non-Sterile,Compounding – Sterile,Mail Order,Retail,Veterinarian

	PERMIT NO	**EXPIRES**
	Y005679	**10/31/2025**

Issued to : All-Care Pharmacy, LLC D/B/A Avrio Pharmacy
Raef Hamaed
9015 E PIMA CENTER PARKWAY STE 3
SCOTTSDALE, AZ 85258

All-Care Pharmacy, LLC D/B/A Avrio Pharmacy
9015 E PIMA CENTER PARKWAY STE 3
SCOTTSDALE, AZ 85258

Kam Gadlin
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF
PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Raef Hamaed
LICENSE NUMBER : Y005679
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

• Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.

• You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

• Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law

• In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.

• Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	All-Care Pharmacy, LLC D/B/A Avrio Pharmacy
Address :	9015 E Pima Center Parkway STE 3 Scottsdale AZ 85258
Registration No :	Y005679
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	06/06/2013
Expiration Date :	10/31/2025
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 04/14/2025

8B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FV9694666
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	■ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Vidrine Pharmaceutical Group, LLC

Physical Address: 404 E. Prien Lake Road

City: Lake Charles State: LA Zip: 70601

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (337) 436-7216 Toll Free # (NAC 639.708, NRS 639.23286): 1-855-305-2110

Fax: (337) 436-7217 Contact Email: jvidrine@bndsrx.com

Website: https://boudreauxsnewdrug.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Kylee Vidrine

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24591

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Vidrine Pharmaceutical Group, LLC

Mailing Address: 404 E. Prien Lake Road

City: Lake Charles State: LA Zip: 70601

Telephone: (337) 499-7760 Email: jvidrine@bndsrx.com

Contact Person Name: Jesse Vidrine

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Boudreaux's New Drug Store (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Jesse Vidrine

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

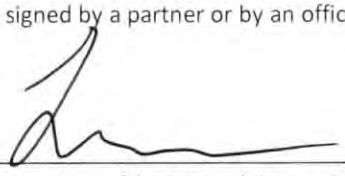
09/30/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jesse Vidrine

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

09/30/24

Date

Board Use Only	Date Received: 10/22/24	Amount: $500 - ck 3161

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: CONSENT ORDER

VIDRINE PHARMACEUTICAL GROUP, LLC D/B/A BOUDREAUX'S NEW DRUG STORE

LOUISIANA PHARMACY PERMIT NO. 8142 Case No. 22-0103

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on June 8, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of VIDRINE PHARMACEUTICAL GROUP, LLC D/B/A BOUDREAUX'S NEW DRUG STORE (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 8142, 404 E. Prien Lake Rd., Lake Charles, LA 70601, with Respondent's representative Jesse Vidrine, Pharmacist-in-Charge Kylee Vidrine and attorney Chris Whittington appearing on behalf of Respondent.

WHEREAS, from September 11, 2020 to March 2, 2022, a total of 3,650 prescriptions were dispensed at Boudreaux's New Drug Store that were purportedly sterile products compounded in the non-HD buffer room in a biological safety cabinet that last had a "PASS" result on its Certification Status on June 2, 2020.

WHEREAS, the Board alleges that such actions constitute violations of the following:

> **La. R.S. 37:1241 (A)(1):** Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.
>
> **LAC, Title 46: LIII §2535(A)(2)(a):** The compounding of sterile preparations pursuant to receipt of a patient-specific prescription shall comply with the provisions of Section 503-A of the FDCA and USP Chapter 797.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

VIDRINE PHARMACEUTICAL GROUP, LLC D/B/A BOUDREAUX'S NEW DRUG STORE is ordered to pay a fine of $25,000.00 and to reimburse the Board $250.00 for administrative costs, and $2,791.01 for investigative costs with total payment due the Board of $28,041.01, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, JESSE VIDRINE, authorized to act on behalf of and acting on behalf of **VIDRINE PHARMACEUTICAL GROUP, LLC D/B/A BOUDREAUX'S NEW DRUG STORE,** understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

SIGNED, AGREED TO AND ENTERED ON THIS 9th DAY OF June, 2022.

Vidrine Pharmaceutical Group, LLC *d/b/a* Boudreaux's New Drug Store
Louisiana Pharmacy Permit No. 8142

BY: JESSE VIDRINE
Authorized Representative

CHRISTOPHER L. WHITTINGTON
Williamson, Fontenot, Campbell & Whittington, LLC
P. O. Box 3035 (70821-3035)
955 McClung Street
Baton Rouge, LA 70802

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on August 17, 2022, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
President & Hearing Officer for the Board

Louisiana Board of Pharmacy

3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov ~ Telephone: 225.925.6496 ~ E-Mail: info@pharmacy.la.gov

Pharmacy Inspection Report

Permit Data	Report No. 040	Inspected by: Savoie/Fidanza	Territory: Savoie	Date: 2/24 & 3/2/2022

Reason for Visit: ☐ Initial Survey ☒ Service Review ☐ Follow-Up Survey ☐ Compliance Check

1. Pharmacy Name	2. Permit No.	3. CDS License	4. Classification	5. Renewal Yr.
Boudreaux's New Drug Store	8142	58480	IR	2022

6. Physical Address	7. Mailing Address	8. City, State, Zip
404 E. Prien Lake Rd.	Same	Lake Charles, LA 70601

9. Phone No.	10. Fax No.	11. E-mail Address	12. Accreditation
(337) 436-7216	(337) 436-7217	kvidrine@bndsrx.com	Yes ☐ ( ) No ☐ N/A ☒

13. Compounding	14. AMS Permit No.	15. Rx Software	16. DEA No.	DEA Expiration
Sterile ☒ Non-Sterile ☒ N/A ☐		ComputerRx, The CompounderRx	FV9694666	5/31/2023

17. Store Hours	18. Pharmacy Hours
8:30AM - 5:30PM (M-F) N/A ☐	Same

Pharmacist-In-Charge

19. PIC Name	20. Sex	21. License No.	22. Renewal Year	23. CE Compliant
Kylee B. Vidrine		21317	2022	Yes ☐ No ☐

24. Address of Record	25. City, State, Zip	26. Phone
404 E. Prien Lake Rd.	Lake Charles, LA 70601	(337) 436-7216

27. Pharmacy Staff	License No.	Renewal Year	C.E. Compliant		
Elizabeth M. Hebert - PST	21059	2022	Yes ☐	No ☐	Exempt ☐
Monica P. Harrington - PST	17453	2022	Yes ☐	No ☐	Exempt ☐
Kimberly N. Trahan - CPT	10797	21-22	Yes ☐	No ☐	Exempt ☐
Ashley A. Wainwright - CPT	10999	21-22	Yes ☐	No ☐	Exempt ☐
Regan E. Bertrand - CPT	14753	21-22	Yes ☐	No ☐	Exempt ☐
Tina M. Guin - CPT	15948	21-22	Yes ☐	No ☐	Exempt ☐
Kimberly D. Smith - CPT	4459	21-22	Yes ☐	No ☐	Exempt ☐
			Yes ☐	No ☐	Exempt ☐
			Yes ☐	No ☐	Exempt ☐
			Yes ☐	No ☐	Exempt ☐
			Yes ☐	No ☐	Exempt ☐

Professional and Occupational Standards

	Compliance Yes	No	N/A		Compliance Yes	No	N/A
28. Credentials current/active	☒	☐	☐	39. Emergency Drug Cabinet	☐	☐	☒
29. Premises Clean/Orderly	☒	☐	☐	40. Electronic Record Keeping	☒	☐	☐
30. Adequate Lighting/Ventilation	☒	☐	☐	41. Required Info. on CDS Rxs	☒	☐	☐
31. Adequate Refrigeration/Temperature	☒	☐	☐	42. CDS Invoices Retrievable/Dated	☒	☐	☐
32. Min. Rx Dept. Size/Aisle Space	☒	☐	☐	43. C-II Order Forms	☒	☐	☐
33. Sterile Compounding see comments	☐	☐	☐	44. Perpetual CII/CDS Annual Inventory			
34. Sink (Location & Temperature)	☒	☐	☐	Inventory Date (10/9/2021)	☒	☐	☐
35. Required References	☒	☐	☐	45. Policy & Procedure Manual	☒	☐	☐
36. Security (Alarm) (Restricted Access)	☒	☐	☐	46. Pharmacist Register/Positive Identification	☒	☐	☐
37. Adequate Equipment	☒	☐	☐	47. Patient Counseling	☒	☐	☐
38. Meds. Misbranded, Non-Labeled, Exp.	☒	☐	☐	48. Intern/CPT/Tech Trainee I.D.	☒	☐	☐

52. Prior Inspection Date:	53. Deficiencies/Non-Compliance on Prior Inspection	54. Correction(s) Observed
6/23/2020	none	----

(continued)

Louisiana Board of Pharmacy

3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov ~ Telephone: 225.925.6496 ~ E-Mail: info@pharmacy.la.gov

Pharmacy Inspection Report

1. Pharmacy Name	2. Permit No.	3. CDS License	4. Classification	5. Renewal Yr.
Boudreaux's New Drug Store	**8142**	**58480**	**IR**	**2022**

55. Comments: NOTE: A finding of satisfactory compliance is not indicative of a detailed inspection/investigation and does not exclude the permit and/or staff from possible future violations of compliance.

>> Advised pharmacy staff credentialed with the Board to send change of mailing address and/or place of employment within 10 days of the actual change. Referred staff to January 2019 newsletter for more information.

>> Advised pharmacy staff credentialed by the Board to ensure all CE hours earned are reported to and are accounted for in CPE Monitor.

>> Discussion with pharmacy staff about the accuracy of the list of current employees displayed on the Board website for the permit.

>> Discussion with pharmacy staff to ensure patients' full name (as appears on their ID) is reported as such when information is submitted to PMP.

Discussion with PIC Vidrine about pharmacist's corresponding responsibility regarding the dispensing of controlled dangerous substances. PIC Vidrine acknowledged an understanding of a pharmacist's corresponding responsibility.

Universal Pharmacy Inspection Form (USP 795 & 797) for compliance measurements...

Pertaining to USP 797...

70.00- Documentation available only for garbing/gowning/hand hygiene and aseptic technique. Not able to locate documentation for completed didactic training and passing written competence assessments.

97.02-, 105.00- PEC located in buffer room was evaluated in December 2020 with FAIL result in downflow velocity, inflow velocity and airflow pattern tests & site installation tests. PEC has not been evaluated by Allometrics since December 2020.

97.06- The PIC/compounding supervisor is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.

100.01- Air pattern analysis for PEC in buffer room has not been evaluated since December 2020.

As per USP 797 Sterile Preparations - Engineering Control Performance Verification (2015): Certification procedures such as those outlined in CAG-003-2006 shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.

Comments continued on third page...

Louisiana Board of Pharmacy

www.pharmacy.la.gov ~ Telephone: 225.925.6496 ~ E-Mail: info@pharmacy.la.gov

Pharmacy Inspection Report

1. Pharmacy Name	2. Permit No.	3. CDS License	4. Classification	5. Renewal Yr.
Boudreaux's New Drug Store	**8142**	**58480**	**IR**	**2022**

55. Comments: NOTE: A finding of satisfactory compliance is not indicative of a detailed inspection/investigation and does not exclude the permit and/or staff from possible future violations of compliance.

Advised PIC Vidrine to immediately quarantine inventory of sterile products compounded in uncertified PEC. Email document(s) listing inventory quarantined to "hsavoie@pharmacy.la.gov"

Uncertified PEC not to be used for sterile compounding until certified.

Request for dispensing records of all sterile products compounded in uncertified PEC since 9/11/2020 to be produced/ delivered by March 9, 2022.

Request for Allometric certification documents since June 2020 certification. Email to "hsavoie@pharmacy.la.gov"

PIC Vidrine authorized inspection report be emailed to "kvidrine@bndsrx.com"

PIC

Authorized Signature & Title

Compliance Officer, Louisiana Board of Pharmacy

Form No. 601

Rev. 01-01-2022

UNITED STATES OF AMERICA

State of Louisiana

Nancy Landry

SECRETARY OF STATE

As Secretary of State of the State of Louisiana, I do hereby Certify that

VIDRINE PHARMACEUTICAL GROUP, LLC

A limited liability company domiciled in LAKE CHARLES, LOUISIANA,

Filed charter and qualified to do business in this State on July 13, 2020,

I further certify that the records of this Office indicate the company has paid all fees due the Secretary of State, and so far as the Office of the Secretary of State is concerned, is in good standing and is authorized to do business in this State.

I further certify that this certificate is not intended to reflect the financial condition of this company since this information is not available from the records of this Office.

In testimony whereof, I have hereunto set my hand and caused the Seal of my Office to be affixed at the City of Baton Rouge on,

August 21, 2024

Nancy Landry

Secretary of State

Web 43975942K

STATE OF LOUISIANA · UNION · JUSTICE · CONFIDENCE · SECRETARY OF STATE

Certificate ID: 11923691#NJ62

To validate this certificate, visit the following web site, go to **Business Services, Search for Louisiana Business Filings, Validate a Certificate,** then follow the instructions displayed.
www.sos.la.gov

Vidrine Pharmaceutical Group, LLC
Office: 337.436.7217 ♦ Fax: 337.436.7217
404 E. Prien Lake Rd. ♦ Lake Charles, La 70601

July 30th, 2024

Ownership Interest: Vidrine Pharmaceutical Group, LLC

Jesse Brett Vidrine

[redacted]

404 East Prien Lake Rd., Lake Charles, LA 70601 337.436.7216

50%

Kylee Brooke Vidrine

[redacted]

404 East Prien Lake Rd., Lake Charles, La 70601 337.436.7216

50%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Boudreaux's New Drug Store

Pharmacy/Wholesaler License # (if applicable) PHY-008142.IR

Physical Address 404 E. Prien Lake Rd

City Lake Charles State LA Zip 70601

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (337) 436-7216 Website https://boudreauxsnewdrug.com/

Licensing Company Email jvidrine@bndsrx.com

Section 2: Personal Information

First Kylee Middle Brooke Last Vidrine

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Houston College of Pharmacy		(09/09-05/13)	
Address	City	State	Zip
4302 University Dr	Houston	TX	77004
Diploma/Degree obtained, if any			
Doctorate in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Texas A&M University		(05/03-12/07)	
Address	City	State	Zip
400 Bizzell St	College Station	TX	77840
Diploma/Degree obtained, if any			
Bachelors in Biology			

School Name		From - To (MM/YY – MM/YY)	
Kingwood High School		(05/99-05/03)	
Address	City	State	Zip
2701 Kingwood Dr	Kingwood	TX	77339
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
(05/21-present)				
From - To (MM/YY – MM/YY)				
(05/05-05/21)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Boudreaux's New Drug Store			(02/20-Present)	
Business Address		**City**	**State**	**Zip**
404 E. Prien Lake Rd		Lake Charles	LA	70601
Phone	**Title**		**Number of Employed Hours**	
(337) 436-7216	PIC		8000	
Description of Duties				
Pharmacist in Charge, record keeping, employee management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?	✓	
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

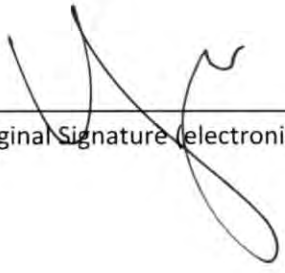
Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 & 7 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached documents



Original Signature (electronic, copies or stamps not accepted)

10/21/2024

Date

I, Kylee Vidrine, **certify that as the designated representative for**

Boudreaux's New Drug Store,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kylee Vidrine

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/21/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kylee Vidrine

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/21/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/21/2024

Date

Subscribed and Sworn to before me this 21 day of October, 2024

Diana G. Andersen

Notary Public Signature

DIANA G. ANDERSEN
Notary Public
State of Louisiana
Calcasieu Parish
Notary ID # 1375
My Commission is for Life

Vidrine Pharmaceutical Group, LLC
Office: 337.436.7217 ♦ Fax: 337.436.7217
404 E. Prien Lake Rd. ♦ Lake Charles, La 70601

October 21st, 2024

Subject: Explanation of Inspection Findings - March 2nd, 2022

Dear Members of the Nevada Board of Pharmacy,

I am writing to provide an explanation regarding the inspection conducted by the Louisiana State Board of Pharmacy on March 2nd, 2022, and the subsequent findings.

During the annual inspection, the Louisiana State Board of Pharmacy identified a discrepancy in the certification records pertaining to one of our Biological Safety Cabinets (BSC) provided by Allometrics. Specifically, it was noted that the BSC had missed an inspection. Upon closer examination, it was discovered that during the scheduled testing, the BSC was operating at 82%, slightly outside the approved range. Consequently, the service technician opted to take the BSC out of service without notifying the PIC.

Regrettably, during the heightened activity surrounding COVID-19, the service technician did not conduct the customary exit interview at the conclusion of the testing period. Furthermore, the technician neglected to clearly mark the BSC as non-compliant or indicate a failing test result. Instead, a minor note was included in the comprehensive 75-page report. Unfortunately, this oversight was not immediately recognized by our Pharmacist In Charge (PIC) during her review of the report.

However, it is important to note that all products produced from the BSC during the period of the missed inspection underwent thorough testing, and all results met the required standards. Upon being informed of the failed test result during the inspection, immediate action was taken by our pharmacy. We promptly procured a new BSC, which was installed in our sterile lab the following day and subsequently tested by Allometrics.

In response to the findings, the Louisiana Board of Pharmacy imposed a fine, which was paid in a timely manner, and the matter was resolved accordingly.

We deeply regret the oversight and assure you that steps have been taken to prevent such occurrences in the future. We remain committed to upholding the highest standards of safety and compliance within our pharmacy operations.

Thank You,

Jesse Vidrine
Owner

Vidrine Pharmaceutical Group, LLC
Office: 337.436.7217 ♦ Fax: 337.436.7217
404 E. Prien Lake Rd. ♦ Lake Charles, La 70601

October 15th, 2024

Nevada State Board of Pharmacy

Re: Vidrine Pharmaceutical Group LLC d/b/a Boudreaux's New Drug Store

Supplemental Response to question about discipline"

Dear Nevada State Board of Pharmacy,

This letter is being submitted to supplement Vidrine Pharmaceutical Group LLC d/b/a Boudreaux's New Drug Store's ("Pharmacy") answer to the Question about discipline on the "Neveda Board of Pharmacy" pharmacy application. Through this correspondence, the Pharmacy is supplementing its response and notifying the Board of an Agreed Board Order that the Pharmacy recently agreed to with the Texas State Board of Pharmacy ("Texas Board") in August 2024 and a Consent Agreement the Pharmacy agreed to with the Louisiana Board of Pharmacy ("Louisiana Board") in August 2022. Along with this correspondence are complete and accurate copies of the Agreed Board Order between the Pharmacy and the Texas Board and the Consent Agreement between the Pharmacy and the Louisiana Board.

The Pharmacy is also hereby giving notice that the Mississippi Board of Pharmacy ("Mississippi Board") recently denied the Pharmacy's application for a non-resident compounding certificate in Mississippi. We would note that this denial was not based on disciplinary action but instead based on the Mississippi Board's belief that the pharmacy was not currently in compliance with USP 795 and USP 797. However, we believe this was a misunderstanding between the Pharmacy and the Mississippi Board as we believe we are in compliance with these provisions of USP and we are currently working with the Mississippi Board to resolve this matter and the related denial. We look forward to reapplying for the compounding permit or otherwise obtaining the compounding permit in Mississippi in the near future.

By way of further detail regarding the Agreed Board Order in Texas, the Pharmacy recently applied for a non-resident pharmacy license in the State of Texas. After the Pharmacy submitted its non-resident pharmacy application, on August 6, 2024, the Texas Board gave the Pharmacy preliminary notice of its intent to grant the Pharmacy's Texas license. However, as a condition of the Texas Board issuing the Pharmacy's non-resident pharmacy license, the Texas Board stated that it would also issue a reprimand along with the non-resident license. After learning of this and discussing in detail with the Texas Board, the Pharmacy voluntarily agreed to the proposed Agreed Board Order.

As to the basis of the Texas Board's reprimand, the reprimand was issued by the Texas Board based on the Pharmacy's voluntary disclosure in its Texas non-resident pharmacy license application regarding a

prior matter in its home state of Louisiana. Specifically, on August 17, 2022, the Pharmacy and the Louisiana Board agreed to resolve certain allegations made by the Louisiana Board against the

Pharmacy through a voluntary Consent Agreement. To be clear, the reprimand issued by the Texas Board was not based on a new matter but rather a prior matter that was amicably resolved between the Pharmacy and the Louisiana Board and later disclosed by the Pharmacy to the Texas Board when it applied for its Texas non-resident pharmacy license.

The Pharmacy would note that the Pharmacy continues to be a duly licensed pharmacy in good standing with the Louisiana Board including after agreeing to the terms and conditions of the August 17, 2022, Consent Agreement. The Pharmacy makes this supplement and disclosure in good faith and will continue to supplement the record, if necessary and appropriate, by disclosing any further action related to Texas Board Agreed Board Order and the Louisiana Consent Agreement although no further action is contemplated or expected as it is the Pharmacy's understanding in communicating with the Texas Board and the Louisiana Board that these matters has been resolved and are considered closed.

Should you have any questions or require any additional information, please contact me by phone at (337) 499-7760 or by email at jvidrine@bndsrx.com. Thank you.

Respectfully submitted,

_____

Jesse Vidrine

CEO, Vidrine Pharmaceutical Group LLC d/b/a Boudreaux's New Drug Store

Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov

August 18, 2022

Christopher L. Whittington
Williamson, Fontenot, Campbell & Whittington, LLC
P. O. Box 3035 (70821-3035)
955 McClung Street
Baton Rouge, LA 70802

RE:
Case No. 22-0103 ~ PHY.008142 – Vidrine Pharmaceutical Group, LLC *d/b/a* Boudreaux's New Drug Store
Case No. 22-0104 ~ PST.021317 – Kylee Brooke Vidrine

Dear Mr. Whittington:

Please find the attached Board Orders as approved by the Louisiana Board of Pharmacy this week.

Please let me know if you have any questions.

Sincerely,

Carlos M. Finalet, III
General Counsel

NOTICE: In compliance with Act 256 of the 2019 Louisiana Legislature, the Board gives public notice that any information submitted to the Board may become public record unless specifically exempted by the Public Records Law, R.S. 44:1 *et seq.*

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: CONSENT ORDER

VIDRINE PHARMACEUTICAL GROUP, LLC D/B/A BOUDREAUX'S NEW DRUG STORE

LOUISIANA PHARMACY PERMIT NO. 8142 Case No. 22-0103

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on June 8, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of VIDRINE PHARMACEUTICAL GROUP, LLC D/B/A BOUDREAUX'S NEW DRUG STORE (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 8142, 404 E. Prien Lake Rd., Lake Charles, LA 70601, with Respondent's representative Jesse Vidrine, Pharmacist-in-Charge Kylee Vidrine and attorney Chris Whittington appearing on behalf of Respondent.

WHEREAS, from September 11, 2020 to March 2, 2022, a total of 3,650 prescriptions were dispensed at Boudreaux's New Drug Store that were purportedly sterile products compounded in the non-HD buffer room in a biological safety cabinet that last had a "PASS" result on its Certification Status on June 2, 2020.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

LAC, Title 46: LIII §2535(A)(2)(a): The compounding of sterile preparations pursuant to receipt of a patient-specific prescription shall comply with the provisions of Section 503-A of the FDCA and USP Chapter 797.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

VIDRINE PHARMACEUTICAL GROUP, LLC D/B/A BOUDREAUX'S NEW DRUG STORE is ordered to pay a fine of $25,000.00 and to reimburse the Board $250.00 for administrative costs, and $2,791.01 for investigative costs with total payment due the Board of $28,041.01, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, JESSE VIDRINE, authorized to act on behalf of and acting on behalf of **VIDRINE PHARMACEUTICAL GROUP, LLC D/B/A BOUDREAUX'S NEW DRUG STORE,** understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[*Remainder of page intentionally left blank; signature page to follow.*]

SIGNED, AGREED TO AND ENTERED ON THIS 9th DAY OF June, 2022.

Vidrine Pharmaceutical Group, LLC *d/b/a* Boudreaux's New Drug Store
Louisiana Pharmacy Permit No. 8142

BY: JESSE VIDRINE
Authorized Representative

CHRISTOPHER L. WHITTINGTON
Williamson, Fontenot, Campbell & Whittington, LLC
P. O. Box 3035 (70821-3035)
955 McClung Street
Baton Rouge, LA 70802

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on August 17, 2022, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
President & Hearing Officer for the Board

JD BANK
LOUISIANA'S COMMUNITY BANK™

CASHIER'S CHECK 5-555/655 **154093**

REMITTER Vidrine Pharmaceutical Group

PAY TO THE ORDER OF Louisiana Board of Pharmacy **July 11, 2022**

****** *Twenty Eight Thousand Forty One and 01/100******* **$ 28,041.01**

Authorized Signature

MEMO Case No: 22-0103

⑈154093 ⑈ [redacted] [redacted]

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: CONSENT ORDER

KYLEE BROOKE VIDRINE

PHARMACIST LICENSE NO. 21317 Case No. 22-0104

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on June 8, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, KYLEE BROOKE VIDRINE (hereinafter referred to as "Respondent"), holder of PHARMACIST LICENSE NO. 21317, with Respondent and attorney Chris Whittington present.

WHEREAS, from September 11, 2020 to March 2, 2022, a total of 3,650 prescriptions were dispensed at Boudreaux's New Drug Store (PHY.008142) that were purportedly sterile products compounded in the non-HD buffer room in a biological safety cabinet that last had a "PASS" result on its Certification Status on June 2, 2020. Respondent serves as the pharmacy's Pharmacist-in-Charge.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

LAC, Title 46: LIII §2535(A)(2)(a): The compounding of sterile preparations pursuant to receipt of a patient-specific prescription shall comply with the provisions of Section 503-A of the FDCA and USP Chapter 797.

LAC, Title 46: LIII §1105(C): Pharmacist-in-Charge. Authority and Accountability. The pharmacist-in-charge shall be ultimately responsible for complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not offer any defense to the allegations of violations cited above and further agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

1. **PHARMACIST LICENSE NO. 21317 belonging to KYLEE BROOKE VIDRINE is hereby issued a LETTER OF WARNING.**

2. **KYLEE BROOKE VIDRINE is ordered to pay a fine of $2,500.00 and reimburse the Board $250.00 for administrative costs, for a total of $2,750.00 due by *certified check or money order* at the signing of this agreement.**

3. **KYLEE BROOKE VIDRINE shall complete Critical Point's QP503 Certification Program no later than August 17, 2023. Should Respondent fail to complete the program, Respondent agrees that her license be placed on indefinite suspension until passage of the QP503 Certification Program.**

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon his signing said Order.

I, **KYLEE BROOKE VIDRINE**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of my case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

Respondent agrees that Respondent's execution of this Consent Agreement grants the Board the authority to collect any monies owed pursuant to this Consent Agreement and not paid to the Board notwithstanding the Board's acceptance of this Consent Agreement.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

SIGNED, AGREED TO AND ENTERED ON 9th DAY OF June, 2022.

KYLEE BROOKE VIDRINE
PHARMACIST LICENSE NO. 21317

CHRISTOPHER L. WHITTINGTON
Williamson, Fontenot, Campbell & Whittington, LLC
P. O. Box 3035 (70821-3035)
955 McClung Street
Baton Rouge, LA 70802

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on August 17, 2022, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
President & Hearing Officer for the Board

JD BANK
LOUISIANA'S COMMUNITY BANK™

CASHIER'S CHECK

6-655
585

154092

REMITTER Vidrine Pharmaceutical Group

PAY TO THE ORDER OF Louisiana Board of Pharmacy

July 11, 2022

**** *Two Thousand Seven Hundred Fifty and 00/100**** $ 2,750.00

Authorized Signature

MEMO Case No. 22-0104

⑈154092⑈ ⑈ [redacted] [redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Boudreaux's New Drug Store

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PHY-008142.IR

Physical Address 404 E. Prien Lake Rd

City Lake Charles State LA Zip 70601

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (337) 436-7216 Website https://boudreauxsnewdrug.com/

Licensing Company Email jvidrine@bndsrx.com

Section 2: Personal Information

First Kylee Middle Brooke Last Vidrine1

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Houston College of Pharmacy		(09/09-05/13)	
Address	**City**	**State**	**Zip**
4302 University Dr	Houston	TX	77004
Diploma/Degree obtained, if any			
Doctorate in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Texas A&M University		(05/03-12/07)	
Address	**City**	**State**	**Zip**
400 Bizzell St	College Station	TX	77840
Diploma/Degree obtained, if any			
Bachelors in Biology			

School Name		From - To (MM/YY – MM/YY)	
Kingwood High School		(05/99-05/03)	
Address	**City**	**State**	**Zip**
2701 Kingwood Dr	Kingwood	TX	77339
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
(05/21-present)	[redacted]			
From - To (MM/YY – MM/YY)				
(05/05-05/21)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Boudreaux's New Drug Store			(02/20-present)	
Business Address		**City**	**State**	**Zip**
404 E. Prien Lake Rd		Lake Charles	LA	70601
Phone	**Title**			
(337) 436-7216	PIC			
Description of Duties				
Pharmacist in Charge, record keeping, employee management				

Business Name			From - To (MM/YY – MM/YY)	
Kroger			(06/13-01/20)	
Business Address		**City**	**State**	**Zip**
1600 N 16th St		Orange	TX	77630
Phone	**Title**			
(409) 883-8521	PIC			
Description of Duties				
Pharmacist in Charge, record keeping, employee management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?	✓	
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6&7 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

please see attached documents

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kylee Vidrine

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/21/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/21/2024

Date

Subscribed and Sworn to before me this 21 day of October, 2024

Diana G. Andersen

Notary Public Signature

DIANA G. ANDERSEN
Notary Public
State of Louisiana
Calcasieu Parish
Notary ID # 1375
My Commission is for Life
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Vidrine Pharmaceutical Group, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) N/A

Physical Address 404 E Prien Lake Rd

City Lake Charles State LA Zip 70601

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 337-436-7216 Website BNDSRX.COM

Licensing Company Email Jvidrine@bndsrx.com

Section 2: Personal Information

First Jesse Middle Brett Last Vidrine

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS markup 129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed)

School Name: McNeese State University			From - To (MM/YY – MM/YY): 04/04 – 09/12	
Address: 4205 Ryan St.	City: Lake Charles	State: La	Zip: 70605	
Diploma/Degree obtained, if any: Bachelor of Business Administration in Finance				
School Name: Elizabeth High School			From - To (MM/YY – MM/YY): 04/00 - 03/04	
Address: 440 Live Oak	City: Elizabeth	State: LA	Zip: 70638	
Diploma/Degree obtained, if any: Yes, High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
[redacted]				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Vidrine pharmaceutical Group LLC			From - To (MM/YY – MM/YY)
Business Address: 404 E Prien Lake Rd.	City: Lake Charles	State: LA	Zip: 70601
Phone: (337) 430-7210	Title: OWNER. President		
Description of Duties: Management of Sales + Finance teams.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jesse Vidrine

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/7/25

Date

Please have this section completed in the presence of a Notary Public.

State of Louisiana, ss. County of Calcasieu

I, Jesse Vidrine, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/7/25

Date

Subscribed and Sworn to before me this 7 day of July, 2025.

Notary Public Signature

DIANA G. ANDERSEN
Notary Public
State of Louisiana
Calcasieu Parish
Notary ID # 1375
My Commission is for Life

(Seal)

The National Association of Boards of Pharmacy (NABP) developed this inspection form for sole use by NABP and its member boards of pharmacy for inspection of facilities licensed by a member board. Disclosure of the form to or use of the form by a third party, other than a facility being inspected by NABP or a member board, is strictly prohibited without NABP's prior written permission or unless required by state law.

National Association of Boards of Pharmacy®
Universal Inspection Form

Pharmacy e-Profile ID: if available			**Inspection Information**
Legal Business Name:		**Day 1:**	8/24/2023 (USP 795)
Doing Business As (DBA):	Boudreaux's New Drug Store	**Start Time: 24-hour format (13:00)**	9:30
Address:	404 E. Prien Lake Rd.	**End Time: 24-hour format (13:00)**	12:00
City:	Lake Charles	**Day 2:**	8/29/2023 (USP 797)
State:	LA	**Start Time: 24-hour format (13:00)**	9:00
Zip Code:	70601-8507	**End Time: 24-hour format (13:00)**	
Telephone number:	(337)436-7216	**Inspector Name:**	Huey Savoie, Compliance Officer
Toll free number:		**Inspection Performed by (NABP, State, etc):**	La. Board of Pharmacy
Fax number:	(337) 436-7217	**Observer Name/Affiliation (if applicable):**	Cary Aaron, Compliance Officer, La. Board of Pharmacy (8/29/2023 - USP 797)
Website:		**Observer Name/Affiliation (if applicable):**	

Pharmacy Hours of Operation	**Check if 24/7** ☐		
	Open		**Closed**
	Start Time: (24-hour format)	**End Time: (24-hour format)**	**(X)**
Sunday			X
Monday	8:30	17:30	
Tuesday	8:30	17:30	
Wednesday	8:30	17:30	
Thursday	8:30	17:30	
Friday	8:30	17:30	
Saturday			X

Key Pharmacy Personnel	**Name**	**Contact (e-mail)**	**e-Profile ID**
Pharmacist in Charge	Kylee B. Vidrine, PST.021317	kvidrine@bndsrx.com	
Nonsterile Compounding Supervisor	Ashley A. Wainwright, CPT.010999		
Sterile Compounding Supervisor	Ashley A. Wainwright, CPT.010999		
Hazardous Compounding Supervisor			

Personnel Present at Time of Inspection	**Name**	**Title**	**License or registration available and current (Y/N)**
1	Kylee B. Vidrine, PST.021317		

2	Ashley A. Wainwright, CPT.010999		
3			
4			

If more than 10, list the first 10 above, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

Business Licensure Information for State of Residence and Federal
(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date
La. Board of Pharmacy	Boudreaux's New Drug Store	PHY.008142-IR	12/31/2023
La. Board of Pharmacy	Boudreaux's New Drug Store	CDS.058480-PHY	12/31/2023
La. Board of Pharmacy	Boudreaux's New Drug Store	CSP.000095-PHY	12/31/2023
Drug Enforcement Administration	Boudreaux's New Drug Store	FV9694666	5/31/2026

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail	X	Telepharmacy	
Open to the Public	X	Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)		Manufacturer	
Veterinary Pharmacy		Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	X

HMO/PBM only		Nonsterile Hazardous Drug Compounding	X
Internet Pharmacy (New Rx)		Sterile Compounding	X
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

National Association of Boards of Pharmacy®
Universal Inspection Form

The National Association of Boards of Pharmacy (NABP) developed this inspection form for sole use by NABP and its member boards of pharmacy for inspection of facilities licensed by a member board. Disclosure of the form to or use of the form by a third party, other than a facility being inspected by NABP or a member board, is strictly prohibited without NABP's prior written permission or unless required by state law.

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: dba Boudreaux's New Drug Store

Inspection Date: 8/24/2023 (USP 795) - 8/29/2023 (USP 797)

		Finding	Notes
	General Operations and Information		
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	Yes	
1.02	Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?	Yes	
1.03	Are nonsterile compounded prescriptions picked up at the pharmacy?	Yes	
1.04	Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?	Yes	
1.05	Are nonsterile compounded prescriptions mailed to patients in their homes or residential facilities?	Yes	
1.06	Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?	Yes	
1.07	Are nonsterile compounded prescriptions mailed to the practitioner for administration to the patient in the office, clinic, or facility?	Yes	
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	No	
2.01	Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?	No	
2.02	Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?	No	
2.03	Does the pharmacy have a sales force that promotes compounded preparations? *List compounds promoted.*	No	
2.04	Does the pharmacy distribute non-patient specific compounded preparations for promotional purposes? *List compounds provided.*	No	
2.05	If yes, does the sales force hand-deliver these compounds? *List compounds provided.*	N/A	
2.06	If yes, are any of these controlled substances? *List compounds provided.*	N/A	
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?	No	
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? *Provide List.*	N/A	
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Provide List.*	Yes	Capsules, liquids, lozenges, troches, lollipops
5.00	Does the pharmacy compound topicals (gels, creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Provide List.*	Yes	Gels, creams, ointments, inserts, suppositories, sprays
6.00	Does the pharmacy compound vitamin or nutritional supplements? *Provide List.*	No	
7.00	Does the pharmacy sell any compounds over-the-counter? *Provide list.*	No	
8.00	Does the pharmacy compound investigational drugs? *Provide List.*	No	

9.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate volume or percent compounded currently.*	Yes	
9.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	Yes	
9.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	Yes	Staff checks multiple sources to verify current status of product in question
10.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding.* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. *Examples include Captopril Oral Solution, Indomethacin Topical precautions. Gel, and Potassium Bromide Oral Solution (Veterinary).*	Yes	~ 15%
11.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding.* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available. *Examples include Morphine Sulfate Suppositories, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.*	Yes	~ 35%
12.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding.* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. *Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.*	No	
13.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of compounding with hazardous drugs.* NIOSH list of hazardous drugs including chemotherapy, hormones, etc.	Yes	~ 50%
13.01	Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?	Yes	
14.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	
15.00	Does the pharmacy compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding.*	Yes	~ 20%; Testosterone, ketamine, phentermine
16.00	**APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes	
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *Indicate the source of APIs.*	Yes	PCCA, Letco, Medisca, Spectrum
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified.*	Yes	Permit requests information from suppliers

16.03	Does the pharmacy use active ingredients that are not from an FDA-registered facility? *If so, indicate sources.*	No	
16.04	Does the computer track on-hand quantities of APIs used for compounding? *If not, explain.*	Yes	
17.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	No	
18.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*	Yes	
19.00	Does the pharmacy use scales/balances for nonsterile compounding?	Yes	
19.01	If so, what type of scale/balanced is used? *List manufacturer and model number*		OHAUS Explorer
19.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency*	Yes	Calibrated daily
19.03	Describe the pharmacist checks for the measurement of each ingredient		
20.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? **Note: If the facility indicates "yes", please ask each question below to verify.**	Yes	
20.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	Yes	
20.02	Does the pharmacy continuous quality improvement program include personnel testing and verification?	Yes	
20.03	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?	Yes	
20.04	Does the pharmacy continuous quality improvement program include end product testing (such as: pH, weight, potency, particulates, consistency, etc.)?	Yes	
20.05	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding nonsterile compounded products?	Yes	
20.06	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes	
20.07	Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?	Yes	
20.08	Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?	Yes	Depending on severity of event
	Component Selection and Use		
	Total Non-Compliant (Includes Unknowns)	**0**	

21.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Compliant	
21.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound.	Compliant	Available online
21.02	USP- or NF-grade substances used, if available	Compliant	
21.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	N/A	
21.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels.*	Compliant	
21.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding	Compliant	Marked for "Veterinary Use Only"
21.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.	Compliant	
21.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*	Compliant	
21.08	All APIs and components received without an expiration date are labeled with the date they were received.	Compliant	
21.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	Compliant	
21.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Compliant	Stored in segregated area
22.00	Where water is an ingredient, purified or distilled water is used.	Compliant	Permit uses purified or sterile water
23.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.	N/A	
24.00	Pharmacy confirms that there are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	Compliant	
25.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	Compliant	
26.00	For **animal compounding:** The compounding meets the same standards as compounding for human patients.	Compliant	
26.01	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	Compliant	

26.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	N/A	
26.03	The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A	
26.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A	
26.05	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A	
	Beyond Use Dating (BUD)		
	Total Non-Compliant (Includes Unknowns)	**0**	
27.00	BUDs are assigned from the day of preparation.	Compliant	
28.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.	Compliant	
29.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*	Compliant	
29.01	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.*	N/A	
30.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.	Compliant	
31.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).	Compliant	
32.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.	Compliant	
	Environment		
	Total Non-Compliant (Includes Unknowns)	**2**	
33.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	Compliant	
34.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.	Compliant	
35.00	Only one preparation compounded at a time.	Compliant	
36.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.	Compliant	
37.00	The compounding area is well lit.	Compliant	
38.00	The pharmacy performs **hazardous** non-sterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*	Unknown	Action plan in place to ventilate CACI and cabinets as per USP 800 revisions
38.01	Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.	Unknown	Action plan in place to ventilate CACI and cabinets as per USP 800 revisions
38.02	If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.	N/A	
39.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available.	Compliant	
39.01	If hazardous drugs are used, appropriate protective attire is available (gowns, gloves, hair and shoe covers, eye and face protection, etc.).	Compliant	
40.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.	Compliant	

41.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is **recommended** - not required)*	Compliant	
42.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.	Compliant	
43.00	**Temperature** in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Compliant	
43.01	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Compliant	
43.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
43.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Compliant	
43.04	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Compliant	
43.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
44.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.	Compliant	
44.01	Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	
44.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
44.03	Humidity monitoring is also performed in **drug storage areas** (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.	Compliant	
44.04	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	
44.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
45.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.	Compliant	
46.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.	Compliant	
47.00	All components and packaging containers and closures are properly rotated to use oldest first.	Compliant	
48.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)	Compliant	
49.00	Trash is disposed of in a safe, sanitary, and timely manner.	Compliant	
49.01	Hazardous waste is disposed of in a safe, sanitary, and timely manner.	Compliant	
	Training *-Verify records of all compounding personnel (up to 10).*		
	Total Non-Compliant (Includes Unknowns)	**0**	

50.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.	Compliant	
51.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.	Compliant	
52.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.	Compliant	
53.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.*	Compliant	
54.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually.	Compliant	
54.01	If performing hazardous nonsterile compounding, there is documentation available showing employees are evaluated at least annually.	Compliant	
55.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.	N/A	
	Compounding Equipment		
	Total Non-Compliant (Includes Unknowns)	**0**	
56.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*	Compliant	
57.00	Scales, balances, or other types of equipment used for measurement shall be routinely inspected, calibrated as necessary (per manufacturer instructions), and checked to ensure proper performance. *Describe procedure used.*	Compliant	
58.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function.	Compliant	Most recent certification performed on 12/2/2022
58.01	Hood filters are checked regularly and replaced when necessary.	Compliant	
59.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.*	Compliant	
60.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.	Compliant	
	Documentation		
	Total Non-Compliant (Includes Unknowns)	**0**	
61.00	The pharmacy creates a master formulation record the first time before compounding a new preparation	Compliant	
61.01	Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.	Compliant	
61.02	The **master formulation record** includes:		
61.03	Official or assigned name, strength, and dosage form	Compliant	
61.04	All necessary calculations	Compliant	

61.05	Description of all ingredients and their quantities	Compliant	
61.06	Compatibility and stability information including references (when available)	Compliant	
61.07	Equipment used for the preparation	Compliant	
61.08	Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors)	Compliant	
61.09	Container used and packaging requirements	Compliant	
61.10	Assigned BUD information	Compliant	
61.11	Labeling information including the name of and quantity or concentration of each active ingredient	Compliant	
61.12	Description of the finished preparation	Compliant	
61.13	Storage requirements	Compliant	
61.14	Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).	Compliant	
62.00	The pharmacy creates a compounding record for each compound prepared	Compliant	
62.01	The **compounding record** includes:		
62.02	Official or assigned name, strength and dosage of the preparation	Compliant	
62.03	Master Formulation Record reference	Compliant	
62.04	Sources, lot numbers, and expiration dates of all components	Compliant	
62.05	Total quantity or number of dosage units compounded	Compliant	
62.06	Person compounding the preparation	Compliant	
62.07	Person performing the quality control procedures	Compliant	
62.08	Person who approved the preparation	Compliant	
62.09	Date of compounding	Compliant	
62.10	Assigned internal identification number or prescription number	Compliant	
62.11	Description of the final preparation	Compliant	
62.12	Assigned BUD	Compliant	
62.13	Duplicate label	Compliant	
62.14	Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)?	Compliant	
62.15	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate	Compliant	

Compounding Procedures

	Total Non-Compliant (Includes Unknowns)	**0**	
63.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.	Compliant	
64.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.	Compliant	
65.00	The containers and closures selected meet USP standards (from container supplier).	Compliant	
66.00	Container selection determined by physical and chemical properties of the preparation.	Compliant	
67.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.	Compliant	
68.00	Personnel don appropriate protective garb when performing compounding.	Compliant	
68.01	If hazardous compounding, personnel don appropriate protective garb when compounding.	Compliant	

69.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*	Compliant	
70.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*	Compliant	
71.00	There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created.	Compliant	
72.00	There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.*	Compliant	
73.00	Personnel are appropriately garbed for protection when cleaning.	Compliant	
74.00	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment.* ***Compounding MUST be observed****, if compounding is not being performed at the time of survey, mark as "Non-Compliant".*	Compliant	
74.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "* ***Denial of Authorization*** *" form. List individual who signs the Denial of Authorization*		
	Finished Preparation Release Checks and Tests		
	Total Non-Compliant (Includes Unknowns)	**0**	
75.00	The finished preparation is observed to appear as expected in the master formulation record and documented.	Compliant	
76.00	As appropriate, the final completed preparation assessed for quality control and is documented, such as weight, mixing, clarity, odor, color, consistency, pH, and strength.	Compliant	
77.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.	Compliant	
78.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.	N/A	
78.01	If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient	Compliant	
78.02	If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.	N/A	
79.00	There are appropriate quality control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Review validation of equipment and personnel performance documentation.*	Compliant	
80.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.	Compliant	
80.01	Labeling contains generic name and quantity or concentration of each active ingredient.	Compliant	
80.02	Labeling contains assigned BUD.	Compliant	
80.03	Labeling contains storage and handling information.	Compliant	

80.04	If hazardous, labeling contains storage and handling information.	Compliant	
80.05	Labeling contains prescription or control number, whichever is applicable.	Compliant	
81.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).	Compliant	
82.00	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Compliant	
83.00	Preparations are stored and secured properly prior to dispensing based upon conditions upon which BUD was assigned.	Compliant	
84.00	Preparations are examined immediately after preparation **AND** again immediately prior to dispensing for any signs of instability.	Compliant	
	Patient Counseling and Communication		
	Total Non-Compliant (Includes Unknowns)	**0**	
85.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of products such as fentanyl, hormones and chemotherapy medications?	Compliant	
86.00	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?	Compliant	
87.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Compliant	
88.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.	Compliant	

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

National Association of Boards of Pharmacy®
Universal Inspection Form

The National Association of Boards of Pharmacy (NABP) developed this inspection form for sole use by NABP and its member boards of pharmacy for inspection of facilities licensed by a member board. Disclosure of the form to or use of the form by a third party, other than a facility being inspected by NABP or a member board, is strictly prohibited without NABP's prior written permission or unless required by state law.

Sterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: dba Boudreaux's New Drug Store
Inspection Date: 8/24/2023 (USP 795) - 8/29/2023 (USP 797)

		Finding	Notes
	Indicate the drug name, dosage or strength, and the size of the sample obtained for testing. (*NA if no sample)*		N/A
	Indicate the areas/rooms of the pharmacy entered to perform the inspection. *If the inspector did not fully garb and enter buffer room(s), indicate reason.*		Entered ante room to view buffer and hazardous rooms
	General Operations Information		
1.00	Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	Yes	
1.02	Are sterile compounded prescriptions picked up at the pharmacy?	Yes	
1.03	Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential facilities?	Yes	
1.04	Are sterile compounded prescriptions delivered/mailed to the practitioner for administration to the patient in the office, clinic, or facility?	Yes	
2.00	Does the pharmacy **distribute** sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	No	
2.01	Does the pharmacy distribute sterile compounded preparations to practitioners for office use?	No	
2.02	Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers?	No	
2.03	Is the pharmacy registered with the FDA as an Outsourcing Facility?	No	
2.04	Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.*	No	
3.00	Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?	No	
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations?	N/A	
4.00	Which of the following sterile compounds are prepared?		
4.01	Allergen extracts	No	
4.02	Parenteral solutions	Yes	
4.03	Parenteral *suspensions*	No	
4.04	Preservative-free parenterals	Yes	
4.05	Ophthalmic preparations	Yes	Autologous eye drops
4.06	Oral or nasal *inhalation* preparations (not topical sprays)	Yes	
4.07	Baths and soaks for live organs and tissues	No	
4.08	Irrigations for wounds and body cavities	Yes	
4.09	Any other sterile preparations (implants, pellets, etc.). *Provide list.*	No	
5.00	Does the pharmacy compound investigational drugs? *Provide list.*	No	

6.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate name and volume/percent compounded currently.*	No	
6.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	N/A	
6.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	N/A	
7.00	Does the pharmacy perform **low-risk** compounding? *Indicate percentage of low-risk sterile compounding.*	Yes	~ 30%
7.01	Are all low-risk compounds assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen)?	Yes	
7.02	If low risk, are the compounds located in segregated area are BUD 12 hours or less?	N/A	
7.03	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		
7.04	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*	N/A	
8.00	Does the pharmacy perform **medium-risk** compounding? *Indicate percentage of medium-risk sterile compounding.*	No	~ 30%
8.01	Are all medium-risk compounds assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen)?	N/A	
8.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		
8.03	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*	N/A	
9.00	Does the pharmacy perform **high-risk** compounding? *Indicate percentage of high-risk sterile compounding.*	Yes	~ 40%
9.01	Are all high-risk compounds assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen)?	Yes	
9.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		
9.03	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*	No	
10.00	Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump?	No	
11.00	Does the pharmacy perform compounding for **immediate use?** *Indicate percentage of immediate use sterile compounding.*	No	
12.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of hazardous sterile compounding.* *NIOSH list of hazardous drugs including chemotherapy, hormones, etc.*	Yes	~ 20%
12.01	Does pharmacy have a plan to comply with USP Chapter <800> by the implentation date? Describe plan.	Yes	
12.02	Are hazardous drugs segregated and stored in a room that is negative pressure (at least -0.01" wc) to adjacent areas and with at least 12 ACPH?	N/A	

12.03	Is hazardous drug waste quarantined in a designated area and disposed of in compliance with local, state, and federal regulations?	N/A	
13.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	
14.00	Does the pharmacy perform compounding using **blood products** (or other biological materials)? Such as wound care, autologous eye drops, etc. *Describe.*	Yes	Autologous eye drops
15.00	Does the pharmacy compound using any Federally **controlled substances I-V**? *Indicate controlled substances used and percentage of controlled substance sterile compounding.*	Yes	Testosterone; ~ 20%
16.00	**APIs:** Does the pharmacy make any sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes	
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *If not, indicate the source of APIs*	Yes	
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified*	Yes	Permit requests information from suppliers
16.03	Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources.*	No	
16.04	Does the computer track on-hand quantities of APIs used for compounding?	Yes	
17.00	Does the pharmacy use scales/balances for sterile compounding?	Yes	
17.01	If so, what type of scale/balanced is used? *List manufacturer and model number.*		OHAUS Explorer & OHAUS Adventurer Pro
17.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency.*	Yes	Calibrated daily & between formulations
18.00	Does the pharmacy have a **lyophilizer**?	No	
18.01	Where is the lyophilizer located? *Indicate location and ISO class of room.*		
18.02	Note the products lyophilized, and the volume or percent of products per week produced using the lyophilizer.		
18.03	Is the lyophilizer part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures?	N/A	
19.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	No	
20.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed*	Yes	Aerobiology Laboratory - viable air & surface sampling
21.00	**Quality Assurance/Quality Improvement**: Does the pharmacy continuous quality improvement program include sterile compounding measures? ***Note: If the facility indicates "yes", please ask each question below to verify.***	Yes	
21.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	Yes	
21.02	Does the pharmacy continuous quality improvement program include nonviable environmental monitoring and testing?	Yes	
21.03	Does the pharmacy continuous quality improvement program include viable environmental testing?	Yes	
21.04	Does the pharmacy continuous quality improvement program include personnel testing and verification?	Yes	
21.05	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?	Yes	

21.06	Does the pharmacy continuous quality improvement program include sterilization method testing and validation?	Yes	
21.07	Does the pharmacy continuous quality improvement program include end product testing (such as: potency, particulates, sterility, endotoxin, etc.)?	Yes	
21.08	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding CSPs?	Yes	
21.09	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes	
21.10	Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks?	Yes	
21.11	Are QREs involving CSPs that may have been contaminated or are recalled reported to the appropriate agency such as the Board of Pharmacy and/or FDA.	Yes	Depending on severity of event
21.12	Are all CFUs detected by any personnel, environmental, or product testing; or any other checks or tests including endotoxin, purity, potency, etc. remediated, appropriately investigated, cause determined, and processes implemented to prevent in the future, where applicable? *Review QA trends.*	Yes	
	Component Selection and Use		
	Total Non-Compliant (Includes Unknowns)	**0**	
22.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Compliant	
22.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products*. NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before being used for compounding.	Compliant	
22.02	USP- or NF-grade substances used, if available.	Compliant	
22.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	N/A	
22.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels*	Compliant	
22.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding.	Compliant	
22.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.	Compliant	
22.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than one (1) year, unless it is supported with data and/or testing. *Note: purity and quality testing may be performed to extend.*	Compliant	
22.08	All APIs are labeled with the date they were received.	Compliant	

22.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	Compliant	
22.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Compliant	
23.00	There are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	Compliant	
24.00	When manufactured products are used for compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	Compliant	
25.00	For **animal compounding**, does the compounding meet the same standards as compounding for human patients?	Compliant	
25.01	The pharmacist is knowledgeable or has the most up-to-date references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	Compliant	
25.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	N/A	
25.03	The pharmacist familiar with, or has the most up-to-date reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A	
25.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A	
25.05	The pharmacist is familiar with, or has the most up-to-date reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A	
26.00	If the pharmacy compounds **stock solutions** or components (that are then used to compound a finished product) using APIs, these stock solutions are categorized as high-risk compounding.	Compliant	
26.01	The stock solutions are assigned BUD based on the USP<797> high-risk compound BUD, OR are assigned on the basis of direct testing or extrapolation from reliable literature sources to support an extended BUD.	Compliant	
26.02	Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements.	Compliant	
	Environment		
	Total Non-Compliant (Includes Unknowns)	**1**	
27.00	If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.	Compliant	
28.00	If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas.	Compliant	Autologous eye drops compounded in negative pressure room
28.01	Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?	Compliant	
29.00	Entry into the sterile compounding areas is limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel).	Compliant	
30.00	The anteroom has a line of demarcation or other separation of the dirty to the clean side. Note: the line of demarcation may NOT be the doorway between the anteroom and the clean/buffer room.	Compliant	
30.01	Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation.	N/A	
30.02	Carts used in the clean/buffer room are kept on the clean side of the line of demarcation.	N/A	

31.00	All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating.	Compliant	
32.00	Walls are constructed of durable material, which is cleanable, such as epoxy-coated or heavy-gauge polymer material. *If panels are used, they are locked together and sealed.*	Compliant	
33.00	The ceiling surface shall be impervious and hydrophobic. *If tiles are used, they shall be locked and the seams between the tiles and where they meet the walls shall be caulked and sealed.*	Compliant	Solid ceiling
34.00	The floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall.	Non-Compliant	Cracks present in flooring material in buffer and chemo room; advised staff to seal cracks ASAP
35.00	The clean/buffer room or anteroom does not have dust collecting overhangs.	Compliant	
36.00	The exposed surfaces of:		
36.01	PEC are free of dirt, rust, chips and particulate matter.	Compliant	
36.02	Light fixtures are smooth, mounted flush, and sealed.	Compliant	
37.00	A working sink, located on the clean side of the line of demarcation, is available that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands and is away from/not adjacent to any PEC(s).	Compliant	
38.00	There is no sink or drain in the clean/buffer room.	Compliant	
39.00	Hand drying is with lint-free disposable towels, or an electronic or HEPA filtered hand dryer.	Compliant	
39.01	If using a hand dryer, particle count and smoke testing validation is performed while dryer is in use (while someone is actively using to dry their hands) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed. *(N/A if only using towels)*	N/A	
40.00	All air ducts controlling air flow into the sterile compounding clean/buffer room and anteroom are equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment and the anteroom with an ISO Class 7 (when adjacent to HD cleanroom) or ISO Class 8 environment.	Compliant	
41.00	Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the anteroom and clean/buffer room.	Compliant	HEPA filters are not flush with ceiling; renovations are planned as part of compliance to USP 797 revisions
42.00	If there are particle generating equipment/appliances in the clean/buffer room or anteroom (e.g. computers, printers, refrigerators, dishwashers, etc), they are located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while in use.	Compliant	
43.00	Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom.	Compliant	
44.00	If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.	Compliant	
44.01	Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment.	Compliant	
45.00	Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure.	Compliant	
45.01	Anteroom is at least 0.02" wc positive pressure to general pharmacy areas.	Compliant	
45.02	Clean/buffer room is at least 0.02" wc positive pressure to Anteroom.	Compliant	
45.03	Hazardous compounding room and drug storage area is at least 0.01" wc negative pressure to ISO Class 7 anteroom.	Compliant	Reading was -0.049" wc negative pressure at time of inspection; advised staff USP 797 revisions may specify specific range for negative pressure room (0.01' to 0.03" wc negative pressure)
45.04	Pressures are reviewed and documented on a log at least every work shift (minimum of once daily) or monitored by a continuous recording device. *View logs*	Compliant	

45.05	Written plan in place to detect and react to pressure differentials outside of limits.	Compliant	
46.00	If the clean/buffer room and anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings.	N/A	
46.01	The air flow is at least 40 feet per minute across the entire opening.	N/A	
46.02	Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*	N/A	
46.03	Written plan in place to detect and react to air flow measurements outside of limits	N/A	
46.04	This area is used only for low- and medium-risk compounding (**HD and high-risk not allowed**).	N/A	
47.00	**Temperature:** The temperature of all compounding and drug storage areas shall be maintained in accordance with standards, and a written plan shall be in place and followed to address any excursions.	Compliant	
47.01	Temperature in the **compounding area** is maintained to provide comfortable working conditions for compounding personnel of 20° C or cooler (68° F or cooler); Temperature can be more restrictive if warranted by specific drug product storage requirements. *Temperature records are maintained.*	Compliant	
47.02	If drugs are stored in the compounding area, temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Temperature records are maintained.*	Compliant	
47.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas). Temperature is maintained at controlled room temperature of 20° - 25° C (68° - 77° F) or as specified by FDA approved labeling for drug product storage.	Compliant	
47.04	Temperature monitoring in the **drug storage area** is performed at least once daily and documented. *Temperature records are maintained.*	Compliant	
47.05	Temperature in the **refrigerator or cooler** is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F) or as specified by FDA approved labeling for drug product storage.	Compliant	
47.06	Temperature monitoring in the **refrigerator** is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. Alternatively, continuous monitoring or retroactive detection using min/max may be used. *Temperature records are maintained.*	Compliant	
47.07	Temperature in the **freezer** is maintained to provide controlled frozen temperature of -25° to -10°C (-13° to 14°F) or as specified by FDA approved labeling for drug product storage.	Compliant	
47.08	Temperature monitoring in the **freezer** is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. *Temperature records are maintained.*	Compliant	
47.09	Action plan in place for any temperature excursions including evaluating excursion effects on drug product integrity for all temperature monitored areas.	Compliant	
48.00	**Humidity:** If warranted by specific drug products, humidity in the compounding area is maintained to provide humidity within the specified ranges. If drug products require storage in a "dry place", humidity is not to exceed 40%. (*Generally recommended range is 35-60% for performing sterile compounding .*)	Compliant	
48.01	If applicable, humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	
48.02	If applicable, excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	

48.03	If applicable, humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).	Compliant	
49.00	Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours.	Compliant	
50.00	When the ISO 5 PEC blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces	Compliant	
51.00	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*	Compliant	
52.00	The inside and outside doors of a pass-through are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*	N/A	
53.00	**If the PEC is a BSC or LAFW that is NOT located in an ISO Class 7 clean/buffer room**: BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities.	N/A	
53.01	Used only for low-risk compounded preparations with a 12-hour or less BUD assigned. *If yes, list percentage.*	N/A	
53.02	All garbing requirements are adhered to.	N/A	
53.03	Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	N/A	
53.04	Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas?	N/A	
53.05	The sink is separated from the immediate area of the ISO Class 5 BSC or LAFW (not adjacent).	N/A	
54.00	**If the PEC is a CAI/CACI that is NOT located in an ISO Class 7 clean/buffer room:** CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP.	N/A	
54.01	The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments.	N/A	
54.02	The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	N/A	
54.03	The sink is separated from the immediate area of the CAI or CACI (not adjacent).	N/A	
54.04	For NIOSH hazardous compounding in a CACI that is NOT located in a clean/buffer room, the CACI is located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH.	N/A	
	Cleaning and Disinfection		
	Total Non-Compliant (Includes Unknowns)	**0**	
55.00	Are all personnel performing cleaning appropriately garbed?	Compliant	
56.00	Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies? *All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).*	Compliant	
57.00	If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area?	Compliant	
58.00	Are reusable tools appropriately labeled to prevent them from being used inappropriately?	Compliant	

59.00	For cleaning and sanitizing agents that are not "ready-to -use" formulations, are there formulas and instructions for mixing or diluting the agents prior to use and is the preparation documented?	N/A	
60.00	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Verify no expired agents present.*	Compliant	
61.00	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?	Compliant	
62.00	Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?	Compliant	
62.01	If heavily soiled, cleaning includes the appropriate agent. *List agent(s) used.*	Compliant	Sterile water, sterile IPA, Virex Tb, Peridox RTU
63.00	Does sanitizing of the ISO 5 PEC include sanitizing with sterile 70% IPA using a nonlinting wipe?	Compliant	
64.00	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?	Compliant	
65.00	Does daily cleaning include the floors starting from the clean/buffer room and working outwards? Floor cleaning is not to occur during compounding.	Compliant	
66.00	If fatigue mats are used, are they cleaned daily and let dry on both sides?	N/A	
67.00	Is a tacky mat used and if so, is there a procedure in place regarding replacement?	Compliant	
68.00	Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? (*This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.)* *Check inside bins and shelving for dust if you are garbed.*	Compliant	
69.00	Is enough time allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents?	Compliant	
	Training *-Verify records of all compounding personnel (up to 10).*		
	Total Non-Compliant (Includes Unknowns)	**1**	
70.00	There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, hazardous drug handling, cleaning/disinfection/spills, garbing/gowning/hand hygiene, and aseptic technique. *Note that "compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding.* *List number of personnel training files viewed.*	Non-Compliant	Documentation available only for garbing/gowning/hand hygiene and aseptic technique; advised personnel to include aseptic technique, hood cleaning/disinfection/spills to training documentation.
70.01	All personnel performing compounding are not allowed to compound until training and initial testing is successfully completed.	Compliant	

70.02	All personnel that SUPERVISE compounding and/or perform verifications of other's compounding are not allowed to supervise or verify compounding until training and initial testing is successfully completed.	Compliant	
71.00	All personnel of reproductive capability who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs. *Teratogenicity, carcinogenicity, reproductive issues.*	Compliant	
72.00	There is documentation, such as an observational checklist, that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas including hazardous compounding areas are appropriately trained in garbing, cleaning and disinfection.	Compliant	
73.00	There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile products. *Documentation needs to include training on operation, and troubleshooting*	N/A	
74.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified. *View documentation.*	N/A	
75.00	There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate compounding risk levels and NIOSH hazardous drugs when applicable. *Indicate frequency, if testing more than annually*	Compliant	
76.00	There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling NIOSH hazardous drugs when applicable. Compounding skills evaluation to include use of equipment. *Indicate frequency, if testing more than annually.*	Compliant	
77.00	There is documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? *Personnel must pass the tests upon initial validation before being allowed to compound . Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations.* *Indicate frequency, if testing more than annually.*	Compliant	
78.00	There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedure and gloved fingertip sampling test. *Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results.* *Indicate frequency, if testing more than annually.*	Compliant	
79.00	There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.* *Indicate frequency, if testing more than annually.*	Compliant	Performing high-risk sterile compounding
80.00	The media-fill testing procedures include:		
80.01	Media selection (including obtaining COAs or growth promotion certificates from suppliers)	Compliant	
80.02	Fill Volume	Compliant	

80.03	Incubation time and temperature (Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.)	Compliant	
80.04	Inspection of filled units	Compliant	
80.05	Documentation	Compliant	
80.06	Interpretation of results	Compliant	
80.07	Action levels set with the corrective actions required	Compliant	
81.00	**High-Risk Sterile Compounding:** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU on both hands upon revalidation. Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than every 6 months.*	Compliant	
82.00	**High-Risk Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.*	Compliant	
83.00	**Failed testing:** Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.	N/A	No failed testing at time of inspection
83.01	Gloved fingertip tests that have failed have the organisms identified down to the genus to determine the most likely source of the contamination. This data is used to develop plans to prevent contamination.	N/A	No failed testing at time of inspection
83.02	There is a plan to evaluate the sterile compounds prepared by an employee with failed gloved fingertip tests or media fills to detect potential contamination of the sterile preparations compounded.	Compliant	
	Garbing		
	Total Non-Compliant (Includes Unknowns)	**0**	
84.00	Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.	Compliant	
85.00	Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas. *Include observations in the comments.*	Compliant	
86.00	Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. before entering clean/buffer room.	Compliant	
87.00	Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.	Compliant	
88.00	Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe).	Compliant	
89.00	Garbing includes head and facial hair covers and masks. *Note that facial hair requires both a facial hair cover AND a mask. Eye shields are optional unless using cleaning agents or preparing hazardous drugs. There is a method available to assure that all hair is covered.*	Compliant	

90.00	Hand cleaning is performed in the anteroom and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with a non-linting disposable towel or a hand dryer. *Scrub brushes are NOT recommended as they cause skin irritation and damage.*	Compliant	
91.00	The gown is nonshedding with sleeves that fit snugly around the wrists and enclosed at the neck.	Compliant	
92.00	All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.).	Compliant	
93.00	Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry. *Note: regular Purell Hand Sanitizer is NOT appropriate. Purell or other brand surgical hand scrub is appropriate - must have residual activity.*	Compliant	
94.00	Upon leaving the sterile product compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift.	Compliant	
95.00	Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes.*	Compliant	
96.00	Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing (wearing just a mask to check technician's work, for example)	Compliant	
	Environmental Monitoring		
	Total Non-Compliant (Includes Unknowns)	**0**	
97.00	The most recent PEC and room certification report is available.	Compliant	
97.01	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*	Compliant	
97.02	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*	Compliant	
97.03	Certification is performed at least every six months (view date of previous certification) and whenever a device or room is relocated or altered, or major service to the facility is performed. *If non-compliant, record the date of the previous certification.*	Compliant	
97.04	Certification is performed to the Controlled Environment Testing Association (CETA) guide (USP: CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities) and is noted on the report.	Compliant	
97.05	If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 guide.	N/A	
97.06	The PIC/compounding supervisor is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.	Compliant	
98.00	The certification report includes information about the equipment used for performing each test including: identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due).	Compliant	
98.01	The equipment used had not exceeded its calibration date at the time of certification.	Compliant	
99.00	The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.	Compliant	

99.01	ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources. *Recirculated air from the PECs may account for up to 15 ACPH in nonhazardous classified rooms only.*	Compliant	
99.02	ISO class 7 anteroom is certified as having a minimum of 30 ACPH. *Anteroom must be ISO class 7 if connected to a NIOSH hazardous compounding clean/buffer room.*	Compliant	
99.03	ISO class 7 hazardous sterile compounding room is certified as having a minimum of 30 ACPH. *Typically all of the air will be from outside.*	Compliant	
99.04	If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.	N/A	
100.00	Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the PECs and rooms). The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc.	Compliant	
100.01	Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate **unidirectional** airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC).	Compliant	
100.02	Air pattern analysis was conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs	Compliant	
100.03	Air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow.	Compliant	
101.00	Differential air pressure between rooms was measured.	Compliant	
101.01	The differential pressure measured was at least 0.02" water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed.	Compliant	
101.02	The differential pressure measured was at least 0.01" water column negative from the hazardous clean/buffer room to the anteroom with the doors closed.	Compliant	Differential pressure measured at -0.049" water column; advised staff about USP 797 revision requiring range to be within -0.01 to -0.03" water column
102.00	Displacement airflow between rooms or areas was measured. This is for a clean/buffer room without a door that closes to the anteroom - may be an open space or may have plastic strips in doorways.	N/A	
102.01	Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the anteroom. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*	N/A	
103.00	Particle counts of particles 0.5um and larger were measured under dynamic conditions.	Compliant	
103.01	ISO Class 5 areas and PECs are certified as having less than 3,520 particles per cubic meter of air (100 particles per cubic foot).	Compliant	
103.02	ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot).	Compliant	
103.03	ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air (100,000 particles per cubic foot).	N/A	
104.00	HEPA filter tests were performed.	Compliant	
104.01	All room HEPA filters were leak tested and if leaks found, they were fixed	Compliant	
104.02	All PEC HEPA filters were leak tested and if leaks found, they were fixed	Compliant	
105.00	PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.	Compliant	
106.00	Viable air (every six months) and surface sampling (periodically) tests have been conducted as required. Document frequency.	Compliant	

106.01	Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high risk compounding.*	Compliant	
106.02	Viable air sampling by active impaction using a volumetric air sampling device. *NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>.*	Compliant	
106.03	Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and anteroom and volume sufficient volume of air (400-1000L) was collected? *Note: 1000L must be collected in ISO Class 5 PECs to be able to detect the action level. Room samples can be 400-1000L.*	Compliant	
106.04	Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each ISO classified room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.	Compliant	
106.05	Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive). Classification Air Sample Surface Sample ISO Class 5 >1 CFU/m3 >3 CFU/plate ISO Class 7 >10 CFU/m3 >5 CFU/plate ISO Class 8 >100 CFU/m3 >100 CFU/plate *CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the raw total microbial count must be multiplied by the appropriate factor to determine the number of CFU/cubic meter.*	Compliant	
106.06	CFUs detected by any means (viable air or surface sampling, gloved fingertip testing, failed sterility tests, etc.) are identified to the genus level. *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*	Compliant	
106.07	If the number of CFUs detected **in the rooms** exceeds action levels, begin immediate remediation (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	Compliant	
106.08	If the number of CFUs detected **in the PECs** exceeds action levels, begin immediate remediation, (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	Compliant	
106.09	If any highly pathogenic microbes (e.g. mold, yeast, coagulase positive staphylococcus, or gram negative rods) were detected (whether or not the number of CFUs exceeds action levels), begin immediate remediation(e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	Compliant	
107.00	Facilities performing routine air or surface sampling with internal qualified personnel routinely verify sampling procedures. *Indicate the outside vendor used to verify procedures and frequency of verifications.*	N/A	
	Equipment		
	Total Non-Compliant (Includes Unknowns)	**0**	
108.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.*	Compliant	
109.00	All environmental monitoring equipment and gauges (differential pressure gauges or probes, air flow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.	Compliant	
110.00	All temperature and humidity (where applicable) monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented	Compliant	

111.00	Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration.	N/A	
111.01	There is documentation of the ACD tubing being changed or discarded every 24 hours	N/A	
111.02	The ACD is used when performing media fill testing.	N/A	
	Compounding Procedures		
	Total Non-Compliant (Includes Unknowns)	**0**	
112.00	Gloves are disinfected with adequate frequency with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA).	Compliant	
113.00	Nonessential objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads)?	Compliant	
114.00	Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area.	Compliant	
115.00	Supplies required for the scheduled operations of the shift are prepared by wiping the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart.	Compliant	
116.00	Compounding employees are using appropriate aseptic technique. *May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA).* ***Compounding MUST be observed****, if compounding is not being performed at the time of survey mark item as "Non-Compliant"*	Compliant	
116.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "* ***Denial of Authorization*** *" form. List individual who signs the Denial of Authorization*		
117.00	Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.	Compliant	
118.00	All rubber stoppers, of vials and bottles and the necks of ampules are disinfected with sterile 70% IPA waiting for at least 10 seconds before they are used to prepare CSPs.	Compliant	
119.00	Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. *If exposed to less than ISO Class 5 air, used within 1 hour and discarded.*	Compliant	
120.00	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. *May not be stored for any time period.*	Compliant	
121.00	Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.	Compliant	
122.00	The compounding record is complete. *View several completed compounding records and answer each of the following questions. List records reviewed.*	Compliant	
122.01	Official or assigned name, strength and dosage of the preparation	Compliant	
122.02	Names, lot numbers and expiration dates of all components	Compliant	
122.03	Total quantity or number of units compounded	Compliant	
122.04	Person compounding the preparation	Compliant	

122.05	Person performing the quality control procedures	Compliant	
122.06	Person who approved the preparation	Compliant	
122.07	Date of compounding	Compliant	
122.08	Assigned internal identification number or prescription number	Compliant	
122.09	Assigned BUD and reference if extended beyond USP guidelines	Compliant	
122.10	Duplicate label	Compliant	
122.11	Sterilization method (if applicable)	Compliant	
122.12	Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable	Compliant	
123.00	Procedure for in-process checks is followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is* ***recommended*** *to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*	Compliant	
124.00	Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Compliant	
125.00	Labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include names and quantity or concentration of active ingredients, BUD, total volume, route of administration, storage conditions and other information for safe use.	Compliant	
126.00	Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY NABP IMMEDIATELY.**	Compliant	
127.00	Preparations without additional stability testing or supported by data are assigned BUDs within USP<797> guidelines. **Low Risk:** 48 hours room temp, 14 days refrigerated, 45 days frozen **Medium Risk:** 30 hours room temp, 9 days refrigerated, 45 days frozen **High Risk:** 24 hours room temp, 3 days refrigerated, 45 days frozen	Compliant	
128.00	If extended BUDs are assigned, are they assigned on the basis of stability data extrapolated from reliable literature sources? *View records, preparation must exactly match the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.*	Compliant	
129.00	If extended BUDs are assigned, has the facility performed its own stability testing? *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc. If so, view records for at least three products and list the products reviewed below. List the products reviewed.*	N/A	
130.00	Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use.	N/A	
131.00	**Filter sterilization** in an ISO 5 environment and documentation includes:		
131.01	If the compounded preparation contains large particles, a prefilter is placed upstream from the sterilizing filter.	Compliant	
131.02	The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP; and the filter is intended for human-use applications for sterilizing CSPs (labeling on the filter does not indicate "research only" or "laboratory only", for example).	Compliant	
131.03	Is the appropriate capacity filter being used for the volume being filtered.	Compliant	

131.04	Filtering is completed rapidly without filter replacement.	Compliant	
131.05	Confirmation of filter integrity/bubble testing is performed and value documented for each filter used with each batch sterilized by filtration. View documentation on compounding records of items sterilized by filtration to confirm.	Compliant	
132.00	**Steam sterilization** documentation includes:		
132.01	The autoclave has been verified for the exposure time and mass of the items to be sterilized	N/A	
132.02	Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices	N/A	
132.03	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization	N/A	
132.04	That the CSP will not be adversely affected by the steam and heat	N/A	
132.05	The description of steam sterilization includes conditions and duration for specific CSPs	N/A	
132.06	That the effectiveness of steam sterilization is verified each time using appropriate biological indicators of Bacillus stearothermophilus and other confirmation methods such as temperature-sensing devices.	N/A	
133.00	**Dry heat sterilization** documentation includes:		
133.01	Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture	N/A	
133.02	Sufficient space is left between materials to allow for air circulation	N/A	
133.03	The description of dry heat sterilization includes conditions and duration for specific CSPs	N/A	
133.04	That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators of Bacillus subtilis and other confirmation methods such as temperature-sensing devices.	N/A	
133.05	Heated filtered air is evenly distributed throughout the chamber with a blower and the oven is equipped with a system for controlling and recording temperature and exposure period.	N/A	
134.00	**Depyrogenation by dry heat** documentation includes:		
134.01	Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes	Compliant	
134.02	The description of the cycle and duration for specific load items	Compliant	
134.03	The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs)	Compliant	
134.04	Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a 3-log reduction in endotoxins	Compliant	
135.00	Other methods of sterilization are used with documented procedures and validation performed. *Indicate method.*	N/A	
	Finished Preparation Release Checks and Tests		
	Total Non-Compliant (Includes Unknowns)	**0**	
136.00	Are products visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release?	Compliant	
137.00	Are there checks for container, closure integrity and any other apparent visual defects?	Compliant	
138.00	Is compounding accuracy documented by verification of steps?	Compliant	
139.00	Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*	Compliant	
140.00	Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*	N/A	

141.00	**Sterility testing (USP <71>).** *If testing is performed to a higher standard than the minimums below, describe.*		
141.01	Sterility testing includes both bacterial and fungal testing.	N/A	
141.02	Sterility testing is performed for all CSPs that have extended BUDS.	N/A	
141.03	Sterility testing is performed for high-risk CSPs prepared in batches of more than 25 identical containers	N/A	
141.04	Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized	N/A	
141.05	The appropriate quantities of units are sterility tested. Parenterals, number of units in the batch is: 1. Not more than 100, test 10% or four units, whichever is greater 2. More than 100 but more than 500, test 10 units 3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less. For non-parenterals (eye drops, inhalation, etc.): 1. Not more than 200 containers, test 5% or 2 containers, whichever is greater 2. More than 200, test 10 containers	N/A	
141.06	For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken. *View testing records and note any products with failed results and actions taken.*	N/A	
141.07	If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. *View testing records and note any products with failed results and actions taken.*	N/A	
142.00	**Endotoxin testing (USP <85>).** *If testing is performed to a higher standard than the minimums below, describe.*		
142.01	Is endotoxin testing performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials)	N/A	
142.02	High-risk CSPs prepared in multiple dose vials for administration to multiple patients	N/A	
142.03	High-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized	N/A	
142.04	For products failing testing, product is quarantined, and an investigation is performed and action taken. *View testing records and note any products with failed results and actions taken.*	N/A	
	Patient Counseling and Communication		
	Total Non-Compliant (Includes Unknowns)	**0**	
143.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?	Compliant	
144.00	Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products?	Compliant	
145.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Compliant	
146.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated CSP was administered are notified of the potential risk.	Compliant	

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Lookup Detail View

Name and Address

Name	PublicAddress
Boudreaux's New Drug Store	404 E Prien Lake Rd Lake Charles, LA 70601-8507

Credential Information with supervision

License	License Type	Issue Date	Expiration Date	Status	Pharmacist In Charge
PHY.008142-IR	Pharmacy - Community ~ Independent	09/09/2020	12/31/2025	Current, without restriction or limitation	Kylee B. Vidrine

List of Current Employees

Name	License	License Type	Expiration Date	Status
Alexis Xuan-Nhi Thi Nguyen	PST.025437	Pharmacist	12/31/2025	ACTIVE
Amanda S. Brassieur	CPT.007495	Certified Pharmacy Technician	06/30/2026	ACTIVE
Ava Klaire Espinosa	CPT.017879	Certified Pharmacy Technician	06/30/2026	ACTIVE
Christopher R. Robin	PST.016333	Pharmacist	12/31/2025	ACTIVE
Ericka Jade Adams	CPT.017987	Certified Pharmacy Technician	06/30/2026	ACTIVE
Jace Lianne Myers	PTC.033929	Pharmacy Technician Candidate	04/22/2027	ACTIVE
Kylee B. Vidrine	PST.021317	Pharmacist	12/31/2025	ACTIVE
Kylie Denae Gaspard	PTC.033923	Pharmacy Technician Candidate	04/22/2027	ACTIVE
Reanna Rose Huckaby	PTC.033867	Pharmacy Technician Candidate	04/08/2027	ACTIVE
Shania Nichole Johnson	CPT.017664	Certified Pharmacy Technician	06/30/2026	ACTIVE
Tina M. Guin	CPT.015948	Certified Pharmacy Technician	06/30/2026	ACTIVE

Prior Board Orders (may or may not be disciplinary in nature)

Case Help

File Number	Status	Date Received	Date Closed	Resolution	Action Documents
2022-103	CLOSED	03/29/2022	08/17/2022	VIDRINE PHARMACEUTICAL GROUP, LLC D/B/A BOUDREAUX'S NEW DRUG STORE is ordered to pay a fine of $25,000.00 and to reimburse the Board $250.00 for administrative costs, and $2,791.01 investigative cost with total payment due to the Board of $28,041.01.	Orders-PHY.008142_BoudreauxNewDrugStore_2022.0817.pdf (ViewPublicLookupDocument.aspx?DocumentIdnt=164494&GUID=7C0F81C5-4A2C-489E-857E-DF653EB0FE56)

CDS Schedules and Restrictions

I	II	II-N	III	III-N	IV	V	Restrictions	Alternative Privileges

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Louisiana Board of Pharmacy Online eLicense Website

The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FV9694666	05-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-11-2023

VIDRINE PHARMACEUTICAL GROUP, LLC
BOUDREAUX'S NEW DRUG STORE
404 E. PRIEN LAKE RD.
LAKE CHARLES, LA 70601

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Vidrine Pharmaceutical Group, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 404 E. Prien Lake Road

City: Lake Charles State: LA Zip: 70601

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (337) 436-7216 Toll Free # (NAC 639.708, NRS 639.23286): 1-855-305-2110

Fax: (337) 436-7217 Contact Email: _____

Website: https://boudreauxsnewdrug.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Kylee Vidrine

Supervising/Managing Pharmacist NV Pharmacist Registration #: _____

Name of Designated Person(s) as defined by revised USP-797 guidelines: Kylee Vidrine

Email of Designated Person(s): kvidrine@bndsrx.com

Telephone of Designated Person(s): (832) 527-3558

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 05/02/2024

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? once a month

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

12. What laboratory performs your sterility or endotoxin testing?

Name: Eagle Analytical Services

Address: 11111 S Wilcrest Dr S1000

City: Houston State: TX Zip: 77099

Telephone: (800) 745-8916

13. What is your procedure for visual inspection of compounded sterile products?

We only use clear vials in order for better visualization. Technicians inspect the final products and verifying pharmacists inspect the final product.

14. How often do you perform glove fingertip and medial fill testing?

every 6 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

All starting employees are sent to PCCA training facilities for 1 week to complete CORE training and Sterility Assurance training. They also complete all training documents included in our SOP 1.6.

Please see attached SOP 1.6.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see attached SOPs 1.25 & 1.4 on our cleaning procedures.

17. Who performs the sterile compounding process at your facility?

Amanda Brassieur, Kylee Vidrine

18. Who is responsible and accountable for the sterile compounding process at your facility?

Amanda Brassieur, Kylee Vidrine

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Overnight or 2-day FedEx Delivery, ice chest coolers, ice packs, temperature indicators

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Are you complying with all USP 800 guidelines?	☐ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	☐ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☐Yes ☐No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?	
6. What is the frequency for using sporicidal agents?	
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	☐ Yes ☐ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	☐ Yes ☐ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kylee Vidrine

Name of Person who Completed the Form

Owner

Title

Signature (copies or stamps not accepted)

10/21/2024

Date

Board Use Only	Date Received: 10/22/24 Date Approved: _____ Approved By: _____

1.0 Purpose

1.1 The purpose of this procedure is to establish requirements for training new and existing staff at Boudreaux's New Drug Store to ensure quality of compounded preparations and safety of staff.

2.0 Definitions

2.1 N/A

3.0 Procedure

3.1 This procedure applies to all staff involved with compounding activities.

3.2 Orientation for new employees shall include:

3.2.1 Tour of Facility

3.2.2 Pharmacy Hours, Work Schedule, Lunch

3.2.3 Dress Code

3.2.4 Telephone Use

3.2.5 HIPAA, Pharmacy Security

3.2.6 Job Description

3.2.7 SOP Manual (includes Safety Training)

3.2.8 Didactic Training (as applicable)

3.2.9 Equipment Training and Competency Assessment (as applicable)

3.2.10 Competency Assessments (as applicable)

3.3 SOP Manual shall be read and Annual Review form located in the front of SOP manual shall be signed by new employees and annually by all employees. Employees shall read SOPs that are pertinent to their position.

3.4 Upon completion of orientation, Orientation Checklist (Attachment 2) along with resume. license verification, Job Description (Attachment 3), Safety Training Checklist (SOP 6.40 Attachment 10), Hazardous Chemical Acknowledgement (SOP 6.40 Attachment 11), Hepatitis B waiver, and documentation of required training and competency assessments shall be filed in employee training file.

3.4.1 Compounders, checking pharmacists and pharmacist-in-charge

shall complete orientation training and competency assessments before performing regular job duties and annually thereafter (as required). Pharmacists shall complete all of the same training and competency assessments as technicians plus pharmacist-specific training and competency assessments.

3.5 Equipment training and competency assessment shall be performed before using equipment and upon evidence of poor technique. Document on Attachment 4 (Equipment Training and Competency Assessment).

3.6 Competency Assessment

3.6.1 Nonsterile Compounding

3.6.1.1 Nonsterile compounding staff shall be trained and observed and interviewed for competency on commonly compounded dosage forms prior to first performing compounding. The competency of nonsterile compounding staff shall be continually evaluated and documented at least annually on Competency Assessment Nonsterile Compounding (Attachment 5)

3.6.2 Sterile Compounding

3.6.2.1 Compounding technique shall be observed by a qualified person with media fills (and observed competency assessments) to assess sterile compounding skills prior to first performing sterile compounding, every six months (high risk) and/or every twelve months (low and medium risk) thereafter and upon evidence of poor technique. The competency of sterile compounding staff shall be continually evaluated and documented at least every six months (high risk) and/or every twelve months (low and medium risk) on Competency Assessment Sterile Compounding (Attachment 6).

3.6.2.2 Sterile compounding staff shall perform media fills (non-sterile to sterile and sterile to sterile, as applicable) to be compounded under conditions that closely simulate the most challenging or stressful conditions encountered. A post garb and post compounding fingertip sample shall be performed on each hand along with a post compounding surface sample of the direct compounding area. Incubate fingertip and surface samples at 30-35C for 48-72 hours. Incubate media fill at 30-35C

for 14 days. Note that sterile compounding staff shall pass three gloved fingertip samples on each hand with zero cfus prior to performing sterile compounding for the first time at this location.

3.6.2.2.1 Basic High Risk Media Fill Procedure

- Dissolve 3g of nonsterile soybean-casein digest medium in 100ml of nonbacteriostatic water to make a 3% nonsterile solution.
- Draw 25ml of the medium into each of three 30ml sterile syringes.
- Transfer 5ml from each syringe into separate sterile 10ml vials. Mark these vials (positive) control.
- Affix a sterile 0.22 micron filter to each syringe and transfer 10ml of sterile medium into each of two sterile 10ml vials. Mark these samples.

3.6.2.3 Low and Medium Risk Media Fill shall be performed (as applicable) using a commercial kit.

3.6.2.4 Sterile compounding staff shall be observed performing skills assessments related to (1) hand hygiene and garbing; (2) CAI cleaning and aseptic technique; (3) Cleaning and disinfecting procedures every six months. Document results on Attachment 6A (Sterile Compounding Skills Assessment - Hand Hygiene and Garbing), Attachment 6B (Sterile Compounding Skills Assessment - CAI Cleaning and Aseptic Technique), and Attachment 6C (Sterile Compounding Skills Assessment - Cleaning and Disinfecting Procedures).

3.6.3 Pharmacists shall be trained and observed and interviewed for competency on checking compounded preparations prior to performing checking, every twelve months thereafter and upon evidence of poor technique. Document on Attachment 7 (Pharmacist Check Training and Competency Assessment).

3.6.4 Pharmacists shall be trained and observed and interviewed for competency on counseling of compounded preparations prior to performing counseling, every twelve months thereafter and upon evidence of poor technique. Document on Attachment 8 (Pharmacist Counseling Training and Competency Assessment.

3.7 Didactic review

3.7.1 Review of USP 795 shall be performed prior to performing nonsterile compounding or checking nonsterile compounded preparations, at least every twelve months thereafter and upon evidence of poor technique. A written quiz shall be completed to document understanding. File a copy of training and quiz in training file. Re-training required for scores < 80%.

3.7.2 Review of USP 797 and aseptic technique shall be performed prior to performing sterile compounding or checking sterile compounded preparations, at least every six months thereafter and upon evidence of poor technique. A written quiz shall be completed to document understanding. File a copy of training and quiz in training file. Re-training required for scores < 80%.

3.8 Regular ongoing training related to compounding shall be performed and may include live training, webinars, demonstrations, journal articles, drug information, calculations, mock recalls, etc. Training may be documented on Attachment 1 (Staff Training), Attachment 10 (Staff Meeting Minutes), NABP e-profile, Training Certificates, etc.

3.9 Training File Checklist (Attachment 9) may be used to track training.

3.10 Staff meetings shall be held regularly and include issues related to quality, privacy or security, and compliance as well as staff training. Staff in attendance shall sign in for meeting and minutes shall be documented on Attachment 10 or equivalent form.

4.0 References

4.1 Louisiana Board of Pharmacy Laws & Rules

4.2 USP <795> Pharmaceutical Compounding – Nonsterile Preparations

4.3 USP <797> Pharmaceutical Compounding – Sterile Preparations

4.4 USP <800> Hazardous Drugs – Handling in Healthcare Settings

5.0 Attachments

5.1 Attachment 1 Staff Training

5.2 Attachment 2 Orientation Checklist

5.3 Attachment 3 Job Descriptions

5.4 Attachment 4 Equipment Training and Competency Assessment

5.5 Attachment 5 Competency Assessment Non-Sterile Compounding

5.6 Attachment 6 Competency Assessment Sterile Compounding

5.7 Attachment 7 Pharmacist Check Competency Assessment

5.8 Attachment 8 Pharmacist Counseling Competency Assessment

5.9 Attachment 9 Training File Checklist

5.10 Attachment 10 Staff Meeting Minutes

☐ Draft ☐ Final Approved by _____ This policy implemented on_____	Annual Policy Review Reviewer/Date _____ Reviewer/Date _____ Reviewer/Date _____

Staff Training

Description of Training – Attach training or include instructions on how to access training.

Is a Quiz required? ☐ Yes ☐ No
Attach quiz ensuring it contains name, date and grade. Re-training required for scores < 80%.

I have completed and understand the above training.

Signature Date

Orientation Checklist

Employee_____ Hire Date _____

(Check all that apply)		**ALL EMPLOYEES**
___Pharmacist-in-charge		___Tour of Facility
___Compounding Pharmacist (NS)		___Pharmacy Hours, Work Schedule, Lunch
___Pharmacy Intern		___Dress Code
___Compounding Technician (NS)		___Telephone Use
___Sterile Compounding		___HIPAA, Pharmacy Security
___Non-Compounding Technician		___Resume and License Verification
___Pharmacy Clerk		___Job Description
___Delivery Driver		___SOP Manual (and Safety Training Checklist)
___Compliance Officer		___Hazardous Chemical Acknowledgement
___HD Designated Person		___Hepatitis B Waiver

Compounders, Checking Pharmacists and PIC shall complete orientation training/competency before performing job duties. Attach all documentation listed (as applicable) and file in employee training file.

Initial Didactic Training (Review of USP 795, USP 797 and Aseptic Technique with Quiz grade >80%)
Complete □ Not Applicable □

Initial Equipment Training/Competency (SOP 1.60 Att 4)
Complete □ Not Applicable □

Initial Process Training/Competency - Nonsterile Compounding (SOP 1.60 Att 5)
Complete □ Not Applicable □

Initial Process Training/Competency – Hazardous Chemical Handling (SOP 1.65 Att 1)
Complete □ Not Applicable □

Initial Process Training/Competency - Pharmacist Check, Pharmacist Counseling (SOP 1.60 Att 7 & 8)
Complete □ Not Applicable □

Documentation of Sterile Training Program
Complete □ Not Applicable □

Gloved Fingertip Initial Assessment (3 samples with zero cfu) (SOP 1.60 Att 6)
Complete □ Not Applicable □

Media Fills with Skills Assessment (SOP 1.60 Att 6)
Hand Hygiene and Garbing, Hood Cleaning and Aseptic Technique, Cleaning and Disinfecting Procedures
Complete □ Not Applicable □

I have completed the above orientation training and competency assessment. I understand the responsibilities of my position and feel competent to perform my job according to the pharmacies SOPs.

Employee signature _____ Date _____

Pharmacist-in-charge signature _____ Date _____

Pharmacist-in Charge Job Description

Job Summary: Responsible for overseeing the operation of Boudreaux's New Drug Store.

Job activities and responsibilities: Pharmacist-in-charge shall be responsible for overseeing the operation of Boudreaux's New Drug Storeand ensuring pharmacy is in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs, and shall be personally in full and actual charge of Boudreaux's New Drug Storeand its staff. Pharmacist-in-charge shall 1) Establish for the employees of the pharmacy policies and procedures for the procurement, storage, compounding, and dispensing of drugs.; 2) Supervise all of the professional employees of the pharmacy.; 3) Supervise all of the nonprofessional employees of the pharmacy insofar as their duties relate to the sale or storage, or both, of drugs.; and 4) Establish and supervise the recordkeeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs. Pharmacist-in-charge shall ensure either personally or through a designee that employees have knowledge of and follow applicable standard operating procedures including compliance with standards for safety, quality, sterility, accuracy, potency and cleanliness. Pharmacist-in-charge shall be the contact person for all state and federal inspections.

Minimum qualifications: Louisiana-licensed pharmacist with compounding training or equivalent experience.

Physical requirements: Position requires good hand-eye coordination and the ability to lift up to thirty pounds.

Appearance: Should reflect positively on Boudreaux's New Drug Store.

Signature:_____ **Date:**_____

Printed name:_____

Compounding Pharmacist (Nonsterile) Job Description

Job Summary: Performs all aspects of nonsterile pharmacy compounding at Boudreaux's New Drug Store.

Job Activities and Responsibilities: Compounding pharmacist shall have knowledge of and follow applicable Standard Operating Procedures. Non-sterile compounding may include but is not limited to the compounding of capsules, oral liquids, topical medications, nasal preparations, suppositories, troches, tablet triturates or lollipops. Hormones and other potentially hazardous chemicals are used in non-sterile compounding. Position requires close attention to detail. Standards for accuracy and potency shall be consistently met. Compounding pharmacist shall perform compounding and supervise pharmacy technicians compounding of preparations, filling and labeling of prescriptions and prepackaging of bulk medications. Compounding pharmacist shall also perform order entry, communicate with providers for the purpose of receiving new prescription orders, clarification of prescriptions or refill authorizations, perform final check on prescriptions, counsel patients and answer questions from patients and providers. Compounding pharmacist shall also monitor inventory levels for re-order of low inventory or expiring chemicals, receive new inventory, ensure maintenance of MSDS and Certificates of Analysis, oversee annual inventory and ensure performance of daily, weekly and monthly cleaning using appropriate disinfectants and techniques and finally, ensure that environmental monitoring and validation testing is performed according to policies and procedures.

Minimum qualifications: Louisiana-licensed pharmacist with compounding training or equivalent experience preferred.

Physical requirements: Position requires good hand-eye coordination and the ability to lift up to thirty pounds.

Reports to: Pharmacist-in-charge.

Appearance: Should reflect positively on Boudreaux's New Drug Store.

Employee Signature: _____ **Date:** _____

Printed Name: _____

Pharmacy Intern Job Description

Job Summary: Performs all aspects of nonsterile pharmacy compounding at Boudreaux's New Drug Store.

Job Activities and Responsibilities: Pharmacy Intern shall have knowledge of and follow applicable Standard Operating Procedures. Non-sterile compounding may include but is not limited to the compounding of capsules, oral liquids, topical medications, nasal preparations, suppositories, troches, tablet triturates or lollipops. Hormones and other potentially hazardous chemicals are used in non-sterile compounding. Position requires close attention to detail. Standards for accuracy and potency shall be consistently met. Pharmacy Intern shall perform compounding, filling and labeling of prescriptions and prepackaging of bulk medications. Pharmacy Intern shall also perform order entry, communicate with providers for the purpose of receiving new prescription orders, clarification of prescriptions or refill authorizations, perform final check on prescriptions, counsel patients and answer questions from patients and providers. Pharmacy Intern shall also monitor inventory levels for re-order of low inventory or expiring chemicals, receive new inventory, ensure maintenance of MSDS and Certificates of Analysis, oversee annual inventory and ensure performance of daily, weekly and monthly cleaning using appropriate disinfectants and techniques and finally, ensure that environmental monitoring and validation testing is performed according to policies and procedures. Pharmacy Intern may perform any activity restricted to a pharmacist, while under the supervision of a registered pharmacist.

Minimum qualifications: Louisiana-registered pharmacy intern.

Physical requirements: Position requires good hand-eye coordination and the ability to lift up to thirty pounds.

Reports to: Pharmacist-in-charge.

Appearance: Should reflect positively on Boudreaux's New Drug Store.

Employee Signature: _____ **Date:** _____

Printed Name: _____

Sterile Compounding Job Description

Job Summary: Sterile compounding pharmacist/technician is responsible for compounding low, medium and high-risk sterile products in a clean room environment.

Job Activities and Responsibilities: Sterile compounder must have knowledge of and follow applicable Standard Operating Procedures. Sterile compounding includes but is not limited to injections, ophthalmics and inhalation solutions. Position requires close attention to detail. Standards for strength, quality, purity, integrity, sterility, and endotoxin content must be consistently met. Sterile compounder will also monitor inventory levels for re-order of low inventory or expiring chemicals. Daily and monthly cleaning performed using appropriate disinfectants and techniques. Environmental monitoring and validation testing performed according to policies and procedures. Technicians work under the supervision of a pharmacist.

Minimum qualifications: Louisiana-licensed pharmacist or Louisiana-registered pharmacy technician with formal training in sterile compounding or equivalent experience.

Physical requirements: Position requires good hand-eye coordination and the ability to lift up to thirty pounds.

Reports to: Pharmacist-in-charge.

Appearance: Scrubs and appropriate PPE required. Long hair should be pulled back and cosmetics and visible jewelry removed.

Employee Signature: _____ **Date:** _____

Printed Name: _____

Compounding Technician (Nonsterile) Job Description

Job Summary: Responsible for compounding non-sterile pharmaceutical preparations under the supervision of the compounding pharmacist.

Job Activities and Responsibilities: Compounding technician shall have knowledge of and follow applicable Standard Operating Procedures. Non-sterile compounding may include but is not limited to the compounding of capsules, oral liquids, topical medications, nasal preparations, suppositories, troches, tablet triturates or lollipops. Hormones and other potentially hazardous chemicals are used in non-sterile compounding. Position requires close attention to detail. Standards for accuracy and potency shall be consistently met. Compounding technician shall compound medication, fill and label prescriptions and prepackage bulk medications. Compounding technician shall also monitor inventory levels for re-order of low inventory or expiring chemicals, receive new inventory, maintain MSDS and Certificates of Analysis and perform daily, weekly and monthly cleaning using appropriate disinfectants and techniques. Environmental monitoring and validation testing shall be performed according to policies and procedures. Technicians shall work under the supervision of a pharmacist.

Minimum qualifications: Louisiana-registered pharmacy technician with formal training in nonsterile compounding or equivalent experience.

Physical requirements: Position requires good hand-eye coordination and the ability to lift up to thirty pounds.

Reports to: Compounding Pharmacist.

Appearance: Scrubs (preferred) and appropriate PPE required.

Employee Signature: _____ **Date:** _____

Printed Name: _____

Non-Compounding Technician Job Description

Job Summary: Responsible for performing non-compounding activities under the supervision of a pharmacist.

Job Activities and Responsibilities: Must have knowledge of and follow applicable Standard Operating Procedures. Technician may be first point of contact for customers so it is very important that customers are greeted and assisted in a friendly and professional manner. Technician shall ensure accuracy of patient information and receive patient payment. Other responsibilities may include checking prescriptions for completeness and entering necessary information into computer to generate a prescription label and batch sheet (if necessary), filling and labeling prescriptions and prepackaging bulk medications, communicating with prescribers to receive refill authorization, receiving patient refills by telephone, directing calls or taking and relaying messages, organization and appearance of the pharmacy front-end, ordering and pricing front-end merchandise. Technician shall work under the supervision of a pharmacist.

Minimum qualifications: Louisiana-registered pharmacy technician with formal training or equivalent experience.

Physical requirements: Ability to use a computer keyboard, fax machine, communicate by telephone, and lift up to thirty pounds.

Reports to: Pharmacist.

Appearance: Should reflect positively on Boudreaux's New Drug Store.

Employee Signature: _____ **Date:** _____

Printed Name: _____

Pharmacy Clerk Job Description

Job Summary: Responsible for performing pharmacy support activities under the supervision of a pharmacist.

Job Activities and Responsibilities: Must have knowledge of and follow applicable Standard Operating Procedures. Clerk may be first point of contact for customers so it is very important that customers are greeted and assisted in a friendly and professional manner. Clerk shall ensure accuracy of patient information and receive patient payment. Other responsibilities may include entering patient information into computer, receiving patient refills by telephone, directing calls or taking and relaying messages, organization and appearance of the pharmacy front-end, ordering and pricing front-end merchandise. Clerk shall work under the supervision of a pharmacist and is not permitted to perform duties restricted to pharmacists or technicians.

Minimum qualifications: High School Diploma preferred.

Physical requirements: Ability to use a computer keyboard, fax machine, communicate by telephone, and lift up to thirty pounds.

Reports to: Pharmacist.

Appearance: Should reflect positively on Boudreaux's New Drug Store.

Employee Signature: _____ **Date:** _____

Printed Name: _____

Delivery Job Description

Job Summary: Delivers medication in the local area without compromising product integrity by using appropriate containers that protect medication from wide variations in temperature, structural damage or unapproved light sources. Brings mail and packages to the post office. Runs other errands as requested.

Job Activities and Responsibilities: Driver shall have knowledge of and follow applicable Standard Operating Procedures. Driver shall deliver hazardous medications at times and shall ensure vehicle contains a spill kit and know how to use it. Driver shall follow all rules in accordance with good driving practices which include following posted speed limits and wearing seat belts (and ensuring all passengers also wear seatbelts). Driver shall not be permitted to drink alcohol or have any alcohol in the vehicle. Driver shall not be permitted to talk on a cell phone or text while driving. (Driver should pull over to the side of the road to use cell phone). Driver shall be responsible for any fines for speeding or vehicular misconduct.

Minimum qualifications: Must have a current Louisiana driver's license.

Physical requirements: Able to safely operate a motor vehicle and lift up to thirty pounds.

Reports to: Pharmacist.

Appearance: Should reflect positively on Boudreaux's New Drug Store.

Employee Signature: _____ **Date:** _____

Printed Name: _____

Compliance Officer Job Description

Job Summary: Oversees compliance activities with regard to pharmacy standard operating procedures, state and federal regulations and accreditation standards.

Job Activities and Responsibilities: Compliance Officer shall have knowledge of and follow applicable standard operating procedures. Responsibilities include monitoring the pharmacy and pharmacy staff for compliance with state and federal regulations, accreditation standards and standard operating procedures; and overseeing Performance Improvement activities including (1) ensuring the collection of incident data (including adverse events, complaints, important aspects related to the service provided, and monitoring of processes that involve risks including infections and communicable diseases); (2) monitoring of trends; (3) investigation of incidents/trends including taking necessary follow-up action; and (4) completion of appropriate documentation. Compliance Officer shall hold a quarterly Performance Improvement meeting to review findings with staff. Compliance Officer shall create a comprehensive, annual Performance Improvement report that describes Performance Improvement activities, findings and corrective actions that relate to the services provided.

Minimum qualifications: Louisiana-licensed pharmacist or Louisiana-registered pharmacy technician with formal training in nonsterile compounding or equivalent experience.

Physical requirements: Ability to use a computer keyboard, fax machine, communicate by telephone, and lift up to thirty pounds.

Reports to: Pharmacist-in-charge

Appearance: Should reflect positively on Boudreaux's New Drug Store.

Employee Signature: _____ **Date:** _____

Printed Name: _____

HD Designated Person Job Description

Job Summary: Oversees compliance activities with regard to USP <800>.

Job Activities and Responsibilities: HD designated person must be qualified and trained to be responsible for developing and implementing appropriate HD procedures; overseeing entity compliance with USP <800> and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas. HD designated person must thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of noncompliance that may compromise safety, and the responsibility to report potentially hazardous situations to management. HD designated person must also be responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results. HD designated person must ensure that all personnel who handle HDs understand the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment.

Minimum qualifications: Louisiana-licensed pharmacist or Louisiana-registered pharmacy technician with formal training or equivalent experience.

Physical requirements: Ability to use a computer keyboard, fax machine, communicate by telephone, and lift up to thirty pounds.

Reports to: Pharmacist-in-charge.

Appearance: Should reflect positively on Boudreaux's New Drug Store.

Employee Signature: _____ **Date:** _____

Printed Name: _____

Equipment Training and Competency Assessment

Employee _____ Title _____

Training

1) SOP read for procedure on operating, cleaning, calibrating and maintenance.

2) Demonstration of procedure on operating, cleaning, calibrating and maintenance performed by supervisor or experienced user.

Competency Assessment

Staff member was observed and interviewed by supervisor or experienced user operating, cleaning, calibrating and maintaining equipment per procedure. Comment on need for additional training or observation on back of form (use additional sheets as necessary).

Equipment	**Experience** Beginner Intermediate Advanced	**Training** Date SOP #	**Demonstration** Date Required for initial training.	**Competency** Date Observed by	**Employee** Date Sign to document competency and understanding	**Supervisor** Date Sign to document competency and understanding

1.60 V 1.0
Attachment 4

Competency Assessment
Nonsterile Compounding

Employee_____ Date _____

- ☐ Capsules
- ☐ Solutions/Suspensions
- ☐ Creams/Ointments/Gels
- ☐ Molded Preparations
- ☐ Other _____

Preparation Name_____

Experience? ☐ Beginner ☐ Intermediate ☐ Advanced

Employee has completed and has documentation of all didactic training related to the process including relevant SOPS? ☐ Yes ☐ No ☐ N/A

Compounding performed per formulation record?	☐ Yes ☐ No
Equipment calibrated/used/cleaned per SOP?	☐ Yes ☐ No
Components/quantities accurate?	☐ Yes ☐ No
Lot numbers and expiration dates accurate?	☐ Yes ☐ No
QC performed (as applicable)?	☐ Yes ☐ No

Equipment used (circle): Powder Hood Balance Capsule Machine EMP Ointment Mill Hot Plate
Other (list):

Employee answers interview questions appropriately and verbalizes understanding of procedure?
☐ Yes ☐ No

Was this preparation sent for potency testing? ☐ Yes ☐ No If yes, attach a copy of lab results.

Interviewed/Observed by _____ Date _____
Is additional training or observation needed? ☐ Yes ☐ No
Comments:

Additional Training/Observation:

By _____ Date _____

Additional Training/Observation:

By _____ Date _____

Additional Training/Observation:

By _____ Date _____

Competency Assessment
Sterile Compounding — High-Risk Media Fill

Compounder_____ Observer _____

Start Date: Time: Temp: Humidity: Pressure:

End Time: Temp: Humidity: Pressure:

Soybean-Casein Digest Lot Number _____ Exp Date _____

SWFI (not bacteriostatic) Lot Number _____ Exp Date _____

Incubate control vials and test vials at 30-35C for 14 days. May stop if vial turns positive.
Document positive "+" or negative "-" on chart below.

Day	Date	Control 1	Control 2	Control 3	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										

Surface Media Lot/Exp _____ Pos/Neg Control _____

Surface Test Location _____ Results ____cfu Pass? Y N

Fingertip Media Lot/Exp _____ Pos/Neg Control _____

Fingertip Post Garb: R Hand Results ___cfu Pass? Y N L Hand Results ___cfu Pass? Y N

Fingertip Post Media: R Hand Results ___cfu Pass? Y N L Hand Results ___cfu Pass? Y N

Incubate surface and fingertip samples at 30-35C for 48-72 hours. Fingertip and surface samples must not exceed 3 cfu.

Surface/Fingertip media results read on Date/Time _____

Media Fill Process: □ Pass □ Fail Confirmed by _____

Bubble Test Passing Reading _____ #1 _____ Pass? Y N #2 _____ Pass? Y N #3 _____ Pass? Y N
Tape Filters to form.

Competency Assessment
Sterile Compounding — Low or Medium-Risk Media Fill

Attach description of Media Fill Procedure.
Circle test performed: Low risk Medium risk

Compounder_____ Observer _____

Start Date: Time: Temp: Humidity:
End Time: Temp: Humidity:

Soybean-Casein Digest Lot Number _____ Exp Date _____

Incubate control vials and test vials at 30-35C for 14 days. May stop if vial turns positive.
Document positive "+" or negative "-" on chart below.

Day	Date										
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											

Surface Media Lot/Exp _____ Pos/Neg Control _____
Surface Test Location _____ Results ___cfu Pass? Y N
Fingertip Media Lot/Exp _____ Pos/Neg Control _____
Fingertip Post Garb: R Hand Results ___cfu Pass? Y N L Hand Results ___cfu Pass? Y N
Fingertip Post Media: R Hand Results ___cfu Pass? Y N L Hand Results ___cfu Pass? Y N
Incubate surface and fingertip samples at 30-35C for 48-72 hours. Fingertip and surface samples must not exceed 3 cfu.
Surface/Fingertip media results read on Date/Time _____
Media Fill Process: ☐ Pass ☐ Fail Confirmed by _____

Sterile Compounding Skills Assessment
Hand Hygiene and Garbing

_____ Presents in a clean appropriate attire and manner.
_____ Removes all jewelry, watches, etc. up to the elbows. (Removes all other visible jewelry, including piercings, that can interfere with the effectiveness of PPE).
_____ Wears no cosmetics.
_____ Brings no food or drinks into or stored in the ante areas or buffer areas.
_____ Is aware of the line of demarcation separating clean and dirty sides and observes required activities. Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation as appropriate.
_____ Dons beard cover if necessary.
_____ Dons head cover assuring that all hair is covered.
_____ Dons face mask to cover bridge of nose down to include chin.
_____ Dons eye protection if necessary. Eye protection is optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs.
_____ Performs hand hygiene procedure by wetting hands and forearms and washing using soap and water for at least 30 seconds starting with cleaning the fingernails under running water using a nail pic then cleaning all four surfaces of each finger and all surfaces of the hands, wrists and arms up to the elbow using a circular motion. Rinses hands holding them upright and allowing water to drip down to the elbows.
_____ Dries hands and forearms using lint-free towel.
_____ Does not touch faucet or sink during hand hygiene procedure.
_____ Dons appropriate-sized gown (free from defects, holes or tears) and ensures full closure.
_____ Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistant activity and allows hands to dry thoroughly, before donning sterile gloves.
_____ Dons appropriate-sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.
_____ Examines gloves ensuring that there are no defects, holes or tears. While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area and after touching items or surfaces that may contaminate gloves.
_____ Removes PPE on the clean side of the ante area.
_____ Removes gloves and performs hand hygiene.
_____ Removes gown and discards it or hangs it up to be reused within the same work day.
_____ Removes and discards mask, head cover and beard cover (if used). Removes shoe covers or shoes one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again.

The person assessed is immediately informed of all unacceptable activities and shown and informed of specific corrections

Name_____ Evaluator _____ Date _____

Sterile Compounding Skills Assessment
Hood Cleaning and Aseptic Technique

_____ Performs proper hand hygiene, garbing and gloving procedures. Uses sterile gloves.
_____ Lets the hood run at least 30 minutes prior to use.
_____ Prepares (or has knowledge of) correct concentration of disinfectant solution and labels with correct expiration date.
_____ At the beginning of each shift, disinfects the hood with lint-free wipes and an appropriate disinfectant in the following order: IV Bar, walls, work surface (from cleanest to dirtiest – top down and back to front).
_____ Disinfects the hood before each batch preparation and every thirty minutes during continuous compounding.
_____ Allows the disinfectant to dry completely.
_____ Disinfects components/vials with an appropriate agent prior to placing in hood.
_____ Introduces only essential materials in a proper arrangement in hood. Brings the correct supplies. Does not block air intake.
_____ Does not interrupt, impede or divert flow of first-air to critical sites. Does not contaminate hood by coughing, sneezing, chewing gum or excessive talking. Keeps head outside hood. Glass shield, if available, lowered to a level of eight inches or less from work surface.
_____ Ensures syringes, needles and tubing remain in their individual packaging and are opened properly in hood.
_____ Performs manipulations in the appropriate area of hood.
_____ Does not expose critical sites to contact contamination or worse than ISO Class 5 air.
_____ Disinfects stoppers, injection ports and ampule necks by wiping with sterile 70% IPA and allowing sufficient time to dry.
_____ Affixes needles to syringes without contact contamination.
_____ Inserts needles into vials correctly to prevent coring.
_____ Removes and adds air to vials appropriately to prevent aspiration of contents.
_____ Allows drug to completely dissolve before removing contents.
_____ Inspects final product for particulate matter.
_____ Knows proper ampule usage (clears ampule neck of fluid before breaking, cleans neck and wraps with alcohol swab breaking away from body, HEPA-filter and other sterile products, uses filter straw/needle to withdraw contents without spilling, uses new needle to inject fluid into final container).
_____ Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations.
_____ Disposes of sharps and waste according to recognized guidelines.
_____ Only sterile alcohol is used in cleanroom.

The person assessed is immediately informed of all unacceptable activities and shown and informed of specific corrections

Name_____ Evaluator _____ Date _____

Sterile Compounding Skills Assessment
Cleaning and Disinfecting Procedures

Daily Tasks:

_____ Prepares correct concentration of disinfectant solution according to manufacturer's instructions.
_____ Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.).
_____ Documents disinfectant solution preparation.
_____ Follows garbing procedures when performing any cleaning activities.
_____ At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding .
_____ Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.
_____ Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.
_____ Cleans all counters and easily cleanable work surfaces.
_____ Mops floors, using the mop labeled "floors," starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.
_____ In the ante-area, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.

Monthly Tasks:

_____ Performs monthly cleaning on a designated day. Prepares a disinfectant solution as stated in daily tasks that is appropriate for the
surfaces to be cleaned.
_____ Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.
_____ Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.
_____ Cleans all buffer area totes and storage shelves by removing contents and using a germicidal detergent soaked lint free wipe, cleans the inside surfaces of the tote and then the entire exterior surfaces of the tote. Allows totes to dry. Prior to replacing contents into tote, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.
_____ Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.
_____ Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.
_____ Documents all cleaning activities as to who performed such activities with date and time noted.
The person assessed is immediately informed of all unacceptable activities and shown and informed of specific corrections

Name_____ Evaluator _____ Date ___

Gloved Fingertip
Initial Assessment

Compounder_____ Signature _____

Start Date	End Date	R Hand cfu	Pass/Fail	L Hand cfu	Pass/Fail	Read by
			□ Pass □ Fail		□ Pass □ Fail	
			□ Pass □ Fail		□ Pass □ Fail	
			□ Pass □ Fail		□ Pass □ Fail	

Incubate surface and fingertip samples at 30-35C for 48-72 hours.
Note: Fingertip samples with zero cfu needed post garbing x 3 before initially performing sterile compounding.
Keep this form retrievable.

Confirmed by _____ Signature _____

Pharmacist Check Competency Assessment

Employee _____ Date _____

Employee experience level with process ☐ Beginner ☐ Intermediate ☐ Advanced

Initial - Employee has completed and has documentation of all didactic training related to the process including relevant SOPS? ☐ Yes ☐ No ☐ N/A

Initial - Demonstration of process by supervisor or experienced pharmacist performed?
☐ Yes ☐ No ☐ N/A by_____ Date_____

Observation of process by supervisor or experienced pharmacist checker performed:

Preparation/Strength/Dosage Form _____

Verified compounding record to original written order or refill information? ☐ Yes ☐ No ☐ N/A
Verified accuracy of original written order (on new prescriptions)? ☐ Yes ☐ No ☐ N/A
Verified accuracy of patient label including IACP and other auxiliary label? ☐ Yes ☐ No ☐ N/A
Verified as follows :

Formula accuracy including calculations?	☐ Yes ☐ No ☐ N/A
Compounding record complete and accurate?	☐ Yes ☐ No ☐ N/A
BUD?	☐ Yes ☐ No ☐ N/A
Quantity?	☐ Yes ☐ No ☐ N/A
Packaging and storage requirements?	☐ Yes ☐ No ☐ N/A
Capsule size and color ?	☐ Yes ☐ No ☐ N/A
Expected weight (including accuracy of dispensing device)?	☐ Yes ☐ No ☐ N/A
Color, odor, uniformity, integrity, viscosity?	☐ Yes ☐ No ☐ N/A
Clarity, no particles or leaks?	☐ Yes ☐ No ☐ N/A
pH?	☐ Yes ☐ No ☐ N/A
Sterility method and testing?	☐ Yes ☐ No ☐ N/A
Bubble test?	☐ Yes ☐ No ☐ N/A

Employee answers interview questions appropriately and verbalizes understanding of procedure?
☐ Yes ☐ No

Is additional training or observation needed? ☐ Yes ☐ No
Comments:

Observed/Interviewed by _____ Date _____

Additional Training/Observation:

By _____ Date _____

Pharmacist Counseling Competency Assessment

Employee _____ Date _____

Employee experience level with process ☐ Beginner ☐ Intermediate ☐ Advanced

Initial - Employee has completed and has documentation of all didactic training related to the process including relevant SOPS? ☐ Yes ☐ No ☐ N/A

Initial - Demonstration of process by supervisor or experienced pharmacist performed?
☐ Yes ☐ No ☐ N/A by_____ Date_____

Observation of process by supervisor or experienced pharmacist checker performed:

Preparation/Strength/Dosage Form _____

Preparation name, strength, dosage form?	☐ Yes ☐ No ☐ N/A
Route of administration?	☐ Yes ☐ No ☐ N/A
Duration of therapy?	☐ Yes ☐ No ☐ N/A
Proper use?	☐ Yes ☐ No ☐ N/A
Proper storage?	☐ Yes ☐ No ☐ N/A
Proper handling?	☐ Yes ☐ No ☐ N/A
Proper disposal?	☐ Yes ☐ No ☐ N/A
Warnings and side effects?	☐ Yes ☐ No ☐ N/A
Signs of Deterioration?	☐ Yes ☐ No ☐ N/A
Action to be taken in the event of a missed dose?	☐ Yes ☐ No ☐ N/A
Refill information?	☐ Yes ☐ No ☐ N/A

Were the patient's questions answered adequately ☐ Yes ☐ No ☐ N/A

Employee answers pre/post-counseling interview questions appropriately and verbalizes understanding of procedure? ☐ Yes ☐ No

Is additional training or observation needed? ☐ Yes ☐ No
Comments:

Observed by _____ Date _____

Additional Training/Observation:

By _____ Date _____

Training File Checklist
Non-Compounding Staff

Annually

Yr _____

____ HIPAA Training
____ Safety Training (including Hazmat & Ack)
____ SOPs Read

Yr _____

____ HIPAA Training
____ Safety Training (including Hazmat & Ack)
____ SOPs Read

Yr _____

____ HIPAA Training
____ Safety Training (including Hazmat & Ack)
____ SOPs Read

Training File Checklist
Nonsterile Only Staff

Year _____

Annually

____ HIPAA Training
____ Safety Training (including Hazmat & Ack)
____ SOPs Read
____ USP 795 Training w/Quiz
____ Calculations

NS Personnel Competency Assessment
____ Capsules
____ Creams, Gels, Ointments
____ Troches, Loz, Supps, Lollipops
____ Solutions, Suspensions
____ Hazardous Chemical Handling

Potency Testing
____ Capsules
____ Creams, Gels, Ointments
____ Troches, Loz, Supps, Lollipops
____ Solutions, Suspensions

Training File Checklist
Sterile Only Staff

Year _____

Every Six Months

Potency Testing
____ ____ Filtration
____ ____ Steam
____ ____ Dry Heat

Sterile Personnel Competency Assessment
____ ____Media Fill
____ ____Skills Assessment
____ ____Fingertip Testing
____ ____USP 797/Aseptic Training w/Quiz

Annually

____ HIPAA Training
____ Safety Training (including Hazmat & Ack)
____ Hazardous Chemical (if applicable)
____ SOPs Read
____ Calculations

Training File Checklist
Sterile/NS Staff
Year _____
Every Six Months
Sterile Personnel Competency Assessment
____ ____High Risk Media Fill
____ ____Skills Assessment
____ ____Fingertip Testing
____ ____USP 797/Aseptic Training w/Quiz

Annually
____ HIPAA Training
____ Safety Training (including Hazmat & Ack)
____ SOPs Read
____ USP 795 Training w/Quiz
____ Calculations
____ Low/Medium Risk Media Fill

NS Personnel Competency Assessment
____ Capsules
____ Creams, Gels, Ointments
____ Troches, Loz, Supps, Lollipops
____ Solutions, Suspensions
____ Hazardous Chemical

Potency Testing
____ Capsules
____ Creams, Gels, Ointments
____ Troches, Loz, Supps, Lollipops
____ Solutions, Suspensions

____ Filtration
____ Steam
____ Dry Heat

Training File Checklist
Pharmacists

Year _____

Every Six Months

Sterile Personnel Competency Assessment

____ ____High Risk Media Fill
____ ____Skills Assessment
____ ____Fingertip Testing
____ ____USP 797/Aseptic Training w/Quiz

Annually

____ HIPAA Training
____ Safety Training (including Hazmat & Ack)
____ SOPs Read
____ USP 795 Training w/Quiz
____ Calculations
____ Low/Medium Risk Media Fill

Pharmacist Personnel Competency Assessment

____ Checking
____ Counseling

NS Personnel Competency Assessment (if applicable)

____ Capsules
____ Creams, Gels, Ointments
____ Troches, Loz, Supps, Lollipops
____ Solutions, Suspensions
____ Hazardous Chemical

Potency Testing (if applicable)

____ Capsules
____ Creams, Gels, Ointments
____ Troches, Loz, Supps, Lollipops
____ Solutions, Suspensions

____ Filtration
____ Steam
____ Dry Heat

Staff Meeting Minutes

Staff Signatures:

Old Business:

New Business:

Any quality issues this week? Errors?
Near Misses? Good Catches?

Any privacy (HIPAA) or security issues
this week?

Compliance Report:

Training:

1.0 Purpose

1.1 The purpose of this procedure is to establish requirements for deactivation, decontamination, cleaning and disinfection of HD and non-HD compounding areas at Boudreaux's New Drug Store to ensure quality of compounded preparations and safety of personnel.

2.0 Definitions

2.1 HD Hazardous Drug

2.2 SDS Safety Data Sheet

2.3 PPE Personal Protective Equipment

2.4 Deactivation renders a compound inactive. If no specific information is available on SDS then use Peridox RTU (using three-minute contact time), Clorox Healthcare Bleach Germicidal Wipes or Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes (using a three-minute contact time), sodium hypochlorite 5000 - 6000 ppm (using 10 minute contact time) or other EPA- registered oxidizer (following labeled contact time).

2.5 Decontamination removes inactivated substances. If no specific information is available on SDS then use Peridox RTU (using three-minute contact time), Clorox Healthcare Bleach Germicidal Wipes or Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes (using a three-minute contact time), sodium hypochlorite 5000 - 6000 ppm (using 10 minute contact time) or other EPA- registered oxidizer (following labeled contact time).

2.6 Cleaning removes organic and inorganic matter. Use one-step disinfectant cleaner on surfaces. Use Alconox (or equivalent) products for glassware and utensils (e.g. Alcotabs in the dishwasher and Liquinox for handwashing).

2.7 Disinfection destroys microorganisms. May use 70% IPA or EPA-registered disinfectant. 70% IPA used in ISO-classified areas must be sterile.

3.0 Procedure

3.1 This procedure applies to all personnel involved with cleaning activities.

3.2 Agents selected must be appropriate for the type of contaminant, location, and surface materials. Agents used in HD areas should be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid spreading HD residue. All disposable materials must be discarded in appropriate waste containers. No cleaning step may be performed when compounding activities are occurring. Ensure adequate contact times. Options include:

3.2.1 Sodium Hypochlorite at 5000 – 6000 ppm. Concentrations vary. BUD is 5 days. Contact time is 10 minutes when used as a sporicidal disinfectant.

3.2.1.1 Bleach 5.25% has 52500 ppm of sodium hypochlorite so for 5000 ppm, use 97.5 ml bleach and 902.5 ml SWFI and for 6000 ppm, use 102.6 ml bleach and 897.4 ml SWFI. Bud is 5 days.

3.2.1.2 Bleach 8.25% has 82500 ppm of sodium hypochlorite so for 5000 ppm, use 60.6ml bleach and 939.4 ml SWFI and for 6000 ppm, use 72.7ml bleach and 927.3 ml SWFI. BUD 5 days.

3.2.2 Or deactivate, decontaminate, and clean with **Peridox RTU** as follows:

1. Remove excess liquid from surface to be treated using a dry wiper
2. Saturate a new dry wiper with Peridox RTU solution.
3. Clean the surface with the saturated wiper, utilizing overlapping, unidirectional strokes.
4. Repeat steps 2-3. Leave the surface wet with Peridox RTU for at least 3 minutes.
5. Finish by wiping surface with 70% Isopropyl alcohol.
6. Discard contaminated wipers in trace hazardous waste container.

3.2.3 Or deactivate, decontaminate, and clean with **Clorox Healthcare Bleach Germicidal Wipes** or **Clorox Healthcare Hydrogen Peroxide Disinfectant Wipes** as follows:

1. Remove excess liquid from surface to be treated using a dry wiper
2. Take a new disinfectant wipe and fold it in half. Wipe the surface until

completely wet. Wipe in unidirectional strokes, overlapping a portion of the previously wiped surface each time. If you are cleaning a large area, you may need to use several wipes.

3. Repeat steps 2 with a new disinfectant wipe. Leave the surface wet with for at least 3 minutes.

4. Finish by wiping surface with 70% Isopropyl alcohol.

5. Discard contaminated wipers in a manner consistent with facility guidelines and local regulations.

3.3 Personnel must be garbed appropriately for the area. See SOPs 1.30 Nonsterile Compounding Area, 1.35 Nonsterile HD Compounding Area, 1.40 Sterile Compounding Area, and 1.45 Sterile HD Compounding Area for garbing and PPE requirements and frequency of activities.

3.4 **Nonsterile Area**

3.4.1 **Non-HD Area** and all reusable equipment and devices must be cleaned. Re-usable storage containers must also be disinfected. A disinfectant with sporicidal activity should be used at least monthly.

3.4.1.1 Cleaning supplies should be stored in and dedicated for use in the Non-HD Area.

3.4.2 **HD Area** and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Re-usable storage containers must also be disinfected. A disinfectant with sporicidal activity should be used at least monthly.

3.4.2.1 Cleaning supplies must be stored in and dedicated for use in the HD Area.

3.4.2.2 Glassware and utensils used in HD compounding must be either wiped with Peridox RTU or Clorox Healthcare Bleach Germicidal Wipes or Clorox Healthcare Hydrogen Peroxide Disinfectant Cleaner (allowing a 3 minute contact time); or soaked in a 5000-6000 ppm sodium hypochlorite solution (for at least 10 minutes) before washing with a lab grade detergent (Alconox product) and rinsing thoroughly.

3.4.2.3 A disinfectant with sporicidal properties (e.g. Peridox RTU

or Clorox Healthcare Bleach Germicidal Wipes) should be used on all surfaces at least monthly. Note: Clorox Healthcare Hydrogen Peroxide Germicidal Wipes do not have sporicidal activity.

3.5 **ISO-Classified Areas**

3.5.1 All cleaning materials, such as wipers, sponges, and mops used in ISO-classified areas must be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the Non-HD or HD ISO-classified and must not be removed from these areas except for disposal. Agents and wipers used in ISO Class 5 must be sterile. Agents and wipers used in ISO Class 7 or 8 should be sterile. Cleaning materials used in HD areas may not be used in non-HD areas.

3.5.2 **Non-HD** ante-room and (positive pressure) buffer room and all reusable equipment must be cleaned and disinfected. A disinfectant with sporicidal activity must be used at least monthly. Floor must have a designated mop labeled 'Floor'. Floor mops may be used in both the buffer room and ante-room, but only in that order.

3.5.3 **HD C-SEC** (negative pressure buffer room) All areas and all reusable equipment and devices must be deactivated, decontaminated, cleaned, and disinfected. A disinfectant with sporicidal activity must be used on all surfaces at least monthly. Floor must have a designated mop labeled 'Floor'.

3.6 **HD Dispensing Area** counting trays and spatulas should be dedicated to HDs and should be decontaminated after each use.

3.7 **HD Receiving Area** tables, countertops and floors must be deactivated, decontaminated, and cleaned each day of use and after spills.

3.8 All personnel who perform deactivation, decontamination, cleaning, and disinfection activities must be trained in appropriate procedures to protect themselves and the environment from contamination.

3.9 FDA Insanitary conditions include visible microbial and nonmicrobial contamination, glass particles, vermin, hair, and rust. Report these conditions to the PIC and remedy immediately.

3.10 See Attachment 1 for Deactivating, Decontaminating, Cleaning and Disinfecting Agents in Use.

4.0 References

4.1 Louisiana Board of Pharmacy Laws & Rules

4.2 USP <795> Pharmaceutical Compounding – Nonsterile Preparations

4.3 USP <797> Pharmaceutical Compounding – Sterile Preparations

4.4 USP <800> Hazardous Drugs – Handling in Healthcare Settings

5.0 Attachments

5.1 Attachment 1 Deactivating, Decontaminating, Cleaning and Disinfecting Agents in Use

☐ Draft ☐ Final Approved by _____ This policy implemented on_____	Annual Policy Review Reviewer/Date _____ Reviewer/Date _____ Reviewer/Date _____

Deactivating, Decontaminating, Cleaning and Disinfecting Agents in Use

Non-HD Nonsterile Area	Hoods, Carts, Work Surfaces	Dwell Time	Equipment	Dwell Time	Floor	Dwell Time	Walls, Ceilings, Storage	Dwell Time	Other	Dwell Time
One-Step Agent	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A
Disinfectant	70% IPA	Until dry	70% IPA	Until dry	N/A	N/A	N/A	N/A	N/A	N/A
Monthly Sporicidal	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A
HD Nonsterile Area	**Hoods, Carts, Work Surfaces**	**Dwell Time**	**Equipment**	**Dwell Time**	**Floor**	**Dwell Time**	**Walls, Ceilings, Storage**	**Dwell Time**	**Other**	**Dwell Time**
DDC Agent	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A
Disinfectant	70% IPA	Until dry	70% IPA	Until dry	N/A	N/A	N/A	N/A	N/A	N/A
Monthly Sporicidal	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A
Non-HD Sterile Area	**Hoods, Carts, Work Surfaces**	**Dwell Time**	**Equipment**	**Dwell Time**	**Floor**	**Dwell Time**	**Walls, Ceilings, Storage**	**Dwell Time**	**Other**	**Dwell Time**
One-Step Agent	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A
Disinfectant	Sterile 70% IPA	Until dry	Sterile 70% IPA	Until dry	N/A	N/A	N/A	N/A	N/A	N/A
Monthly Sporicidal	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A
HD Sterile Area	**Hoods, Carts, Work Surfaces**	**Dwell Time**	**Equipment**	**Dwell Time**	**Floor**	**Dwell Time**	**Walls, Ceilings, Storage**	**Dwell Time**	**Other**	**Dwell Time**
DDC Agent	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A
Disinfectant	Sterile 70% IPA	Until dry	Sterile 70% IPA	Until dry	N/A	N/A	N/A	N/A	N/A	N/A
Monthly Sporicidal	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A
HD Receiving Area	**Tables, Carts, Work Surfaces**	**Dwell Time**	**Floor**	**Dwell Time**	**HD Dispensing**	**Dwell Time**	**Counting Trays**	**Dwell Time**	**Other**	**Dwell Time**
DDC Agent	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A
Disinfectant	70% IPA	Until dry	N/A	N/A	70% IPA	Until dry	70% IPA	Until	N/A	N/A
Monthly Sporicidal	Peridox RTU	3 m	Peridox RTU	3 min	Peridox RTU	3 m	Peridox RTU	3 min	N/A	N/A

1.0 Purpose

1.1 The purpose of this procedure is to establish requirements for the sterile non-hazardous compounding area at Boudreaux's New Drug Store to ensure quality of compounded preparations and safety of personnel.

2.0 Definitions

2.1 HD Hazardous Drug

2.2 Ante-room An ISO Class 8 or better transition room between the buffer room(s) and nonsterile compounding area. Ante-room leading into an HD buffer room must be ISO Class 7 or better.

2.3 Buffer room An ISO Class 7 or better room containing the Primary Engineering Control.

2.4 Primary Engineering Control (PEC) Laminar Airflow Workbench (LAFW) or Compounding Aseptic Isolator (CAI) which provides an ISO Class 5 environment for sterile compounding.

2.5 CFU Colony forming unit

2.6 ACPHs Air changes per hour.

3.0 Procedure

3.1 This procedure applies to all personnel involved with sterile compounding activities.

3.2 Boudreaux's New Drug Store must perform sterile non-HD compounding in accordance with USP <797> (and other applicable USP chapters) and standards of practice adopted by the Louisiana Board of Pharmacy and by national practices and standards adopted by government and non-government standard setting organizations.

3.3 Compounding and storage of HDs must not occur in sterile non-HD compounding areas except as permitted by assessment of risk.

3.4 Only authorized personnel must be permitted to enter ISO-classified areas. No food or beverages may be consumed and no lip balm or cosmetics may be applied in these areas. Personal items must not be brought into these areas. .

3.4.1 Sterile compounding personnel must be garbed according to task. Garb must include scrubs (preferred), gown, shoe covers, hair covering, beard cover (if applicable), mask, and eye protection (as needed). Sterile gloves must be worn in ISO-classified areas.

3.4.2 Before entering the ante-room, remove

3.4.2.1 Bandanas, coats, hats, jackets, scarves, sweaters, vests, etc. Religious headwear should be cleaned daily.

3.4.2.2 Cosmetics.

3.4.2.3 Hand, wrist and other visible jewelry.

3.4.2.4 Nail polish and artificial nails. Natural nails should be kept neat and trimmed.

3.4.3 Don garb from dirtiest to cleanest starting by donning shoe covers as you cross the line of demarcation onto the clean side then don hair cover, beard cover (if applicable), mask and eye protection (as needed) before hand washing.

3.4.5 Hand washing must be performed by first cleaning fingernails under running water using a disposable nail pic then vigorously washing all surfaces of hands and forearms for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) followed by thorough rinsing and drying.

3.4.6 After hand washing, don a nonshedding knee length gown closed at the wrists and neck then enter the (positive pressure) non-HD buffer room. Prior to donning sterile gloves, antiseptic hand cleansing must be performed using waterless alcohol-based surgical hand scrub with persistent activity.

3.4.7 After donning sterile gloves, sterile 70% isopropyl alcohol must be used to disinfect gloves. Gloves must be disinfected periodically throughout the compounding process and whenever nonsterile surfaces are touched. When performing cleaning or pre-sterilization activities before compounding in the ISO-5 PEC, don a new pair of sterile gloves in the buffer room before compounding in the ISO-5 PEC.

3.4.8 When compounding is complete, gown may be reused during the

work shift if not visibly soiled but other disposable garb must be removed and discarded. Gown must remain in the ante-room.

3.5 Sterile non-HD compounding must be performed in a PEC situated in an ISO Class 7 or better buffer room with at least 30 ACPH and a minimum pressure of 0.02 inches of water. PEC must be turned on a minimum of thirty minutes prior to compounding. Document pressure each day of use on Sterile Compounding Area Cleaning and Environmental Monitoring Log (Attachment 1) or equivalent log.

3.5.1 Pre-sterilization procedures such as weighing and mixing of powder APIs must be completed in a powder containment hood located in no worse than an ISO Class 8 environment.

3.5.2 ISO-classified areas must be certified under dynamic conditions by an authorized service provider before first use, when adding or removing fixtures or equipment, after maintenance, and at least every six months.

3.5.2.1 Viable and nonviable particle sampling

3.5.2.1.1 Viable particle sampling using impaction method must include testing for bacteria and fungus using two media (TSA and MEA or other suitable fungal medium). Document lot numbers and expiration dates of media. Collect 400-1000 liters of air per sample (1000 liters preferred, especially in PEC). Report results in cfu per cubic liter. Report control sample for each medium. Document time of day sampling was performed. Results must not exceed cfu > 1 ISO Class 5, cfu > 10 ISO Class 7, cfu> 100 ISO Class 8 or be identified as highly pathogenic (regardless of number of cfu). All growth must be identified to at least the genus level.

3.5.2.1.2 Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination must be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem must be eliminated, the affected area cleaned, and resampling performed.

3.5.2.2 Filter integrity

3.5.2.2.1 Filter integrity testing must be performed on HEPA filters located in ceiling and PEC every six months.

3.5.2.3 Air exchanges

3.5.2.3.1 ACPH must be no less than 30.

3.5.2.4 Air pressure

3.5.2.4.1 Pressure must be in the range of 0.02 to 0.05 inches of water in positive pressure areas and in the range of – 0.01 to -0.03 inches of water in negative pressure areas.

3.5.2.5 Smoke testing

3.5.2.5.1 Perform smoke testing on rooms initially and after maintenance or moving equipment.

3.5.2.5.2 Perform and record smoke testing under most strenuous dynamic conditions on PEC every certification cycle.

3.5.2.6 Issues with clean room certification must be investigated and documented per SOP 6.20 Quality-Related Events.

3.6 Temperature should be maintained at 20°C (68°F) or cooler and humidity should be maintained under 60%. Document temperature and humidity of sterile compounding area on Cleaning and Calibration Log (SOP 1.30 Attachment 1B) or equivalent log. See SOP 1.30 Nonsterile Compounding Area for excursion allowances.

3.7 ISO-classified areas must be clean and organized to prevent mix-ups or cross-contamination. Areas must be examined for signs of rust and if found, removed immediately. Cleaning should be performed by using germicidal detergent or one-step cleaner-disinfectant using a low lint wipe. An appropriate disinfectant must be used allowing adequate contact time. See SOP 1.25 Cleaning Procedures for current cleaning agents in use.

3.7.1 **Primary engineering control** Clean and disinfect from cleanest to dirtiest (i.e. top to bottom and back to front) each day of use at the beginning of each work shift, before each batch preparation, every 30 minutes during continuous

compounding, when spills occur and when surface contamination is known or suspected. Document initial cleaning and disinfection on Sterile Compounding Area Cleaning and Environmental Monitoring Log (Attachment 1) or equivalent log. Document subsequent cleaning and disinfection on compounding record.

3.7.1.1 Sporicide must be used at least monthly.

3.7.1.2 Excess equipment or supplies must not be kept in PEC.

3.7.2 **Non-HD Buffer Rooms and Ante-room** Cleaning and disinfection must not occur at the same time as compounding.

3.7.2.1 **Work Surfaces** – Daily cleaning and disinfection.

3.7.2.2 **Sink** – Daily cleaning and disinfection

3.7.2.3 **Floors** – Daily Non-HD buffer rooms first from far wall to door followed by ante-room from far wall to door using germicidal detergent or one-step cleaner-disinfectant.

3.7.2.4 **Trash** must be removed daily and trash containers cleaned and disinfected (if present).

3.7.2.5 **Ceiling – Monthly** cleaning and disinfection using sporicidal agent. Non-HD buffer rooms first from far wall to door followed by ante-room from far wall to door. Ceiling tiles must be sealed.

3.7.2.6 **Walls – Monthly** cleaning and disinfection using sporicidal agent. Non-HD buffer rooms first from far wall to door followed by ante-room from far wall to door.

3.7.2.7 **Storage areas and carts – Monthly** cleaning and disinfection using sporicidal agent.

3.7.2.7 Document cleaning and disinfection on Sterile Compounding Area Cleaning and Environmental Monitoring Log (Attachment 1 and 1C) or equivalent log.

3.8 **Equipment and supplies** Remove supplies from shipping containers before entering ante-room. Stage equipment and supplies by wiping with sterile 70% isopropyl alcohol using a low lint wipe before entering ante-room, buffer room, and ISO-

Class 5 PEC. Only supplies needed for compounding must enter the buffer room. Cardboard must not enter the buffer room and paper should be kept to a minimum. Sterile syringes and similar items packaged in paper may be opened at the edge of the PEC rather than being wiped with disinfectant.

3.9 **Environmental monitoring** using surface testing must be performed to verify cleaning and disinfection processes. Obtain media (TSA with Lecithin and polysorbate 80), document lot number and expiration date. Aseptically remove cover and touch agar to surface then replace cover. Surface samples must be taken from PECs, buffer room, ante-room, and pass-throughs upon completion of sterile compounding and prior to cleaning. Minimum initial requirements are weekly for three weeks then if below action level may perform monthly. Positive and negative controls must be performed. Certificate of analysis should be kept on file for two years.

3.9.1 Incubate TSA with Lecithin and polysorbate 80 at 30°-35°C for 48 to 72 hours. Document results on Sterile Compounding Area Cleaning and Environmental Monitoring Log (Attachment 1A) or equivalent log. Results must not exceed cfu > 3 Gloved Fingertips and ISO Class 5, cfu > 5 ISO Class 7, cfu> 100 ISO Class 8. All growth that exceeds these limits must be identified to at least the genus level.

3.9.2 If cfus exceed limits, a thorough cleaning and/or review of aseptic technique and manipulative skills and/or appropriate review of disinfecting of nonsterile components when introducing them into the clean room should be performed and documented according to SOP 6.20 Quality-Related Events. To verify any improvements or changes to procedures, surface testing is to be performed every week for three weeks then monthly.

3.10 **Aseptic technique** must be used at all times when working in the PEC. Use slow purposeful movements. Avoid coughing or sneezing over the work area. Minimize talking. Avoid leaning over the work area and resting hands on the work area. Direct Compounding Area (DCA) begins four inches above surface. Ensure critical sites receive first air from HEPA filter. Do not allow hands, equipment or supplies to come between (shadow) critical sites and first air. Do not allow critical sites to touch hands or

any nonsterile surface. Critical sites include but are not limited to needles; syringe tips, inner shafts and barrels; rubber stoppers on vials and IV bags; and open tops of vials and beakers. Disinfect sterile gloves with sterile 70% isopropyl alcohol every time they leave the PEC before re-entering PEC.

4.0 References

4.1 Louisiana Board of Pharmacy Laws & Rules
4.2 USP <797> Pharmaceutical Compounding – Sterile Preparations (2008)
4.2 USP <800> Hazardous Drugs – Handling in Healthcare Settings (2020)

5.0 Attachments

5.1 Attachment 1 Sterile Area Cleaning and Environmental Monitoring Log

☐ Draft ☐ Final Approved by _____ This policy implemented on_____	Annual Policy Review Reviewer/Date _____ Reviewer/Date _____ Reviewer/Date _____

Sterile Compounding Area
Cleaning and Environmental Monitoring Log Non-HD Area Month/Year _____

Perform daily cleaning with one-step disinfectant cleaner. Document agent/contact time:
Daily Disinfectant: Sterile 70% IPA

	Pressure 1 Ante to NS	**Pressure 2** + Buffer to Ante	**Non-HD BSC** Cleaned & Disinfected	**S Balance 1** Calibrated	**S Powder Hood 1** Cleaned & Disinfected	**Work Surfaces** Cleaned & Disinfected	**Equipment/Devices** Cleaned & Disinfected	**Sink** Cleaned & Disinfected	**Floors** Cleaned & Disinfected	**Trash Empty** Trash can cleaned & disinfected
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
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Notify PIC if out of range and document per SOP 6.20. Positive pressure areas at least 0.02 inch of water.

Reviewed By: _____ Date: _____

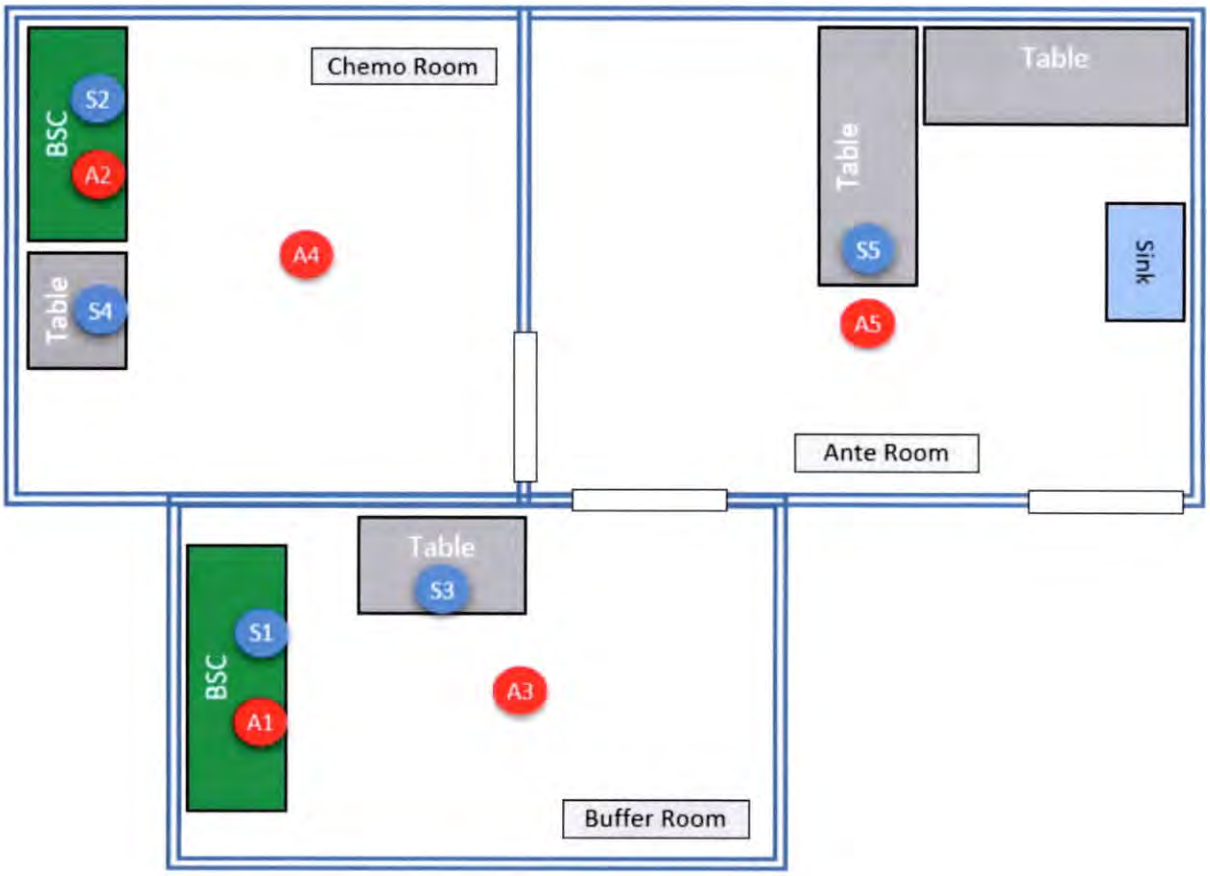
Sterile Compounding Area
Cleaning and Environmental Monitoring Log

Date _____

Surface Testing (Incubate TSA 30-35C 48-72 hours.)

Date	Location	Media	Media Lot/Exp	Temp	Date Read	Result # CFU	Pass? (Y/N)
	Ante	TSA					
	Non-HD Buffer	TSA					
	Non-HD BSC	TSA					
	HD Buffer	TSA					
	HD BSC	TSA					
	Control-Neg	TSA					

Notify PIC if cfu > 3 ISO 5: cfu > 5 ISO 7 and document per SOP 6.20.



Map depicts air and surface sample locations taken by cleanroom certification company.
Document surface sample locations taken by pharmacy personnel.

Reviewed By: _____ **Date:** _____

Sterile Compounding Area
Cleaning and Environmental Monitoring Log Month/Year _____

Monthly Cleaning and Disinfection
Non-HD Sterile Compounding Area
Clean and disinfectant anteroom and buffer room. Disinfectant must have sporicidal activity. Document agents and dwell times.

Start time _____ End time _____

	Agent	Dwell Time	Agent	Dwell Time	Performed by
LAFW 1	Peridox RTU	3 min	Sterile 70% Isopropyl Alcohol	Until dry	
Ceiling, walls	Peridox RTU	3 min	Sterile 70% Isopropyl Alcohol	Until dry	
Floor	Peridox RTU	3 min	Sterile 70% Isopropyl Alcohol	Until dry	
Storage, carts, etc.	Peridox RTU	3 min	Sterile 70% Isopropyl Alcohol	Until dry	

Monthly Deactivation, Decontamination, Cleaning and Disinfection
HD Sterile Compounding Area
Deactivate, decontaminate, clean, and disinfect HD buffer room. One agent must have sporicidal activity. Document agents and dwell times.

Start time _____ End time _____

	Agent	Dwell Time	Agent	Dwell Time	Agent	Dwell Time	Performed by
HD BSC 1 & under tray.	Peridox RTU	3 min	Peridox RTU	3 min	Sterile 70% Isopropyl Alcohol	Until dry	
Ceiling, walls	Peridox RTU	3 min	Peridox RTU	3 min	Sterile 70% Isopropyl Alcohol	Until dry	
Floor	Peridox RTU	3 min	Peridox RTU	3 min	Sterile 70% Isopropyl Alcohol	Until dry	
Storage, carts, etc.	Peridox RTU	3 min	Peridox RTU	3 min	Sterile 70% Isopropyl Alcohol	Until dry	

Monthly cleaning in both HD and non-HD areas must be completed in the same day not during compounding operations.

Quarterly Pre-Filter Check Date _____? Changed? ☐ Yes ☐ No, not needed. By _____

DP Review _____ Date_____

9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Packaging Coordinators, Inc.

Physical Address: 3001 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 215.613.3600 Website: www.pci.com

Name of Designated Representative (DR): Catherine Cabrera

Licensing Company Email: compliance.pcipharma@gmail.com DR Email: catherine.cabrera@pci.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Over-the-counter (OTC) Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Pharmaceutical Co.		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:
N/A

C. C

Original Signature (electronic, copies or stamps not accepted)

03/11/25

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Packaging Coordinators, Inc.

Corporation/Organization Name: Packaging Coordinators, LLC

Mailing Address: 3001 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Telephone: 215-284-8661 Email: catherine.cabrera@pci.com

Contact Person Name: Catherine Cabrera

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Packaging Coordinators, LLC

Facility Name

Catherine Cabrera

Print Name of Authorized Person Submitting Application

C. C

Original signature of Authorized Person (copies or stamps not accepted)

03/11/25

Date

Board Use Only	Date Received: 5/22/25	Amount: $1000-ck1582

January 27, 2023

Packaging Coordinators, LLC
3001 Red Lion Rd.
Philadelphia, PA 19114
FEI: 1000522077
Dates of Inspection: 01/09/2023 – 01/12/2023
Email: ORABIOInspectionalCorrespondence@fda.hhs.gov
ORAPharm1_responses@fda.hhs.gov

RE: Response to FDA-483

Dear FDA Investigator:

This letter is in response to the FDA-483 observations for Packaging Coordinators, LLC conducted of our facility located at 3001 Red Lion Road, Philadelphia, PA 19114.

Please find below Packaging Coordinators response to your observations.

Observation 1:

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

a. Your environmental monitoring plan as defined in SOP, SOP-00790, "Environmental Monitoring for Non-Sterile Packaging", Rev 18, effective date 29 September 2021, is insufficient for aflibercept PFS assembly and blistering line E2 as no surface environmental monitoring is conducted for the product contact/indirect product contact surfaces such as the syringe assembly area and associated surfaces. According to SOP-00790, "Environmental Monitoring for Non-Sterile Packaging", Rev 18, section 7.4.2.2 states that sample sites for surface (floor and walls) viable shall be based on the following: "Sites and/or processes where microbial contamination is deemed likely to have an adverse effect on product quality, sites that represent the most difficult areas to clean, and activities in the area that contribute to the spread of contamination."
b. Complaints received by your client included moisture observed in the syringe blister package. Post aflibercept (Eylea) PFS VHP, there is no procedural requirement in confirmation of load dryness and absence of moisture in the syringe blister packaging or any other defect that may pose a risk to product quality.
c. The sterilization of the aflibercept (Eylea) PFS within the blister pack is conducted by VHP that includes Chamber Leak Test at 500 mbar, Pre-condition Parameter at 500 mbar, Exposure Parameter at 500 mbar, Aeration Parameter 1 at 800 mbar and Aeration Parameter 2 at 500 mbar. The aflibercept shipping validation supports a pressure change at 572 mbar in support plunger stopper movement, assuring the

sterile barrier is maintained. The worst-case pressure level applied at 500 mbar during the syringe VHP process has not been validated to assure the sterile barrier is maintained.

d. Document titled, Product Assessment - Eylea (aflibercept) - Product/PPE/Room/Health and Risk Assessment was performed by your internal PCI Safety, with standard gowning to be applied during manufacture that does not include a face mask. The assessment is deficient as it failed to account for the manufacturing bioburden control strategy, with the donning of a mask providing enhanced bioburden control.
e. Document RA-1331 (risk assessment), "Secondary Manufacturing of EYLEA Pre-Filled Syringe in Non-Classified Spaces at PCI" indicates that production rooms are positive pressure to the hallways per PCI SOP-00793; however, there is no calibrated magnehelic or BMS system to provide assurance of adequate continuous differential pressure control for the production rooms.
f. The requalification of the aflibercept (Eylea) VHP sterilization process includes 10,336 blister packs sealed and without pre-filled syringes, with 45 blister packs containing an aflibercept PFS spaced throughout the load for sterility testing and 240 blister packs total containing an aflibercept PFS for 120 (CI units) and 120 (BI units). The use of 10,336 empty blister packs is not representative of the commercial maximum load.

Background:

The validation studies performed at the PCI Philadelphia facility demonstrated that the VHP sterilization process consistently achieves at least 10^{-6} sterility assurance level (SAL). In addition, the process has been successfully qualified to maintain package integrity and confirmed on each lot through container closure integrity testing.

The PCI Environmental Monitoring program consists of performing quarterly sampling of each packaging room involving testing viable surface monitoring (floors and walls) along with active air monitoring for viable and non-viable particulate. Below is a table outlining the average environmental monitoring results for all packaging rooms for the calendar year of 2022.

Sample Locations	Average
Floor (TYMC)	< 1 cfu/25 cm^2
Floor (TAMC)	< 2 cfu/25 cm^2
Wall (TYMC)	< 1 cfu/25 cm^2
Wall (TAMC)	< 1 cfu/25 cm^2
Air Viable (TYMC)	< 3 cfu/m^3
Air Viable (TAMC)	< 5 cfu/ m^3
Non-Viable	4552 Particles/ft^3

Based on the capability of the sterilization process and the historical data from

Environmental monitoring testing, PCI is confident that the validated VHP sterilization process transferred from Regeneron ensures the sterility of the packaged product.

To address the Agency's concerns raised in the 483, in collaboration with Regeneron, PCI has developed the action plan outlined below.

Response:

a. As an enhancement to the Environmental Monitoring program, the procedure SOP-00790 EM Requirements for Non-Sterile Packaging will be updated to include a risk-based sampling approach that will integrate additional sampling points on and around the packaging equipment itself based on risk of contamination to product. The production lines involved in the packaging process prior to sterilization (assembly and blistering) will be assessed and the increased sampling plan implemented. This information will provide additional ongoing data related to the overall bioburden as it relates to product movement through the process.

   Action Due Date: 17-April-2023

b. PCI is committing to perform a risk assessment for possible defects that could occur related to the blister units and the enclosed pre-filled syringes as they are sterilized through the VHP process.

   Along with the risk assessment that will characterize the possible defects, PCI will perform a study on a minimum of three (3) lots of Eylea® that have been processed through the VHP Sterilization process. This study will involve visual inspection of the blister units themselves for the presence of visible drops of moisture within the cavities. This information will be characterized and assessed within the Risk Assessment.

   Action Due Date: 15-July-2023

c. A study will be conducted on packaged units related to plunger rod movement at the worst-case pressure experienced through a VHP cycle (approximately 500 mbar). During the inspection, Regeneron provided a document outlining the commitment to execute the study.

   Action Due Date: 30-June-2023

d. The observation outlines a reference to the Product Assessment for Eylea. This type of assessment is conducted to determine the appropriateness for a product to be packaged within a facility as well as the associated Personal Protective Equipment required to protect an employee from the material. The gowning requirements for protecting product would be developed through our Contamination/Cross-Contamination Risk Assessment RA-2021-011 as well product specific FMEAs.

As an overarching action, PCI is committed to performing an additional study to characterize the bioburden prior to sterilization. This study will be performed in collaboration with Regeneron. It will establish and evaluate the impact of pre-sterilization bioburden and further demonstrate the capability of the validated VHP sterilization process.

Characterization of bioburden load on the blister-packaged syringes (prior to sterilization) will be performed under protocol, and will include the following:

- Testing will be performed on three lots of blister-packaged syringes (prior to sterilization), with a statistical sampling based on total lot size. This will be performed once per quarter for a period of 1 year to capture seasonal variability.
- Based on the results, the protocol may be extended to include additional periodic testing.
- The determination of population will be based on ISO 11737-1 and the bioburden testing will be performed according to USP<61>.

The protocol will be comprehensive in outlining the steps involving the sampling and testing to be conducted spanning a period of twelve (12) months. The protocol will be in approved for execution by 17-April-2023. The study results will be evaluated and additional controls for bioburden will be implemented, as necessary.

The study will provide the background information in order to appropriately update the PCI Contamination/Cross-Contamination Risk Assessment RA-2021-011 which will include the output of any updates to gowning requirements based on the data obtained.

Action Due Date: 15-June-2024

e. PCI balances each packaging room to ensure positive pressurization on an annual basis. A risk-based approach will be taken regarding the process steps in which the continuous differential pressure monitoring is implemented across all production rooms at the site. The assessment will determine the rooms where continuous monitoring probes will be implemented and the associated procedure SOP-00793 "Air Handling System" will be updated to reflect the changes. The overall CAPA action includes the risk assessment, procedural updates, and implementation timeframe for the continuous monitoring program for room differential pressure.

Action Due Date: 15-November-2023

f. A review of the protocol and batch documentation associated with this observation was performed. The re-qualification was performed using blisters containing pre-filled syringes. This information was not clearly communicated during the inspection.

Evidence to this effect is noted below with pictures of the "dunnage" material utilized in the study which consists of the pre-filled syringes enclosed in blister units.

PCI has an established part number PCR-VHP-DUNNAGE within our qualified ERP system. A photo of the ERP system generated label is noted below indicating the part number PCR-VHP-DUNNAGE along with the corresponding materials consisting of a blister unit with an assembled syringe. Therefore, the study was performed using the same loaded cycles as a routine commercial sterilization cycle. The requirements for executing the sterilizer re-qualifications are outlined in the individual re-qualification protocols.



Observation 1 will be addressed under CAPA-2023-0063.

Observation 2:

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

Your Building 1 air compression system supporting aflibercept (Eylea) sterilization by VHP system (VHP 2) is not of oil free design, with the air distribution system to the VHP 2 sterilizer including black iron piping. Though the air compression system includes hydrocarbon removal and distribution system in-line point of use hydrocarbon and particulate filtration, the system design is inconsistent with current GMP expectations.

Response:

The distribution from the air compressor includes a series of three filters along with an additional point of use filter prior to delivery of the air to the VHP sterilizer. The filters are noted below in sequence:

(1) Particulate Filter:	Particulate Removal 1 micron
(2) Coalescing Filter:	Particulate Removal 0.01 micron; ISO 8573-1 Class 1
(3) Vapor Filter:	Particulate Removal 0.01 micron, ISO 8573-1 Class 1

The series of three filters are on a Preventive Maintenance cycle in which the vapor filter is replaced on a six (6) month cycle. The Particulate and Coalescing Filters are replaced on a twelve (12) month cycle.

In addition to the series of three filters to remove particulate, water, and oil vapor, there is an additional filter installed downstream immediately prior to distribution into the VHP unit itself. This filter is a Pharmaceutical Grade Sterilizer Filter with an absolute removal rating of 0.2 microns in liquids and 0.003 microns in gases. This filter is replaced on a twelve (12) month frequency.

The filtration system in place provides the appropriate air quality to the VHP sterilizer. The compressed air testing conducted post filtration is within the acceptance criteria. PCI is committed to enhancing our process through the CAPA actions listed below.

PCI has committed to source, install, and qualify a new oil-free compressed air system for the VHP 2 sterilizer. The installation will involve installing new piping constructed of copper/stainless steel.

Action Due Date: 04-February-2024

As an interim measure, PCI is increasing both the frequency of testing on the compressed air after the filtration system as well as the Preventive Maintenance program. The testing of the compressed air system (moisture, hydrocarbons, particulate, air viable) will be conducted on a bi-weekly basis downstream from the series of three filters. The Preventive Maintenance program will be enhanced related to the filtration system to include an inspection of the filter gauges on the same bi-weekly basis.

Action Due Date: 10-March-2023

Observation 2 will be addressed under CAPA-2023-0064.

Observation 3:

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, your firm failed to follow the following procedures:

a. According to your standard operational procedure entitled "QA Batch Record Review and Product Release,". SOP-00765, rev 45, Section 2.5, the Quality Associate is responsible "to review, verify presence of all batch record pages, verify correct batch record pagination and accuracy, coordinate error corrections with the Quality Associate or designee, assure Deviation Reports are complete and closed, and approve the batch record for PCI release." The following are examples of drug products that were released by your Quality Unit for commercial distribution with inaccurate lot numbers and/or expiration dating.

   • DEV-2022-0244, Alkermes Vivitrol 380mg (naltrexone for extended-release injectable suspension) Kit, lot# 190592C, expiration 04/30/2024 released with an incorrect expiry of 05/31/2024
   • DEV-2022-0244, Alkermes Vivitrol 380mg (naltrexone for extended-release injectable suspension) Kit, lot# 190604C, expiration 04/30/2024 released with an incorrect expiry of 05/31/2024 ·
   • EVENT-2022-5953, Flexion Therapeutics Zilretta 32mg (triamcinolone acetonide extended-release injectable suspension) Finished Kits, lot# 111003, expiration 11/2023 released with an incorrect lot number of 22-9006
   • EVENT-2022-6666, Amgen Repatha AMG 145) HMP, 120mg/mL, 3.5mL (evolocumab), lot# 1153429, expiration 12/3112024 released with an incorrect expiry of 10/31/2024

b. Your procedure, SOP-00240 "Corrective Action and Preventative Action (CAPA)", revision 01, effective 11/05/2021, section 5.1.8 states that "effectiveness checks should be considered as part of the CAPA plan and the scope and method of confirmed effectiveness should be detailed as part of the plan." CAPA 433782 which was opened on 12/14/2021 to document the correction for installing the proposed changes indicator for setting the crimper clearance and pressure settings for E5 Doboy. This CAPA was closed on 05/20/2022. Your firm applied a new effectiveness check review board to address current and future CAPAs however did not address the CAPA(s) that were opened within the effective date of your procedure.

This is a repeat observation from the previous inspection conducted 10/17/2022-10/21/2022.

Response:

a. In reviewing the list of deviations and the associated lots outlined in observation 3a, none of these products had shipped from the facility. Upon discovery of the discrepancy, PCI initiated deviations and the product impact was assessed and Corrective Actions implemented accordingly for each situation.
   • DEV-2022-0244 was related to the expiration dating assigned to two lots of

product. The process involves kitting different components into a carton. The expiration dates on the components dictate the overall expiration dating on the kit itself. A change was made to the lot of a component due to availability in which an update to the resulting expiration date was not performed. The units will be re-processed with the correct expiration date.

- EVENT-2022-5953 involved a kitted product in which the lot number on the vial is different than the lot number on the carton. The process deviated as the lot number that was assigned for the vial was the same as the carton. This was identified during the packaging operations and resolved prior to release of the lot.
- EVENT-2022-6666 related to a product in which the expiration dating is assigned based on the date of the packaging activity as supplied by the customer. There was a delay in the timeframe of the packaging activity start date from October 2022 to December 2022 at which point the new packaging date was assigned. The documentation associated with this lot was not updated so it resulted in the lot being packaged with an expiration date that was two months shorter than the intended dating. It was determined the material could be released without further action needed as the discrepancy in dates resulted in a shorter timeframe.

PCI has addressed each of the situations noted above and applied corrective and preventive actions accordingly. In order to address the specific observation, PCI is holistically implementing an additional verification step during the batch record review process as outlined in SOP-00765 "QA Batch Record Review and Product Release". This additional step will confirm the expiration date and lot information is correct as intended and there were no changes from the source information that resulted in a change to the variable data.

Action Due Date: 30-March-2023

b. PCI has executed the action plan as outlined in our response letter dated November 3, 2022. CAPA-2022-0273 Effectiveness was completed as per the due date in the PCI eQMS system. The other three CAPAs outlined (PR433753, PR433782, PR433754) were generated out of the prior eQMS system in which CAPA Effectiveness plans were not linked to each CAPA nor was it a procedural requirement in utilizing the system. In order to fully remediate the concerns raised in the observation, PCI is reviewing all CAPA actions from the PCI legacy system for CAPA Effectiveness that were closed after the date of August 2022. In August 2022, PCI implemented a new eQMS system in which the Effectiveness Check is integrated to the CAPA plan. The due date below outlines the date in which this retrospective CAPA Effectiveness check will be completed.

Action Due Date: 30-March-2023

Observation 3 will be addressed under CAPA-2023-0065.

Observation 4:

Buildings and equipment used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

a. Deteriorated insulation and a deteriorated gasket was observed at a finger flange assembly system for syringe labeling and plunger rod insertion System 1712, Area E3. Excess grease was observed on the plunger rod shafts.
b. The air compression system located in Building #1 and used for oil free compressed air to the VHP 2 sterilizer was observed in an dirty state, including debris observed at an air compressor intake.
c. Walk-in 2 - 8°C refrigerator 150845 was observed with waste material such. as dirt and debris on the floor and behind and between pallets. Refrigerator 150845 is used to store finished drug products such as aflibercept PFS and materials needing temperature control.
d. An automated door leading to E2, syringe blistering was observed not functioning.

Response:

PCI provided corrective actions related to each observation during the inspection to outline the replacement of the insulation and gasket on the Equipment Asset 1712, cleaning of grease from the equipment shafts, cleaning of the utility area around the air compression system, cleaning of extraneous material from the Refrigerators, and repair to the E2 door. The actions below outline the preventive measures that are being implemented.

a. The Preventive Maintenance program for the Equipment Asset 1712 along with any additional similar units within the facility is being updated to include a quarterly inspection of the integrity of the insulation and gasket. The PM for the Groninger equipment related to the observation of excessive grease is also being updated for a quarterly inspection and cleaning for excessive grease.

   Action Due Date: 17-March-2023

b. The procedure SOP-00803 "Cleaning Procedure for the Facility" is being updated to integrate the utility area for the Air Compressor and all additional GMP areas within the facility. The standard work for the cleaning requirements and documentation associated with confirming cleaning was completed will be updated to include the specific daily, weekly, and monthly requirements including the area of cleaning. The program will be enhanced by having a physical review documented at a periodic interval.

   Action Due Date: 25-March-2023

c. The preventive measures related to the refrigerator will be addressed through the same actions outlined above in response to observation 4b.

d. A Preventive Maintenance program for the production doors will be implemented as a monthly action item to service the doors and prevent breakdowns.

   Action Due Date: 25-March-2023

   An additional measure will be added to the preventive action plans related to the doors. An audible alarm will be installed on the doors that will be triggered if the door is open over a defined period of time to alert area personnel that the door is not closed.

   Action Due Date: 23-October-2023

Observation 4 will be addressed under CAPA-2023-0066.

Please feel free to reach out to me regarding any questions or comments.

Sincerely,

Cathy Cabrera
Director of Quality Systems
215-613-3670
215-613-3601 [Fax]
Catherine.Cabrera@pci.com

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SUMMARY

This preannounced abbreviated surveillance inspection and pre-approval inspection of a contract labeler, packager and repackager of human biological and pharmaceutical drug was initiated according to eNSpect Assignment # 231968 and as a part of PHARM1 FY23 work plan. This inspection was conducted in accordance with CPGM 7356.002- Drug Manufacturing Inspections, CPGM 7356.002M - Inspection of Licensed Therapeutic Drug Products; and CP 7346.832 - Pre-approval Inspections/Investigations in support of BLA 125387 S78 for (aflibercept injection), EYLEA, applicant Regeneron Pharmaceuticals, Inc. This inspection is reported under PACs S6002 and 46832. Profile codes SVT, SVS, LIQ, CSG, SUP SVL, and OIN were covered.

The previous inspection conducted on 10/17/2022 – 10/21/2022 was classified Voluntary Action Indicated and the firm was issued a Form FDA 483, Inspectional Observations, for: 1) Buildings used in manufacture, processing, packing or holding of drug product are not maintained in a clean and sanitary condition and 2) The responsibilities and procedures applicable to the quality unit are not fully followed. During the current inspection, the corrections from the previous inspection were evaluated without comment with the exception of Observation 2 which was a repeat observation.

The current inspection revealed that the firm continues to operate as a contract labeler, packager and repackager of human biological and pharmaceutical drug products. The current inspection provided coverage of the Quality System and Packaging and Labeling System. Documents reviewed included but not limited to laboratory records, change controls and SOPs. The inspection covered the packaging process of BLA 125387 S78 for (aflibercept injection), EYLEA a review of complaints, environmental monitoring, Quality Agreements, batch records, Annual Product Reviews, deviations, change controls, packaging and labeling controls, and corrective actions and preventative measures.

A Form FDA 483, Inspectional Observations, was issued at the conclusion of the inspection for:

1. Failure to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.
2. Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.
3. The responsibilities and procedures applicable to the quality unit are not fully followed
4. Buildings used in the manufacture, processing, packaging or holding of drug products are not maintained in a clean and sanitary condition.

Additionally, the following discussion items were presented to the firm at the closeout meeting:

1. The H1 cartoning line was inspected during a manufacturing break, with three Eylea cartons containing product observed on the active conveying track.
2. A field complaint was received for the Eylea DP, with the DP appearance gray in color. Regeneron did not evaluate the syringes for potential contamination. PCI should also work collaboratively with Regeneron to have a clear and complete understanding for absence of microbial contamination.

No refusals were encountered, and no samples were collected. No rodent, insect, or avian activity was observed.

ADMINISTRATIVE DATA

Inspected firm	Packaging Coordinators, LLC
Location:	3001 Red Lion Road Philadelphia, PA 19114
Phone:	215-613-3001
Fax	215-613-3091
Mailing address:	3001 Red Lion Road Philadelphia, PA 19114
Email address:	jeannie.metzinger@pciservices.com
Dates of inspection:	01/09/2023 – 01/12/2023
Days in the facility:	4
Participants:	**Christina K Theodorou, Investigator** **Wayne Seifert, Investigator** **Brandy LePage, Investigator** **Ben Du, Investigator**

This inspectional report was collectively written by Investigators Theodorou (CKT), Seifert (WS), LePage (BNL) and Du (BD). "We", "Our" and "Us" refers to Investigators Theodorou, Seifert, LePage and Du collectively. "I" refers to the Investigator that is identified as writing the applicable section of the report. For the purposes of this report, Packaging Coordinators, LLC will be referred to as the "firm", or "PCI", throughout this report.

On 12/30/2022, Investigator Seifert contacted Ms. Catherine Cabrera, Director of Quality Systems and preannounced the inspection. He asked Ms. Cabrera to provide any firm requirements related to COVID-19, who replied that there were none.

On 01/09/2023, we presented our credentials and issued a Form FDA 482, Notice of Inspection (attached), to Jeannie Metzinger, Chief Compliance and Quality Officer, who advised that she was the firm's most responsible person on-site.

At the close of the inspection, we issued a Form FDA 483, Inspectional Observations (attached), to Mr. Gill Valdez, SVP, Commercial Packaging Technology and Supply Chain.

Post-inspectional FDA correspondence should be sent to the following address:
Packaging Coordinators, LLC
Jeannie L. Metzinger, Chief Compliance & Quality Officer
3001 Red Lion Road,
Philadelphia, PA 19114-1123 jeannie.metzinger@pciservices.com.

HISTORY

(This section written by Investigator Theodorou)

According to Mr. Thomas Cligget, Director of Quality Operations, the firm's history remains unchanged from the previous inspection ending on 10/21/2022. That history is provided below.

Packaging Coordinators, LLC is a privately-owned company with global commercial locations in Philadelphia, PA; Rockford, IL; Mississauga, ON; Hay-on-Wye, UK; Tredegar, UK; and Dublin, Ireland. The firm was previously inspected on 12/15/2020 through 12/18/2020. This inspection was limited in scope and focused on the review of the firm's labeling and packaging of Janssen and AstraZeneca COVID-19 vaccines. No FDA 483 was issued and the inspection was classified as NAI.

On 10/17/2022, Mark Burke, Executive Director of Quality, stated the firm planned to manufacture the AstraZeneca COVID-19 vaccine, but did not proceed with any manufacturing operations. Prior to the limited inspection in December 2020, the firm was inspected on 8/29/2017 through 9/6/2017, as part of the OPQOI FY17 workplan. No FDA 483 was issued, and the inspection was classified as NAI.

The firm operates continuously and has approximately 675 full-time employees.

Information bellow was collected during the current inspection (01/09/2023 – 01/12/2023):
The firm was inspected by the Agency ending on 10/21/2022 as a joint inspection between the Office of Biological Products Operations (OBPO) and the Office of Pharmaceutical Quality Operations (OPQO) and conducted as part of the OBPO/Team Biologics FY23 workplan under eNSpect ID# 232419. The inspection was classified as Voluntary Action Indicated. A two-item 483 was issued to firm management at the conclusion of the inspection.

The following entities are subsidiaries of PCI:

Lyophilization Services of New England
- LSNE Contract Manufacturing, Madison, WI 53719 (FEI: 3011856764)
- LSNE Contract Manufacturing, 23 Commerce Dr, Bedford, NH 03110 (FEI: 3008546445)
- LSNE Contract Manufacturing, Parque Tecnológico de León, C. Nicostrato Vela, s/n, 24009 León, Spain (FEI: 3011566408)

Penn Pharmaceutical Services (FEI: 3010385970)
Sherpa Clinical Packaging, LLC (FEI: 3012261037)
Millmount Healthcare Limited (FEI: 3020744728)
Pharmaceutical Packaging Professionals
Bellwyck Pharma Services Inc (FEI: 3007309095)

The following are PCI Pharma Services locations throughout North America, Europe and Asia
- PCI Pharma Services 4545 Assembly Dr, Rockford, IL 61109 (FEI:1421377)

- PCI Pharma Services, 6166 Nancy Ridge Dr, San Diego, CA 92121 (FEI: 3001433984)
- PCI Pharma Services Ohio, LLC 8946 Global Way, West Chester Township, OH 45069 (FEI: 3010160S07)
- PCI Pharma Services New England, LLC, 75 Fruit St, Bridgewater, MA 02324 (FEI: 3026113534)
- PCI Pharma Services Canada Inc, 977 Century Dr, Burlington, ON L7L 5J8, Canada (FEI: 3009747238)
- PCI Pharma Services Canada Inc, 1 Rimini Mews, Mississauga, ON L5N 4K1, Canada (FEI: 3007309095)
- PCI Pharma Services Wye Valley Business Pk/Brecon Rd, Hereford HR3 5PG, UK (FEI: 3001670824)
- PCI Pharma Services Tafarnaubach Industrial Estate, 23-24, Tafarnaubach, Tredegar NP22 3AA, UK (FEI:1000370240)
- PCI Services, Block 7, City North Business Campus, Stamullen, Co. Meath, Ireland (FEI: 3025114923)
- PCI Pharma Services Germany GmbH, Am Wall 5, 14979 Großbeeren, Germany (FEI: 3018809765)
- PCI Pharma Services, 3/31 Sabre Dr, Port Melbourne VIC 3207, Australia (FEI: 3010069401)

Mr. Cligget provided me with a list of PCI's Board of Directors (**Exhibit 01**)

- Matt Jennings, Chairman of the Board, Kohlberg
- Sam Frieder, Managing Partner, Kohlberg
- Gordon Woodward, Chief Investment Officer, Kohlberg
- Chris Anderson, Partner Kohlberg
- Alex Forrey, Managing Director Kohlberg
- Robert Cucuel, Operating Partner Kohlberg
- Salim Haffar, CEO PCI
- Dr. Remy Hauser, Managing Director Partners Group
- Sujit John, Managing Director Partners Group
- Camilla Macapili Languille, Head of Life Sciences Mubadala
- Varini Sharma, CEO Mubadala

INTERSTATE COMMERCE

(This section written by Investigator Theodorou)

The firm continues to receive unlabeled finished product for labeling, packaging and repackaging depending on the product and client.

Mr. Cligget provided me a copy of a Bill of Lading for Cortef (hydrocortisone) 10mg 100ct lots CCFTK2, CCFTK2 and CCFTK (**Exhibit 02**).

According to Mr. Cligget the firm's top suppliers are:

- Essentra (AKA MM Group)
  - Headquartered in Kidlington, Oxford United Kingdom
- CCL Label
  - Headquartered in Ontario, Canada
- Rondo-Pak
  - Located in Camden, NJ

The firm's top customers are:

- Amgen Inc
  - Headquartered in Thousand Oaks, CA
- Regeneron Pharmaceuticals
  - Headquartered in Tarrytown, NY
- Novartis Pharmaceutical Company
  - Headquartered in East Hanover, NJ

JURISDICTION

(This section written by Investigator Theodorou)

Exhibit 03 is the firm's product list. This list shows all of the products packaged by the firm. The firm continues as a packager, repackager and labeler for human pharmaceutical products.

According to Mr. Cligget, the firm no longer provides any type of packaging service for animal drug products. The last batch for an animal drug product was Symparica 80mg, 6ct blister, lot 500890A packaged on 04/29/2021 with an expiration date of 07/2023.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

(This section written by Investigator Theodorou)

Exhibit 04 consists of the firm's organizational chart.

Exhibit 09 consists of a list of individuals we spoke to throughout the inspection.

The following employees participated in the inspection and provided information or records:

Jeannie L. Metzinger, Chief Compliance & Quality Officer, is the most responsible person and provides oversight for the quality units at all the firm's locations. Mrs. Metzinger has been in her current position for approximately 10 years. Mrs. Metzinger reports to Salim Haffer, Chief Executive Officer. Mrs. Metzinger has ten direct reports. Mrs. Metzinger was only present on 01/09/2023.

Mark J. Burke, Executive Director of Quality, oversees the firm's quality unit at this site. Mr. Burke has been with the firm for approximately eight years and in his current position for approximately two and half years. Mr. Burke reports to Jeannie Metzinger, Chief Compliance & Quality Officer. He has four direct reports. Mr. Burke accompanied us on the inspection, provided information contained in this report, and was present at the close-out meeting.

Catherine NMI Cabrera, Director of Quality Systems, oversees the firm's quality unit at this site. Mrs. Cabrera has been with the firm for approximately 20 years and in her current position for approximately two and half years. Mrs. Cabrera reports to Mark Burke, Executive Director of Quality. She has three direct reports. Mrs. Cabrera served as the host for this inspection. Mrs. Cabrera accompanied us on the inspection, provided information contained in this report, and was present at the close-out meeting.

Additionally, the following individuals accompanied us on the inspection and provided information contained in this report:
Jennifer Carrion, Sr. Quality Operations Manager
Tammi Leith, Regulatory Affairs Specialist
Thomas Cliggett, Director of Quality Operations
Manoj Subramani, Warehouse Lead
Taras Scott, Warehouser
Bob Kane, Principal Engineer
Jose Rodriquez, Operations Supervisor
Dennis Gerlach, Director of Validation
James Azhambault, Packer
Khareem Preston, Packer
Marion Bennett, Director of Operations
James Reingruber, Validations Specialist
Alex Tenerelli, Process Engineer
Siju John, Validation Manager
Eileen Echevarria, VHP Line Leader
Alex Weaver, Senior Director of Engineering
Pat Cligget, Quality Account Manager

The following individuals were Subject Matter Experts from Regeneron that contributed to questions during this inspection:
Dwight Ricci, Regeneron SME
Theresa Bode, Regeneron SME
Andrew Cook, Regeneron SME
Dustin Blodgett, Regeneron SME
Matthew Rainka, Regeneron SME

FIRM'S TRAINING PROGRAM

(This section written by Investigator Theodarou)

I reviewed the firm's procedure, SOP-00777 *Training*, rev 38, effective 02/14/2022 which establishes the system by which employees are trained and how training documentation is tracked, approved and filed. The firm implements a training system that uses both self-training using ComplianceWire, On-the-Job Training (OJT) and group or Instructor Led Training (ILT).

CGMP training is offered to new hires who must pass an examination with a score of 80% to be allowed to work. If not, they can't begin any work until they have retaken and achieved an acceptable score of 80%. Annual or Refresher CGMP training is offered annually at the minimum for all employees. Periodic CGMP training is conducted on topics selected by the Senior Management Team. Selection of the topics is contingent on new FDA guidances or updates, repeated events, new processes, any significant process change, etc. I reviewed this document with no objections.

MANUFACTURING/DESIGN OPERATIONS

Exhibit 05 consists of the firm's Site Master File. **Page 37-38** contains the facility's floor plans. There are forty-six packaging lines at the firm, with area E3 new for the BLA 125387 S78 (aflibercept injection), EYLEA. The firm does not package potent or toxic products and has ceased operations for animal drug products.

Walkthrough

(This section was written by Investigator Seifert)

On 09 January 2023, we (WS, BD, CT, and BL) proceeded on a walkthrough of the facility starting in shipping and receiving. Deliveries proceed from guard station, where transport is considered a delivery or pickup. SOP 010511 support receipt of materials, with materials received on heat treated pallets (no wood allowed in production). A purchase order is compared to the shipment, packing slip, and number of units are verified. Goods can be rejected based on damage, infestation, etc. J.D. Edwards is the validated materials management system, with electronic quarantine. Materials for manufacture are stored in the validated ambient GMP warehouse, 59 to 86°F temperature control by an automated pallet storage and retrieval system (ASRS). Materials for manufacturing are sampled, with the amount sample deducted from available inventory. Eylea is sampled under 2 - 8°C storage conditions. A caged reject area was observed with badge access.

We proceeded to 2 - 8°C walk-in unit 9 (150845). Observed was Regeneron Lot 8231500283, one pallet. The quantity in J.D. Edwards and the storage location of the specified lot was accurate. The walk-in refrigerator was observed in an unclean state, see **Exhibit 06.**

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 4.c.

Outside the walk-in unit, equipment identified as high claim was being stored, placed in a location identified as B15 - Trash, see **Exhibit 07**. During the inspection, the firm provided corrective action that included storage of the equipment in an appropriate area, see **Exhibit 08.**

We proceeded to area G3, existing labeling area that includes plunger rod insertion to the Eylea syringe. The new area for said function is E3, with syringe finger flange assembly to the syringe and blistering being conducted in area E2. Within the E3 area, a Groninger syringe tub conveying system was observed, unit 5349, followed by labeling and plunger rod insertion system, asset 1712. A finger flange unit was observed with deteriorated insulation and gasket, see **Exhibit 10**. The plunger rod shafts were observed with excess grease, see **Exhibit 11.**

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 4.a.

We proceeded to Eylea finger flange assembly and blistering, with the area assess door observed non-functional, see **Exhibit 12**. The finger flange to the syringe is semi-automated, placement by hand with a machine locking the finger flange into place. Molded trays are formed, with syringe placement followed by blistering by HAPA KLO NFR Packaging Machine. A challenge test is conducted every four hours for the packaging system that includes automated detection of missing flange, empty tray, printed lot and expiration, incorrect lot and expiration, etc. The area includes ceiling MERV 13 filters. Blistered syringes are stored at 2 - 8°C pending further manufacturing.

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 4.b.

We proceeded to VHP unit 1 and 2, Steris units. The area includes HEPA filter filtration. Recirculated air is at 90%, fresh 10%.

We proceeded to area H1, final packaging, cartoning that includes Eylea product, insert into a carton and corrugated shipper. The process included carton formation with a single Eylea blister placed into the carton with insert. A check weight system verifies carton contents, with carton serialization 100% check by camera system. 24 Eyleas cartons are packaged to one shipper. A system challenge is conducted every four hours as prior for missing insert, etc. The line was inspected at an end of a break, with three Eylea carton containing product observed on the active conveying track, see **Exhibit 13**. I (WS) questioned why the units were not positioned into an overpack prior to break, with the firm rejecting, discarding the units.

Reference Discussion Item 1 in General Discussion with Management.

On 10 January, we (WS and BD) proceeded VHP 1, with 8 carriers to a load, 1,292 syringes per carrier. Post VHP there is no visual inspection of the load that may include wetness, moisture in the blister

or other defects that could have an impact on product quality. Visual inspection in H1, cartoning only pertains labeling requirements. In Eylea blistering operations prior to VHP, there is 200% visual inspection with AQL.

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 1.b.

On 11 January 2022, we (WS and BD) proceeded to the air compressors, 1x Atlas Copco and 1x Hitachi, both oil free in design with redundant dryers, 2x receivers, coarse and fine filter, with copper to stainless distribution system for VHP1. The observed dewpoint was -107.7°C.

We proceed to Plant 1 for 2x air compressors used for VHP2, not oil free in design. Post air compression, filtration occurs followed by 3x driers to a receiving tank. Post receiving tank, the air is distributed by black iron piping (100s feet of piping), with copper to stainless at the VHP2 system point of use. Hydrocarbon filters are located within the compressor and at the newly installed filtration unit near the VHP 2 sterilizer. The compressors are supplied with food grade oil in air compression. The system was originally for instrument air and through filtration and testing, the system meets process air requirements for GMP use. There is no hydrocarbon alarm capability, with the system tested for hydrocarbon quarterly. There is a plan to replace the system, not scheduled with the equipment not ordered. The compressors in Plant 1 and the general area were observed in an unclean state, see **Exhibit 14.**

OBJECTIVE 1: READINESS FOR COMMERCIAL MANUFACTURING

As part of assessing the firm's readiness for commercial manufacturing, a review of the GMP Systems below were assessed as they pertain to the PAI product, BLA 125387 S78 for (aflibercept injection), EYLEA.

Quality System

Management Responsibility

(This section written by Investigator Theodorou)

The responsibilities applicable to the Quality Control Unit were reviewed and evaluated during the current inspection. Mr. Thomas Cligget provided the firm's procedure, SOP-00773 *Responsibilities of the Quality Unit*, rev 05, effective 09/27/2021 which defines the responsibilities of the Quality Unit such as making decisions and recommendations based solely on quality considerations. During our inspection, I reviewed various SOPs, investigations, batch records, and validation reports. Each of the reports we reviewed were reviewed and approved by the quality unit. No deficiencies were noted unless further specified in this report.

Exhibit 15 consists of a list of the firm's SOPs.

Deviations

(*This section written by Investigator LePage*)

The procedure that governs unplanned quality events and deviations is entitled SOP-00113, rev 02, "Deviation: Reporting and Investigation" (**Exhibit 16**). The procedure indicates that an event or deviation is to be initiated in the eQMS, or on FORM-000308, immediately upon realization. In January 2021, the firm transitioned their electronic quality management system from Trackwise to MasterControl. The current quality designations of "event" or "deviation" in MasterControl were termed "public record" in Trackwise. According to Thomas Cliggett, Director of Quality Operations, all events are assessed for product impact and escalated to a deviation as necessary. Deviations are further classified as No Impact, Minor, Major and Critical through the joint evaluation of SMEs and Quality. Root cause analysis is required for all deviations classified as minor, major, and critical. Deviations are required to be closed 30 business days after initiation unless an extension is approved by Quality. I reviewed the following deviations, events, and public notices in depth: PR-424733, PR-414723, PR-415690, DEV-2022-0591, DEV-2022-0829, DEV-2022-0568, PR-424609, PR-422935, DEV-2022-024, Event-2022-5953, Event-2022-6666, and some examples are described below:

PR-DN424609 (**Exhibit 17**)
Open: 11/20/2019
Closed: 12/06/2019
The customer Eirgen contacted PCI on 11/20/2019 to inform them that they received an unreleased lot of the product Rayaldee FG Lot #3868797. QA approved the batch record release on 10/25/2019 and released the shipment on 11/15/2019 (see **Exhibit 18**). The firm determined the root cause to be human error. The firm initiated CAPA 424768 and conducted "Awareness" training for the Quality Teams personnel associated with batch release. The customer kept the drug product lot sent in error and distributed it in lieu of the originally requested lot.

DEV-2022-0244 (**Exhibit 19, pg. 1-17**)
Opened: 04/04/2022
Closed: In Progress

Vivitrol® (naltrexone for extended-release injectable suspension) 380mg/vial, lot #2022-3005T, expiration 04/30/2024 kits (see **Exhibit 20**) were assembled with some of the following components.

- Vivitrol® microspheres (naltrexone for extended-release injectable suspension) 380mg/vial, lot #0000110944, expiration 10/2024
- Administrative needle (1.5") lot# 190592C, expiration 04/30/2024
- Administrative needle (1.5") lot #190604C, expiration 05/31/2024
- WIP Diluent Vial, lot #00108206B, expiration 03/2025

- 5mL Luerlock Syringe, lot# 210112V, expiration 12/31/2025

The expiration date of the kit is based off the component that expires first, therefore the kits should have received an expiration date of 04/30/2024, which correlates to the administration needle (1.5") lot# 190592C. The kits were assigned the incorrect expiration date of 05/31/2024, which corresponds to the administration needle (1.5") lot #190604C.

Vivitrol® (naltrexone for extended-release injectable suspension) 380mg/vial, lot #2022-3005T was released on 03/24/2022 by QA (see **Exhibit 20**). On 03/31/2022 PCI was notified by their customer that the drug product released to them was incorrectly labeled with the wrong expiration date. The 3600 affected kits were repackaged to reflect the correct expiry of 04/30/2024. CAPA-2023-0020 **(Exhibit 19, pg 29 - 43)** was initiated on 01/10/2023 during the inspection and is still in progress.

Event-2022-6666 **(Exhibit 21)**
Opened: 12/20/2022
Closed: 12/20/2022
On 12/19/2022, PCI was notified by their customer that they had received Repatha® Pushtronex® system (evolocumab) 420mg/3.5mL, lot# 1153429, expiration 12/31/2024 labeled with the incorrect expiration date of 10/31/2024. QA approved the batch record release on 12/19/2022 and released the shipment on 12/20/2022 (see **Exhibit 22**). The firm determined the root cause to be human error and did not initiate a corrective action. The product was short-dated the expiry by two months, therefore, the error was determined to not impact the quality of this lot. There was no preventative action directed for this event.

(*This section was written by Investigator Seifert*)
On 12 January 2023, Pat Cliggett, Quality Account Manager provided an overview of deviation selected as follows:

Deviation DEV-2022-0485: Opened 08 July 2022, Closed 18 August 2022. Regeneron, Eylea blister failed leak test, Lot 8231400007. The root cause was a wire line defect in the blister pack, imperfection in cavity. The event is associated with blistering operations and has been added to the defect library. Repackaging was conducted according to protocol, meeting the TOR, with stability data supportive of the additional VHP cycle.

Corrective Actions and Preventative Actions
(*This section was written by Investigator Theodorou*)
Exhibit 23 consists of SOP-00240, *Corrective Action and Preventative Action (CAPA).*

I reviewed the firm's SOP, SOP-00240, *Corrective Action and Preventative Action (CAPA),* revision 01, effective 11/05/2021 which outlines the procedure to document the process for assigning,

monitoring and tracking corrective action and preventative action (CAPA) plans arising from quality events and assigned Root Cause Analysis (RCA). When a CAPA is needed, it will be generated in MasterControl. Required data such as the CAPA type, Parent Record (Event, deviation, etc. that necessitated a CAPA), description of CAPA including planned actions, due dates and action deliverables, and a description of required effectiveness check or a justification if an effectiveness check is not required. Depending on the risk categorization of the CAPA, a timeline is assigned. High risk – 30 calendar days, Medium Risk – 60 calendar days, and Low Risk – 90 calendar days. A guideline for effectiveness checks is also identified in the SOP based on the frequency of the impacted activity. If the activity is a daily activity, the minimum effectiveness check period should be 3 months, weekly – 6-month period, at least monthly – 12-month period, if the frequency is greater than monthly or undetermined, a 24-month minimum effectiveness check period is applied.

According to Mr. Cliggett, as a correction to an observation from the previous inspection, the firm created a CAPA Management Team to better plan, track and review CAPAs and to monitor the correction and perform Effectiveness Checks as required by the SOP.

I reviewed the following CAPAs:
CAPA-2022-0658
CAPA-2022-0659
CAPA-2022-0695
CAPA-2022-0766
CAPA-2022-0821
CAPA-2022-0825
CAPA-2022-0825
CAPA-2023-0009

CAPA-2022-0659
Exhibit 24 consists of the firm's CAPA-2022-0659 which was opened to document the firm's corrections to Observation 2 that was made during the previous inspection ending 10/21/2022.

I noted the firm implemented an effectiveness check review board which meets routinely to determine if a CAPA effectiveness is needed, assigns a review date, and monitors the status of the CAPA throughout the process. As of the date of this inspection, the firm did not have any completed effectiveness checks by the review board for me to review. I also discussed with Mr. Cliggett that if the purpose of the meeting is to make quality decisions, the firm should maintain a record of either the meeting notes or meeting minutes. How the record is kept, whether a new tracking system is made for them or if copies of the meeting notes are added to each CAPA that is discussed at each meeting should be at the discretion of the firm.

I also noted in my review that the firm did not conduct any effectiveness checks for the CAPAs that were identified in the observation from the previous inspection. **Exhibit 25** consists of CAPA 433782

which was opened on 12/14/2021 to document the correction for installing the proposed changes indicator for setting the crimper clearance and pressure settings for E5 Doboy.

At the time of the creation of the CAPA, SOP-00240 was in effect. SOP-00240, section 5.1.8 states that "effectiveness checks should be considered as part of the CAPA plan and the scope and method of confirmed effectiveness should be detailed as part of the plan." Please refer to **Observation 3.b** in the **FDA 483 Inspectional Observations** and in the **Objectionable Conditions and Management Response** section of this report.

I also reviewed the firm's corrections to observations made during the previous inspection ending in 10/20/2022 which I discuss in the **Voluntary Corrections** section of this report.

Change Management/Change Controls

(*This section was written by Investigator LePage*)

The procedure that governs change control is SOP-00460, rev 01, "Philadelphia Change Control Procedure." This procedure includes, but is not limited to, changes in process controls, GMP documentation, validation and any system which can potentially impact a manufactured product. Change controls are initiated by completing FORM-0003005, "Change Control Form," or by opening a MOC in the eQMS. The impacted department(s) and Quality Unit reviews and approves all changes. Lastly, the final review and close of change controls is performed by the Quality Unit. I assessed the following change controls from the list provided by the firm during the inspection: MOC-2022-1404, MOC-2022-2297, MOC-2022-1908, MOC-2022-1320, MOC-2022-0031. Some examples of the change controls evaluated are described below.

MOC-2022-0031
Open: 01/06/2022
Closed: TBD
This change control was initiated to install a secondary filtration system precursory to the equipment air supply connection that is fed from the firm house air distribution pipe. The filter was added to reduce the workload of the filtration system downstream in the Vaporized Hydrogen Peroxide (VHP) unit, specifically # VHP2. No significant discrepancies were noted.

MOC-2022-1320
Open: 07/05/2022
Closed: 07/14/2022
This change control was initiated to update the MasterControl eQMS with the firm customer's (AstraZeneca) shipping instructions. No significant discrepancies were noted.

(This section was written by Investigator Seifert)

On 10 January 2022, the firm provided an overview of the following change control:
Change Control MOC-2022-0032: Initiated 6 January 2022, Closed: Moved to verification January 6, 2022 pending closure. The change control was for the installation of pre-filters, upstream of the VHP unit 2 for the compressed air. The rationale was black iron compressed air distribution piping from the compressors and the compressors not being oil free in design. Three filters were installed in series, with the filter changed on a routine basis, but not integrity tested. The filters are 1 micron, 0.01 micron, and 0.01 micron, followed by sample port, and copper piping to stainless steel, Pall filter at 0.02 micron see **Exhibit 26**. The pall filter is changed on an annual basis. VHP unit 1 has the same Pall filter, with the VHP 1 system supplied with oil free compressed air, distribution piping of appropriate design.

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 2.

Complaints

(This section was written by Investigator Theodorou)
I requested a list of complaints from the firm and randomly selected the following for review. No deficiencies were noted with my review of these complaints.

PR 413500
PR 413501
PR 413948
PR 414374
PR 415202
PR 415241
PR 418746
PR 418838
PR 419927
PR 420120
PR 421514
PR 422606
PR 426396
PR 427277
PR 427297

Consumer Complaint 162058
I discussed with the firm a complaint received by the Agency on 04/30/2020 for Cortef Hydrocortisone, no lot number or expiration date given which is opened to document the complaint that was made regarding the effectiveness of the hydrocortisone. The complainant called to report

that the hydrocortisone he had been prescribed was not working as it was supposed to. He said after taking it his cortisol was 1.5 repeatedly and the reference range was approximately 5-20. The complainant consulted his doctor who was also puzzled as to why the drug did not perform as intended. The complainant has Addison's disease and needs the medication. He stated he called the manufacturer and all they said was, "Thank you for the complaint." The firm receives complaints from their client Pfizer who is the recipient of the originating complaint and forwards them as applicable to their contract manufactures and packagers. The firm did not receive this complaint from Pfizer.

(This section was written by Investigator Seifert)
On 11 January 2023, Ms. Tara Mayka, Quality Supervisor, Complaints and Matthew Rainka, Regeneron SME (Virtual) provided an overview of complaints according to SOP-01174, "Customer Complaint Procedure", Rev 27, Effective date 02 June 2022. We (WS and BD) reviewed the following complaints:

COMP-22-4113: Opened 01 December 2022, Closed 03 January 2023. 30 days is allowed to complete the complaint deviation investigation, Regeneron requirement. 5x different complaints COMP-2022-4112 (condensate in blister), COMP-2022-4113 (condensate in blister), COMP-2022-4056 (condensate in blister), COMP-2021-0058 (leak in blister), and COMP-2022-4111 (water) were for moisture in the blister pack Tyvek closure. PCI LLC indicated the root cause was external to PCI, with no failures or anomalies associated with the batch. Post VHP, residual VHP converts to water vapor and oxygen that dissipates. I (WS) questioned if there is any visual inspection post VHP sterilization of the syringe blister units in verification of load dryness, with the firm indicating no. The units were returned opened, impacting the ability to understand the moisture in the blister unit. I (WS) questioned Tara Mayka, Quality Supervisor, Complaints and Dennis Gerlach, Director of Validations if moisture in the syringe blister would be an objectionable condition, with the firm indicating yes. There is no inspection of the Eylea syringe blister packs post VHP for absence of moisture.

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response Observation 1.b.

COMP-2022-2819: Opened 24 August 2022, Closed 22 September 2022. The scope of the complaint was a gray color for the DP, 3x syringe units. The root cause was explained as external to the PCI manufacturing process. Eylea is to be clear in appearance to pale yellow. The deviation investigation at PCI was a paperwork review. The batch in question was PCI Eylea batch 8231500222, Regeneron complaint 03249-22, with the syringes not evaluated for contamination. A study was conducted exposing syringes to an elevated temperature, with the same color or similar color change in the DP observed. I (WS) questioned why Regeneron did evaluate the syringes for contamination, where if there wasn't enough volume for test, perhaps the DP material could be plated in confirmation of absence of contamination. The concern is associated with Regeneron. Reserve samples were

checked, acceptable.

Reference Discussion Item 2 in Section GENERAL DISCUSSION WITH MANAGEMENT.

Complaints for Damaged Syringes, see **Exhibit 27.** Approximately 76 complaints over the past two years for damaged syringes, with the root cause external to PCI LLC and associated with the DP manufacturing facility. Fractographic analysis was conducted identifying the defect as stainless steel contact with the glass syringe at the DP manufacturing facility. A CAPA was initiated in corrective action.

Six (6) complaints were received for debris in the carton, external to the blister pack. There was no impact to product quality.

Quality Agreements

(This section was written by Investigator Seifert)

On 11 January 2023, the firm provided the quality agreement under QA-AGMT-01628 2, *"Regeneron PCI Quality Agreement May 2021: Regeneron Pharmaceuticals, Inc. 81 Columbia Turnpike, Rensselaer, NY 12144 and Packaging Coordinators, LLC, 3001 Red Lion Road, Philadelphia PA 19114"*. The quality agreement was extensive.

Batch Record Review and Release

(This section was written by Investigator LePage)

The procedure that governs the batch record review and release process for all packaging and labeling operations is SOP-00765, rev 45, "QA Batch Record Review and Product Release" (**Exhibit 28**). According to Mark Burke, Executive Director of Quality, batch record review, and release duties are managed by the Quality Operations segment of the PCI Quality Unit. The PCI Organizational Charts (**Exhibit 04**, page 5 & 9), indicate the Quality Operations management as, Thomas Cliggett, Director of Quality Operations, and Jennifer Carrion, Sr. Manager, Quality Operations, who reports directly to Mr. Cliggett.

Per SOP-00765, Section 2.6, (**Exhibit 28, page 1**), Quality Associate responsibilities include "review the Customer Samples (e.g., Lot number and Expiration date, and contents) ...for correctness before they are shipped as well as the PCI site samples before they are logged and stored. This is to be performed during the batch record review." I noted in my documentation review that QA reviewed and subsequently released numerous drug products that were labeled with incorrect lot numbers and/or expiration dates. All the mislabeled drug products were sent to the customer, who placed the order directly with PCI, and not further distributed. See **OBSERVATION 3.a** in the **OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE** for more details.

(This section was written by Investigator Seifert)

On 11 January 2023, the firm presented the batch record for VHP, *"Manufacturing Packaging Instructions, Regeneron, MPI Title: PCR-WIP-VHP, Rev 70, Product 0023369, WO 1940331, FG Lot# 8231500281, Expiration 10/2023, Bulk Lot# 8231500281"*, 28 October 2022. Chemical indicators are positioned with the production load.

Annual Product Review

(This section was written by Investigator LePage)

The standard operating procedure for annual product reviews is detailed in SOP-01158, rev 07, "Annual Product Quality Review." According to the procedure, the Annual Product Quality Review requirements and review periods are determined by the customer, which are specified in their respective Quality Agreements. Elements of APQRs include, but are not limited to:

- Batches Packaged/Shipped
- Rejected/Aborted Batches
- Reworked Batches
- Change Controls
- Deviations
- Validation
- Equipment Qualification
- Complaints
- Returns
- Field Alerts/Recalls

Annual Product Quality Reports are assessed and approved by the Director of Quality. We evaluated the annual product reviews for Vascepa Capsules 1g (review period: 04/01/2021-03/31/2022), Entyvio (Vedolizumab) Vials 300mg (review period: 06/01/2021-05/31/2022), Miconazole Softgels 1200mg, (review period: 05/01/2021-04/30/2022). No significant discrepancies were noted.

Production System

Environmental Monitoring and Control Program

(This section was written by Investigator Seifert)

On 09 January 2023, Mr. Dennis Gerlach, Director of Validation provided an overview of environmental monitoring. We (WS and BD) reviewed SOP-00791, *"Environmental Monitoring for Hallway, Airlock, and Gowning Areas"*, Rev 1, 08 November 2021, **see Exhibit 29.** Total particle is conducted quarterly for trending purposes only. We reviewed SOP-00790, *"Environmental Monitoring for Non-Sterile Packaging"*, Rev 18, Effective date 29 September 2021, with environmental monitoring for E3, E2 and H1 quarterly that includes static and dynamic testing for total particle, viable air, and surface monitoring of walls and floors, see **Exhibit 30.** In E2, assembly

and blistering, there is no environmental monitoring of the drug product, blistering indirect product contact work surfaces.

We (WS and BD) reviewed the EM results for 2021 - 2022 for E3, E2 and H1 for non-viable, viable air, and wall and floor monitoring. A contractor, AATL, supports EM monitoring with the firm audited, with training conducted for PCI LLC. EM sampling and reporting procedures. There is PCI oversight of AATL during sampling, with validation review of the test results.

We reviewed the Q3 2022 E2 average viable wall results, with some TYMC above alert, no trend. We reviewed the Q3 G03 average wall viable TYMC equal to the alert limit, no trend. No other rooms exceeded the alert limit.

On 11 January 2023, Mr. Dennis Gerlach, Director of Validation provided an overview of the risk assessment in determination of EM points. The non-viable EM monitoring is conducted by potable calibrated Bioluminometer and for E2, blistering, quarterly. EM testing includes viable air, bi-annual. Viable surface sampling is conducted quarterly. An environmental monitoring position paper, 28 August 2017 includes static and dynamic sampling, **see Exhibit 31.** Sampling is conducted at the location or process where microbial contamination is deemed likely to occur or where it has the potential to adversely impact product quality. Environmental sampling locations includes locations that are difficult to clean, locations where the product is exposed to the environment, and any area that has the potential to contribute to the spread of contamination.

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 1.a.

Facilities & Equipment

Facility Maintenance, Cleaning, Disinfection and Sanitization

(This section was written by Investigator Seifert)

On 09 February, Mr. James Azhambault, Packer and Khareem Preston, Packer provided an overview of the facility cleaning procedure according to SOP-00849, *"Potable Equipment Cleaning"*, Rev 5, Effective date 25 August 2021. The procedure describes the cleaning process, sanitization process from January to June with 70% IPA, and July to December with 6% Steri-Perox. We (WS and BD) reviewed SOP-00803, *"Cleaning Procedure for Facility"*, Rev 22, Effective date 4 November 2021, with the procedure similar to the prior, a description of cleaning for rooms, gowning, airlock, etc. once per shift. We (WS and BD) reviewed SOP-00804, "Cleaning Procedure for Packaging Rooms", Rev 47, Effective date 5 January 2023. The frequency of cleaning is every lot change. The cleaning agents 70% IPA and 6% Steri-Perox are ready to use. Cleaning is conducted by PCI LLC no external contractor.

We (WS and BD) reviewed the cleaning efficacy, *"Final report for the 6% Steri-Perox Disinfectants/Sanitizer Efficacy Study - 11/25/2015"*. The scope was efficacy of the disinfectants, sanitizers on product contact parts and primary packaging lines, 3x studies. The equipment contact parts were cleaned and swabbed after 5-days. The acceptance criteria was the swab 4in^2 must be NMT 20 CFU, with no *Salmonella, Escherichia* coli, or *Staphylococcus aureus. Candida albicans* and counts of mold are not to exceed 20% of total allowable counts or NMT 4 CFU mold. Positive and negative controls were prepared.

On 10 January 2023, Siju John, Validation Manager provided an overview of Steri-Perox and the 70% IPA, base cleaning process and sanitization protocol, change validation protocol for cleaning primary packaging lines CS14-068, product methotrexate, worst-case 20 May 2014. For the 70% IPA, 3x batches of Methotrexate were manufactured, followed by cleaning by procedure, with the 70% IPA suitable for microbiological and detergent residues. The acceptance criteria for bacteria and mold were NMT 20 CFU/4in^2, and no objectionable organisms that include *P. aeruginosa, S. aureus, and Salmonella.* The dirty and clean hold was validated at 30-days.

We (WS and BD) reviewed the Steri-Perox 6% R15-218 under *"Final Report for the Steri-Perox Disinfectant/Sanitizer Efficacy Study"*, 23 November 2015. The same study design and acceptance criteria was applied as the 70 % IPA, acceptable. Testing included positive and negative controls, with contractor, test lab AATL performing testing.

Utilities

(This section was written by Investigator Seifert)

On 10 January 2023, the firm provided an overview of the oil free compressed air 2022, EM testing under VAL-00013807, *"EM Testing Report,"* with testing 4x per year. We (WS and BD) reviewed the compressed air testing under VAL-0013807, only at the compressors and not at the points of use. Testing was for particles ≥ 0.5 micron < 100,000 PPCM, ≥ 5.0 micron ≤ 2,000 PPCM, bacterial ≤ 25 CFU/ft^3, mold ≤ 25 CFU/ft^3, oil at ≤ 1.0 mg/m^3, and dew point ≤ 4°F. The outside testing firm, AATL, conducts the EM testing. Routine testing at the points of use have not started, with the procedure updated and approved for point of use testing. A single test was conducted at the VHP system, ATLL sample under #22-016481/1 R1 03/09/22. Particle, bacterial, TYMC, hydrocarbon and dew point were to specification.

Risk Assessment

(This section was written by Investigator Seifert)

On 10 January 2022, the firm provided an overview of the risk assessment, FMEA SOP-211.22.d.2, *"Risk Assessment # RA2021-011,"* 2021, see **Exhibit 32**. The scope is cross contamination mitigation and is not specific microbiological control for Eylea. The scope further includes facility design, labeling design, line clearance, cleaning and equipment, cleaning validation, material movement,

gowning, and HVAC. In Eylea blistering operations, a lab coat, gloves, foot booties, and hairnet are required, with no face mask. The firm explained that the manufacturing process is bioburden control.

We (WS and BD) reviewed the Regeneron Risk Assessment RA-1331, Secondary Manufacturing of Eylea Pre-filled Syringes in Non-classified Space at PCI, Effective V1.0, 07 November 2022 see **Exhibit 33.** The scope was a risk-based impact assessment summary report. Risk of microbial contamination includes rooms for manufacture positive to the corridor. The facility SOP under 00793, Air Handling System Differential Pressure Check is Annual by testing, see **Exhibit 34.** There is no magnehelic or BMS system in support the differential pressure is to specification, during routine manufacture. The risk assessment is a description of the PCI LLC process for manufacture but fails to look at other sources of microbiological contamination.

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 1.e.

Procedure SOP-00783, *"Gowning Cleanliness and Sanitary Practice of Personnel"*, Rev 34, 29 September 2021 includes gowning materials, **Exhibit 35.** Another SOP explains gowning for blistering, a bioburden control process with masks not required. We (WS and BD) reviewed the product assessment, Eylea, Product/PPE/Room/Heath and Risk Assessment, see **Exhibit 36**. Safety performed the heath assessment, original assessment that may have not included the bioburden control strategy, blistering system with Eylea syringe sterilized. Standard gowning is applied in Eylea blistering with no mask required as described in the batch record, PCR-WIP-VHP, *"Master Packaging Instruction: Regeneron"*.

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 1.d.

Equipment Qualification

(This section was written by Investigator Seifert)

On 09 January 2023, Mr. James Reingruber, Validation Specialist provided an overview of equipment qualification for labeling area E3 and blistering E2. E3 equipment qualified included a syringe de-nester, labeling system, plunger rod insertion and the option to install the finger flange (manufacturing process at a later date). The system for labeling and plunger rod insertion, was moved from area G4 to area E3 under change control. We (WS and BD) reviewed the IOQ for the specified equipment under Protocol VP19-097, *"Installation and Operational Qualification Groninger Syringe De-Nesting and Assembly Machine"*, 08/2019. There were no deviations in execution of the IOQ.

We (WS and BD) reviewed the *"IOQ Qualification Addendum - Groninger Syringe Labeler 1712 - VP21-177"*, January 2022. The IOQ was for a drive motor replaced, with no deviations.

VHP Unit PQ

(This section was written by Investigator Seifert)

On 09 January 2023, Mr. Alex Tenerelli, Process Engineer, provide an overview of the VHP PQ under *"Final Summary Report Confirming Validation for Sterilization of Eylea Prefilled Syringe Blister Packs, Performance Requalification Product Sterilization Process, VP22-118, FR22-118"*, 19 December 2022, VHP-Sterilizer H3971 VHP(1). The maximum and minimum load was originally qualified, with only the maximum load based on worst case qualified in requalification. Each system, VHP unit 1 and 2 have a different sterilization recipe. The sterilization process includes leak test with a limit of 10 mbar over 10 minutes, air removal, temperature regulation at ≤ 28 ± 2°C between probes and 2°C from each probe, jacket ≤ 30°C, and exposure phase that includes 5x injection pulses with 35% VHP by hot plate. The amount of H2O2 dispensed is by calibrate scale at 626g total. Post exposure the VHP is dissipated with 0.2 µm filtered oil free compressed air. The oil free compressed air by central utility is copper to stainless steel for VHP 2, and black iron, copper to stainless for VHP 2, with EM monitoring including total particle count, viable air, and hydrocarbon.

In validation, 120 chemical and 120 biological indicators were positioned throughout the load, with Regeneron and Steris supporting the process and Eurofins supporting biological indicator testing. PCI has audited Eurofins for testing. In requalification, full load, 10,336 blister are sealed without syringes, with 45 Eylea blistered units for sterility test, with 120 BI and CI units distributed with blistered syringe units throughout the load. The requalification load does not represent the commercial load.

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 1.f.

On 10 January 2023, Siju John, Validation Manager provided an overview of the vacuum conditions applied in the syringe, blister pack sterilization process that includes Leak Test at 500 mbar, Pre-condition Parameters at 500 mbar, Exposure at 500 mbar, Aeration 1 at 800 mbar and Aeration 2 at 500 mbar. The process is to replace ambient air with oil free compressed dry air.

On 10 January 2023, Mr. Dennis Gerlach, Director of Validations provided an overview of the VHP unit qualification under PQ-P17-233.01, *"Performance Qualification Addendum for the Sterilizer Asset #3840"*, 05 April 2019, VHP1. I reviewed the "Final Report for PQ for VHP Sterilizer Asset #3840 R17-223-01", rev 0, VHP Sterilizer Asset #3840, Sterilizer Room. According to Section 7.3.1 Maximum Load - Full Load of Syringes, 3x maximum loads, 10,336 blister packed syringes included 120 BI and 120 CI units, (trays containing pre-filled syringes) see **Exhibit 37**. 3x minimum load studies were conducted for 5,472 blister packed syringes. The biological indicators were located completely inside the blister pack and sealed by tape for BI entry point. 4x VHP pulses were validated, with product applying 5 pulses. We (WS and BD) reviewed PCR-WIP VHP Rev 7.0, *"Manufacturing Packaging Instructions Regeneron"*, with 5,472 and 10,336 syringes identified as the validated loads. The

biological indicators were *Geobacillus sterothermophilus,* with Eurofins providing test results. We (WS and BD) reviewed VHP2, *"Final Report for the PQ of the VHP Sterilizer Asset #3971, FR20-018, Rev 0, Regeneron, Steris, PQ, VP20-018 of the VHP Sterilizer, Asset #3971, 05/2020, VHP2".* 3x maximum loads at 10,336 syringes and 3x minimum load at 5,472 syringes included 120 CI and 120 BI units. All testing was acceptable. We (WS and BD) reviewed the most recent requalification with testing for 40 sterility samples, 120 chemical indicators, 120 biological indicators and > 10K empty carton units, see **Exhibit 38**. Testing was acceptable.

A rented Tracksense datalogger supported temperature mapping for the annual distribution profile, with TCs pre and post calibrated. There is no minimum load study, with the maximum load study worst-case.

We (WS and BD) reviewed the most recent requalification for VHP 1 under *"Final Summary Report Continuous Validation for Sterilization of Eylea Pre-filled Syringe Blister Pack, Performance Requalification, Product Sterilization Process - VP22-118 FR22-118, Eylea Pre-Filled Syringe Blister Pack VHP Sterilizer #3978 (VHP 1)".* The maximum load was conducted 21 December 2022, empty chamber with 30 TCs geometrically placed ≤ 35°C, acceptable. We reviewed the maximum load with 120 CI and 120 BI units, acceptable.

We (WS and BD) reviewed the VHP-2, *"Final Summary Report, Validation for Sterilization of Eylea Pre-filled Syringe Blister Packs, Performance Requalification Product Sterilization Process, Protocol VP22-119, Report # FR72-119, Regeneron, Eylea Pre-filled Syringe Blister Packs VHP Sterilizer #3971 (VHP2), Sterilizer Room, 22 December 2022".* Testing was the same as prior, acceptable.

On 11 January 2023, Mr. Alex Weaver, Senior Director of Engineering provided follow up to the VHP units, with VHP2 just started commercial manufacturing in May 2022. I (WS) questioned if there was a plan to replace the non-oil free compressors and black iron distribution system with a system meeting current industry expectations, with Mr. Weaver indicating yes. The current system as designed supported by testing meets the established acceptance criteria.

On 11 January 2022, Mr. Andrew Cook, Regeneron SME (Virtual), Mr. Dustin Blodgett, Regeneron SME (Virtual), and Dwight Ricci, Regeneron SME (Virtual) provided follow up to the VHP2 unit, with the system released for commercial manufacture May 2022, with Eylea approved for manufacture 2019. In a t-con with Regeneron, it was discussed that 500 mbar for the sterilization cycle exceeds the vacuum level evaluated in the shipping study and that it was unclear how the additional vacuum applied during the VHP cycle could impact the plunger stopper movement and the sterile barrier. It was also discussed that the two aeration steps post VHP exposure were to reduce residual VHP and to dry the load, with loads not confirmed as dry post VHP (commercial manufacture). The blister packaging, Tyvek supports a microbial barrier, tortuous path, with the cutsheet for the Tyvek used in manufacture provided, see **Exhibit 39.** The Tyvek is designed for the intended application.

The VHP qualification was conducted in 2017, full load of syringes, with the elimination of the full load of syringes and replacement with empty blister in 2018. A memo addressed the load change based on risk, see **Exhibit 40.** The empty blister packs fail to represent the commercial maximum load. A dye leak test is conducted at Regeneron for the blister packs, beginning, middle and end of the run.

This resulted in a 483 Observation and is additionally discussed under Objectionable Conditions and Management Response 1.f.

Packaging and Labeling System

(*This section was written by Investigator Theodorou*)

I reviewed the following batch records to determine the firm's packaging and labeling process.

- Miconazole 1200mg pouch, lot 4730498
- Miconazole 1200mg pouch, lot 5022198
- Miconazole 1200mg pouch, lot 4842883
- Vascepa1 G Capsules 120ct lot 2B09703
- Vascepa 1 G Capsules 120ct lot 1L09120

I also reviewed the following master packaging instructions:
Santyl Ointment 30g/90g
SURGIPHOR/SURGIRINSE
Tobramycin (TOBI) 300MG/5ML 56 AR

A majority of the firm's packaging process will have a visual camera system that verifies that printed lot and expiration dates are correct, and check weigher to determine that the container is within the designated weight specification for the product. Equipment challenges are performed during start up, in process and at the end of packaging activities depending on the product where in equipment such as the cap detection system, the induction liner system, and the bottle label vision system are challenged in various ways as identified in the batch record under a pass/fail qualification. In process checks are conducted following ANSI/AQL standards. Non Tolerable/Critical defects for In-Process Checks are: Incorrect/foreign product, dosage form or strength, or container not internally clean/free from harmful foreign material, incorrect lot# or expiration date, illegible or missing lot #, expiration date, serial number and/or variable data (as applicable) printed on primary labeling to identify a few.

I reviewed the firm's procedure, SOP-01100 *Labeling Control*, rev10 effective date 09/01/2021 which provides the requirements for the receipt, issuance, and accountability of labeling. The procedure states that the shipping and receiving department is responsible for identifying the labeling by product, code/specification

I reviewed the firm's procedure, SOP-00715 *Packaging Line review and Quality Verification,* rev02, effective 11/27/2022 which describes the usage, completion, and escalation methods of performing activities described on the Packaging Line Review Sheet. The Review Sheet establishes the minimum requirements required for a standard packaging run within operations. The Review Sheet ensures that activities performed within a packaging run conforms to written procedures, requirements and instructions established by the firm.

My review of these documents and records where unremarkable, however as discussed under the Deviations, and in **Observation 3.a** in the **Objectionable Conditions and Management Response** section of this report, the firm shows a history of failing to identify errors with the lot number and/or the exp date printed on the primary packaging of drug products and subsequently releasing them to their clients for distribution.

OBJECTIVE 2: CONFORMANCE TO APPLICATION

Application Conformance

(This section was written by Investigator Seifert)

The manufacturing process conformed to the application.

Data Omissions

(This section was written by Investigator Seifert)

There were no data omissions.

OBJECTIVE 3: DATA INTEGRITY AUDIT

Data Integrity

(This section was written by Investigator Seifert)

On 12 January 2023, Ms. Cathy Cabrera, Director of Quality Systems provided an overview of data integrity, computer systems. I reviewed Doc # WI-00033 Rev 1 - 11 June 2021, *"Completing System Regulatory Impact Determination (RID) Form"*. The scope is all computer systems for regulatory impact. I reviewed Doc Form-000319, v3, *"Regulatory Impact Determination (RID)"*, VHP units. The VHP units are standalone systems with proprietary software that included an HMI. The prior form includes a questionnaire for user levels, PCI operator, PCI line leader, PCI supervisor, PCI engineer, and PCI administrator. The administrator for the VHP units is Engineering. The questionnaire further includes an assessment for audit trail, calibration and maintenance, safety, migration interface, and data integrity. Data integrity according to ALCOA includes user login, electronic signature, deletion of data not possible, alter date and time not possible, audit trail is always active, and can't overwrite. For each batch, the data is printed with manual electronic backup. We (WS and BD) reviewed the audit trail review according to procedure 211.56.b.6, *"Steris VHP Sterilizer Unit Administration Responsibility, Password Management, Access, Backup, and Roles and Responsibilities"*, Rev 0, July

28, 2020. The scope is user and password management, audit trail management, batch report management and PLC/HMI backup and recovery.

In data integrity, run data is printed, but not the audit trail. The VHP cycle recipe is verified every quarter by Engineering. The audit trail is reviewed annually by Engineering and quality. The printing of the run data supports data integrity as there is evidence of the run number. Regarding Eylea manufacture, there is limited computer systems, with the VHP system run data supporting evidence of data integrity with system use access of appropriate design.

MANUFACTURING CODES

(*This section was written by Investigator Theodorou*)

According to Mr. Cligget, the firm's lot numbering system for finished products has not changed since the previous inspection conducted 10/21/2022. Specifically, the firm receives unique and specific lot information for the labeling/packaging and the product; these are identified as the PACKET# and the BULK LOT#, respectively. This information is recorded in the batch record and is associated with a seven-digit Work Order number (WO#). This Work Order # is then used as the lot number on the final packaged product. The expiry date is specific to each product and the format is dictated by the customer

COMPLAINTS

(*This section was written by Investigator Theodorou*)

Please see the Quality System Section of this report which contains a dedicated section of complaints that were covered during this in section. No observations were made of any documents that were reviewed.

RECALL PROCEDURES

(*This section was written by Investigator Theodorou*)

According to Mr. Cliggett, the firm has not been involved in any recalls since the previous inspection. The firm recently completed its mock recall program in Nov 2022 which is performed on an annual basis

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

A close-out meeting was held on 01/12/2023 with Gill Valdez, SVP, Commercial Packaging Technology and Supply Chain, Catherine Cabrera, Director of Quality Systems, Mark J. Burke, Executive Director of Quality Jennifer Carrion, Sr. Quality Operations Manager, Tammi Leith, Regulatory Affairs Specialist and Thomas Cliggett, Director of Quality Operations at which time a Form FDA 483, Inspectional Observations, was issued.

OBSERVATION 1

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

a. Your environmental monitoring plan as defined in SOP, SOP-00790, "Environmental Monitoring for Non-Sterile Packaging", Rev 18, effective date 29 September 2021, is insufficient for aflibercept PFS assembly and blistering line E2 as no surface environmental monitoring is conducted for the product contact/indirect product contact surfaces such as the syringe assembly area and associated surfaces. According to SOP-00790, "Environmental Monitoring for Non-Sterile Packaging", Rev 18, section 7.4.2.2 states that sample sites for surface (floor and walls) viable shall be based on the following: "Sites and/or processes where microbial contamination is deemed likely to have an adverse effect on product quality, sites that represent the most difficult areas to clean, and activities in the area that contribute to the spread of contamination."
b. Complaints received by your client included moisture observed in the syringe blister package. Post aflibercept (Eylea) PFS VHP, there is no procedural requirement in confirmation of load dryness and absence of moisture in the syringe blister packaging or any other defect that may pose a risk to product quality.
c. The sterilization of the aflibercept (Eylea) PFS within the blister pack is conducted by VHP that includes Chamber Leak Test at 500 mbar, Pre-condition Parameter at 500 mbar, Exposure Parameter at 500 mbar, Aeration Parameter 1 at 800 mbar and Aeration Parameter 2 at 500 mbar. The aflibercept shipping validation supports a pressure change at 572 mbar in support plunger stopper movement, assuring the sterile barrier is maintained. The worst-case pressure level applied at 500 mbar during the syringe VHP process has not been validated to assure the sterile barrier is maintained.
d. Document titled, Product Assessment - Eylea (aflibercept) - Product/PPE/Room/Health and Risk Assessment was performed by your internal PCI Safety, with standard gowning to be applied during manufacture that does not include a face mask. The assessment is deficient as it failed to account for the manufacturing bioburden control strategy, with the donning of a mask providing enhanced bioburden control.
e. Document RA-1331 (risk assessment), "Secondary Manufacturing of EYLEA Pre-Filled Syringe in Non-Classified Spaces at PCI" indicates that production rooms are positive pressure to the hallways per PCI SOP-00793; however, there is no calibrated magnehelic or BMS system to provide assurance of adequate continuous differential pressure control for the production rooms.
f. The requalification of the aflibercept (Eylea) VHP sterilization process includes 10,336 blister packs sealed and without pre-filled syringes, with 45 blister packs containing an aflibercept PFS spaced throughout the load for sterility testing and 240 blister packs total containing an

aflibercept PFS for 120 (CI units) and 120 (BI units). The use of 10,336 empty blister packs is not representative of the commercial maximum load.

Reference: 21 CFR 211.100(a)

Supporting Evidence and Relevance:
(This section was written by Investigator Seifert)

Observation 1A
SOP-00790, *"Environmental Monitoring for Non-Sterile Packaging"*, Rev 18, Effective date 29 September 2021 identifies environmental monitoring for areas E3, E2 and H1 quarterly, static and dynamic testing for total particle, viable air, and surface monitoring of walls and floors, see **Exhibit 30.** An environmental monitoring position paper, 28 August 2017 includes static and dynamic sampling, see **Exhibit 31.** Sampling is conducted at the location or process where microbial contamination is deemed likely to occur or where it has the potential to adversely impact product quality. Environmental sampling locations includes locations that are difficult to clean, location where the product is exposed to the environment, and any area that has the potential to contribute to the spread of contamination.

In E2, assembly and blistering, there is no environmental monitoring of the drug product, blistering indirect/direct product contact work surfaces that may offer a better understanding of the biological flora on the drug product is exposed to and impact on product quality.

Observation 1B
Five different customer complaints for moisture were in the Eylea drug product blister packaging: COMP-2022-4112 (condensate in blister), COMP-2022-4113 (condensate in blister), COMP-2022-4056 (condensate in blister), COMP-2021-0058 (leak in blister), and COMP-2022-4111 (water). PCI LLC indicated the root cause was external to PCI, with no failures or anomalies associated with the batch. Post VHP, residual VHP converts to water vapor and oxygen that dissipates, with moisture in the VHP DP blister package an objectionable condition. There is no inspection of the Eylea syringe blister packs post VHP for absence of moisture or any other defects that would pose a product quality concern.

Observation 1C
In a t-con with Regeneron, it was discussed that 500 mbar for the VHP sterilization cycle exceeds the vacuum level evaluated in the shipping study and that it was unclear how the additional vacuum applied during the VHP cycle would have on the plunger stopper movement and maintaining the sterile barrier.

Observation 1D

Product assessment, Eylea, Product/PPE/Room/Heath and Risk Assessment, identifies the level of gowning in Eylea manufacture, see **Exhibit 36**. Safety performed the heath assessment, original assessment that may not have included the bioburden control strategy required for blistering of the Eylea syringe, followed by VHP sterilization. Standard gowning is applied in Eylea blistering with no mask required as described in the batch record, PCR-WIP-VHP, *"Master Packaging Instruction: Regeneron"* and as observed during the inspection tour of Eylea blistering operations.

Observation 1E

Regeneron Risk Assessment RA-1331, Secondary Manufacturing of Eylea Pre-filled Syringes in Non-classified Space at PCI, Effective V1.0, 07 November 2022 includes rooms for manufacture positive to the corridor, see **Exhibit 33**. The facility SOP under 00793, Air Handling System Differential Pressure Check is annual by testing, see **Exhibit 34**. There is no magnehelic or BMS system in support the differential pressure is to specification, during routine manufacture.

Observation 1F

VHP unit qualification was conducted under PQ-P17-233.01, *"Performance Qualification Addendum for the Sterilizer Asset #3840"*, 05 April 2019, VHP1. The final report was included under "Final Report for PQ for VHP Sterilizer Asset #3840 R17-223-01", rev 0, VHP Sterilizer Asset #3840, Sterilizer Room. According to Section 7.3.1 Maximum Load - Full Load of Syringes, 3x maximum loads, 10,336 blister packed syringes included 120 BI and 120 CI units, (trays containing pre-filled syringes) see **Exhibit 37.**

VHP2, *"Final Report for the PQ of the VHP Sterilizer Asset #3971, FR20-018, Rev 0, Regeneron, Steris, PQ, VP20-018 of the VHP Sterilizer, Asset #3971, 05/2020, 'VHP2"* included 3x maximum loads at 10,336 syringes and 3 x minimum load at 5,472 syringes included 120 CI and 120 BI units.
The most recent requalification included testing for 40 sterility samples, 120 chemical indicators, 120 biological indicators and > 10K empty carton units, see **Exhibit 38**. The > 10K empty cartons does represent the commercial maximum load in manufacture.

Discussion with Management:

Observation 1A

On 12 January 2023, the firm questioned during the close meeting if environmental monitoring of the product indirect/product contact work surfaces was an expectation. I (WS) indicated the DP packaging conveyors is an example of a surface that may provide a better understanding of the bioburden load and impact on drug product quality. According to the position paper, environmental sampling locations should include locations that are difficult to clean, location where the product is exposed to the environment, and any area that has the potential to contribute to the spread of contamination, the product conveyors for example, product indirect/direct contact surfaces. The firm understood the objectionable condition.

Observation 1B
During the closeout meeting on 12 January 2022, the firm had no questions.

Observation 1C
The applicant Regeneron committed to performing a plunger stopper movement study to assess the vacuum applied during the VHP process, see **Exhibit 41.** During the close meeting on 12 January 2023, the firm had no questions.

Observation 1D
During the close meeting on 12 January 2023, the firm had no questions.

Observation 1E
The firm had no questions during closeout meeting on 12 January 2023.

Observation 1F
The VHP qualification was conducted in 2017, full load of syringes, with the elimination of the full load of syringes and replacement with empty blister packs in 2018. A memo addressed the load change based on risk, see **Exhibit 40**. The empty blister packs failed to represent the commercial maximum load. During the closeout meeting on 12 January 2023, the firm had no questions.

OBSERVATION 2
Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, your Building 1 air compression system supporting aflibercept (Eylea) sterilization by VHP system (VHP 2) is not of oil free design, with the air distribution system to the VHP 2 sterilizer including black iron piping. Though the air compression system includes hydrocarbon removal and distribution system in-line point of use hydrocarbon and particulate filtration, the system design is inconsistent with current GMP expectations.

Reference: 21 CFR 211.63

Supporting Evidence and Relevance:
(This section was written by Investigator Seifert)
Plant 1 includes 2x air compressors used for VHP2, not oil free in design. Post air compression, filtration occurs followed by 3x driers to a receiving tank. Post receiving tank, the air is distributed by black iron piping (100s feet of piping), with copper to stainless at the VHP2 system point of use. Hydrocarbon filters are located within the compressor and at the newly installed filtration unit near the VHP 2 sterilizer. The compressors are supplied with food grade oil in air compression. The system

was originally for instrument air and through filtration and testing, the system meets process air requirements in support of the VPR process. Although the filtration and testing of the air meets the intended air quality specification, the system doesn't meet current GMP design expectations.

Discussion with Management:
(This section was written by Investigator Seifert)
The firm commits to upgrading the Plant 1 air compression system and distribution piping to meet current industry expectations, see **Exhibit 42.**

OBSERVATION 3
The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, your firm failed to follow the following procedures:

a) According to your standard operational procedure entitled *"QA Batch Record Review and Product Release,"* SOP-00765, rev 45, Section 2.5, the Quality Associate is responsible "to review, verify presence of all batch record pages, verify correct batch record pagination and accuracy, coordinate error corrections with the Quality Associate or designee, assure Deviation Reports are complete and closed, and approve the batch record for PCI release." The following are examples of drug products that were released by your Quality Unit for commercial distribution with inaccurate lot numbers and/or expiration dating.
   - DEV-2022-0244, Alkermes Vivitrol 380mg (naltrexone for extended-release injectable suspension) Kit, lot# 190592C, expiration 04/30/2024 released with an incorrect expiry of 05/31/2024
   - DEV-2022-0244, Alkermes Vivitrol 380mg (naltrexone for extended-release injectable suspension) Kit, lot# 190604C, expiration 04/30/2024 released with an incorrect expiry of 05/31/2024
   - Event-2022-5953, Flexion Therapeutics Zilretta 32mg (triamcinolone acetonide extended-release injectable suspension) Finished Kits, lot# 111003, expiration 11/2023 released with an incorrect lot number of 22-9006
   - Event-2022-6666, Amgen Repatha AMG 145) HMP, 120mg/mL, 3.5mL (evolocumab), lot# 1153429, expiration 12/31/2024 released with an incorrect expiry of 10/31/2024

b) Your procedure, SOP-00240 *"Corrective Action and Preventative Action (CAPA)"*, revision 01, effective 11/05/2021, section 5.1.8 states that "effectiveness checks should be considered as part of the CAPA plan and the scope and method of confirmed effectiveness should be detailed as part of the plan." CAPA 433782 which was opened on 12/14/2021 to document the correction for installing the proposed changes indicator for setting the crimper clearance and pressure settings for E5 Doboy. This CAPA was closed on 05/20/2022. Your firm applied a new

effectiveness check review board to address current and future CAPAs however did not address the CAPA(s) that were opened within the effective date of your procedure.

This is a repeat observation from the previous inspection conducted 10/17/2022 – 10/21/2022.

Reference: 21 CFR 211.22(d)

Supporting Evidence and Relevance:

Observation 3.a
(*This section was written by Investigator LePage*)
According to the standard operational procedure entitled "QA Batch Record Review and Product Release," SOP-00765, rev 45, Section 2.5 (see **Exhibit 28**), the Quality Associate is responsible "to review, verify presence of all batch record pages, verify correct batch record pagination and accuracy, coordinate error corrections with the Quality Associate or designee, assure Deviation Reports are complete and closed, and approve the batch record for PCI release." I noted in my documentation evaluation that QA reviewed and subsequently released numerous drug products that were labeled with incorrect lot numbers and/or expiration dates. All the mislabeled drug products were sent to the customer, who placed the order directly with PCI, and not further distributed. The following are examples of drug products that were released by your Quality Unit for commercial distribution with inaccurate lot numbers and/or expiration dating.

DEV-2022-0244 (**Exhibit 19**)
Vivitrol® (naltrexone for extended-release injectable suspension) 380mg/vial, lot #2022-3005T, expiration 04/30/2024 kits (see **Exhibit 20**) were assembled with some of the following components.

- Vivitrol® microspheres (naltrexone for extended-release injectable suspension) 380mg/vial, lot #0000110944, expiration 10/2024
- Administrative needle (1.5") lot# 190592C, expiration 04/30/2024
- Administrative needle (1.5") lot #190604C, expiration 05/31/2024
- WIP Diluent Vial, lot #00108206B, expiration 03/2025
- 5mL Luerlock Syringe, lot# 210112V, expiration 12/31/2025

The expiration date of the kit is based off the component that expires first, therefore the kits should have received an expiration date of 04/30/2024, which correlates to the administration needle (1.5") lot# 190592C. The kits were assigned the incorrect expiration date of 05/31/2024, which corresponds to the administration needle (1.5") lot #190604C. Vivitrol® (naltrexone for extended-release injectable suspension) 380mg/vial, lot #2022-3005T was released on 03/24/2022 by QA (see **Exhibit 207**). On 03/31/2022 PCI was notified by their customer that the drug product released to them was incorrectly labeled with the wrong expiration date. The 3600 affected kits were

repackaged to reflect the correct expiry of 04/30/2024.

Event-2022-5953
Flexion Therapeutics Zilretta 32mg (triamcinolone acetonide extended-release injectable suspension) Finished Kits, lot# 111003, expiration 11/2023 released with an incorrect lot number of 22-9006. This event was listed in error on the FDA Form 483, as the discrepancy was caught during the batch record review process.

Event-2022-6666 (**Exhibit 21**)
On 12/19/2022, PCI was notified by their customer that they had received Repatha® Pushtronex® system (evolocumab) 420mg/3.5mL, lot# 1153429, expiration 12/31/2024 labeled with the incorrect expiration date of 10/31/2024. QA approved the batch record release on 12/19/2022 and released the shipment on 12/20/2022 (see **Exhibit 22**). The customer kept the product and distributed it, indicating that the product was not affected since the expiry was short dated by two months.

In addition to the aforementioned lots indicated on the FDA Form 483, I noted during my document review that several other drug products were released by QA with incorrect lot and/or expiration dates that were discovered and reported by the PCI customers. The following are the deviations and the associated released drug product lots.

PR-DN424609 (**Exhibit 17**)
The customer Eirgen contacted PCI on 11/20/2019 to inform them that they received an unreleased lot of the product Rayaldee 30mcg, 30ct, Lot #3868797. QA approved the batch record release on 10/25/2019 and released the shipment on 11/15/2019 (see **Exhibit 18**). The firm determined the root cause to be human error. The firm initiated CAPA 424768 and conducted "Awareness" training for the Quality Teams personnel associated with batch release. The customer kept the drug product lot sent in error and distributed it in lieu of the originally requested lot. Rayaldee 30mcg, 30ct, Lot #3868797 expired 12/2020.

PR-DN422935 (**Exhibit 43**)
On 07/31/2019 PCI was contacted by their customer, Pfizer, and notified that three lots of Cortef 10mg, 100ct, received at their distribution center were labeled with incorrect expiration dates. The three lots of Cortef packaged at PCI were CCFTK (see **Exhibit 44**), CCFTK1 (see **Exhibit 45**) and CCFTK2 (see **Exhibit 46**) with an expiration date of 02/2022 but were labeled the expiration date 02/2023. QA released the shipment on 07/10/2019. These Cortef 10mg, 100ct lots were manufactured in the US and packaged for distribution in Hungary.

Observation 3.b
(*This section was written by Investigator Theodorou*)

Exhibit 23 consists of SOP-00240, Corrective Action and Preventative Action which was in effect at the time of the creation of CAPA 433782. Section 5.1.8 states that "effectiveness checks should be considered as part of the CAPA plan and the scope and method of confirmed effectiveness should be detailed as part of the plan."

Exhibit 24 consists of the firm's CAPA, CAPA-2022-0659 which was opened to document the corrections for the observation made during the previous inspection. Review of this document shows that the firm did not address the effectiveness checks for the identified CAPAs. However, it was noted that only CAPA 433782 was initiated after SOP-00240 was in effect.

Exhibit 25 consists of CAPA 433782 which was opened on 12/14/2021 to document the correction for installing the proposed changes indicator for setting the crimper clearance and pressure settings for E5 Doboy.

As part of its corrections to the observations that were made during the previous inspection ending 10/21/2022, the firm did not address the CAPAs mentioned in the observation. Nor did the firm provide any kind of statement stating if an effectiveness check was or wasn't needed and its justification

Mr. Burke and Mr. Cliggett stated that at the time the CAPAs were created the firm was still using the TrackWise system and that SOP 211.100.b.14 *CAPA Effectiveness*, rev2.0, effective 11/24/2020 would have been in effect as this CAPA was documented in the TrackWise system and not in MasterControl. Mr. Burke created a timeline for my review which I took a picture of (**Exhibit 52**).

At the time of the previous inspection, the firm had just implemented the migration of data into MasterControl and was using MasterControl to document new CAPAs. CAPA 433782 was opened on 12/14/2021. SOP-00240, Corrective Action and Preventative Action was in effect (effective date 11/5/2021) at the time of the creation of CAPA 433782.

Discussion with Management:

Observation 3.a

(*This section was written by Investigator LePage*)

During my document review I discussed with Thomas Cliggett, Director of Quality Operations, the numerous instances where the firm QA released batches to their customers without properly verifying batch information as indicated in their procedure. I emphasized that situations such as these may lead to product recalls and are concerning. I reiterated this during the closing meeting. The firm management indicated that they understood and would respond to the Form 483 in writing, within 15 business days.

Observation 3.b
(*This section was written by Investigator Theodorou*)
Management stated that they understood and promised to respond in writing within 15 business days.

OBSERVATION 4
Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically.

a. Deteriorated insulation and a deteriorated gasket was observed at a finger flange assembly system for syringe labeling and plunger rod insertion System 1712, Area E3. Excess grease was observed on the plunger rod shafts.
b. The air compression system located in Building #1 and used for oil free compressed air to the VHP 2 sterilizer was observed in an upkept state, including debris observed at an air compressor intake.
c. Walk-in 2 - 8°C refrigerator 150845 as observed in with waste material such as dirt and debris on the floor and behind and between pallets. Refrigerator 150845 is used to store finished drug products such as aflibercept PFS and materials needing temperature control.
d. Automated doors leading to E2, syringe blistering, and syringe VHP were observed not functioning correctly.

Reference:21 CFR 211.56(a)

Supporting Evidence and Relevance:
(This section was written by Investigator Seifert)

Observation 4A
Within are E3 a Groninger syringe tub conveying system was observed, unit 5349, followed by labeling and plunger rod insertion system, asset 1712. A finger flange unit was observed with deteriorated insulation and gasket, see **Exhibit 10**. The plunger rod shafts were observed with excess grease, see **Exhibit 11.**

Observation 4B
The air compressors in Plant 1 (Building 1) and the system in general that includes the work area was observed in an unclean state, see **Exhibit 14.**

Observation 4C

The 2 - 8°C walk-in unit 9 (150845) was observed in an unclean state, see **Exhibit 06**

Observation 4D
The Eylea finger flange assembly and blistering area assess door was observed non-functional, see **Exhibit 12.**

Discussion with Management:
(This section was written by Investigator Seifert)

Observation 4A
The firm provided corrective action by order confirmation of materials, McMaster-Carr for insulation and Vinyl foam to replace the deteriorated insulation and gasket, **see Exhibit 47**. Furthermore, the firm provided corrective action by workorder MNT-02996-2023 for removal of excess grease from the plunger rod shafts, see **Exhibit 48**. During the closeout meeting on 12 January 2023, the firm had no questions.

Observation 4B
The firm provided corrective action that included cleaning of the compressors, dryers and general work area, see **Exhibit 49.**

Observation 4C
The firm provided evidence of corrective action by providing pictures of the walk-in unit cleaned and in good state of cleanliness, see **Exhibit 50.** During the closeout meeting, the firm had no questions.

Observation 4D
The firm provided corrective action by workorder MNT-02993-2023, Room E2 Reset Automatic Door Controller, see **Exhibit 51**. During the closeout meeting, the firm had no questions for the objectionable condition.

GENERAL DISCUSSION WITH MANAGEMENT

At the close-out meeting, the following items not included on the Form FDA 483 were discussed with firm management. Mr. Valdez indicated that he understood and promised corrections.

1. The H1 cartoning line was inspected during a manufacturing break, with three Eylea cartons containing product observed on the active conveying track, see **Exhibit 13**. It was questioned why the units were not positioned into an overpack prior to the break, with the firm rejecting, discarding the units. Leaving the units on the conveying track may cause degregation of the carton.

2. A field complaint was received for the Eylea DP, gray color for the DP, 3x syringe units. The root cause was explained as external to the PCI manufacturing process, with Eylea to be clear in appearance to pale yellow. The deviation investigation at PCI was a paperwork review. Regeneron conducted an elevated temperature study for Eylea, with the same color or similar color change in the DP observed. In discussion with the firm, it was questioned why Regeneron did not evaluate the syringes for contamination, where if there wasn't enough volume for test, perhaps the DP material could be plated in confirmation of absence of contamination. Although PCI is a CMO, assuring the absence of microbial contamination is also critical to PCI. In discussion with PCI, PCI should also work collaboratively with Regeneron to have a clear and complete understanding for absence of microbial contamination.

VOLUNTARY CORRECTIONS

(*This section was written by Investigator Theodorou*)

During the current inspection, I verified corrections to the following deficiencies from the previous inspection conducted 10/21/2022:

Observation 1

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

CAPA-2022-0658

- PCI opened a Work Order to repaint and caulk the baseboard lining in the rear wall along the seam of the wall.
- The water-stained ceiling tile was replaced.
- The roof was inspected by a licensed contractor and no roof leaks were identified.
- A contracted service will be resurfacing and resealing the exterior wall of that side of the building to prevent any potential leaks from extreme weather.
- The back wall of H3 and adjoining packaging rooms will be re-surfaced for ease of cleaning. The back wall will be flat and run straight across the room.

All above mentioned repairs to the interior and exterior of the building were completed by 12/2023.

In addition, the firm updated the cleaning logbooks to include more specific information around the cleaning of the packaging rooms. The new format will require specific entries around the cleaning of the walls, floors, and equipment as opposed to a single entry for both the individual performing the function and for Quality Assurance verification.

Observation 2

This was partially addressed by the firm but resulted in a repeat observation during this inspection.

EXHIBITS COLLECTED

Exhibit #	Description	Pages
1	Board of Directors	1
2	Bill of Lading Cortef Hydrocortisone	32
3	Product List	3
4	Organizational Charts	35
5	SMF-00020 Site Master File	41
6	Pictures of Walk in Fridge	7
7	Picture of Equipment in corridor	1
8	Picture of Correction	1
9	List of Individuals met during inspection	4
10	Pictures of finger flange unit	6
11	Pictures of plunger rod	2
12	Pictures of door to E2	2
13	Pictures of product on track	2
14	Pictures of Compressors	11
15	List of SOPs	12
16	SOP-00113 Deviation Reporting & Investigation	13
17	Packaging Record DN 424609	10
18	Packaging Record Rayaldee 3868797A	136
19	DEV-2022-0244	43
20	Packaging Record Vivitrol 380mg2022-3005T	203
21	EVENT-2022-6666	16
22	Packaging Record Repatha Kit 1153429	240
23	SOP-00240 Corrective Action and Preventative Action (CAPA)	8
24	CAPA-2022-0659	54
25	CAPA 433782	8
26	Pall filter information	1
27	Complaints for damaged syringes	18
28	SOP-00765 QA Batch Record Review and Product Release	22
29	SOP-00791 Environmental Monitoring for Hallways Gowning Areas	21
30	SOP-00790 Environmental Monitoring NonSterile Packaging	23
31	Environmental Monitoring Position Paper	6
32	FMEA SOP-21122d2 Risk Assessment RA2021-011	19
33	RA-1331 Secondary Manufacturing of Eylea Pre-filled Syringes	24
34	SOP-00793 Air Handling System Differential Pressure Check	9
35	SOP-00783 Gowning Cleanliness and Sanitary Practice of Personnel	19
36	Product PPE Room Heath and Risk Assessment	20

37	R17-223-01 Final Report for PQ for VHP Sterilizer	2
38	Final Report for the PQ of the VHP Sterilizer	43
39	Dupont Reference Guide for Medical Packaging	44
40	PPQ Addendum Risk Statement	3
41	Regeneron Correction Plunger Stopper Study	2
42	PCI Correction Upgrade Piping	1
43	PR DN422935	5
44	Packaging Record Cortef CCFTK	135
45	Packaging Record Cortef CCFTK1	144
46	Packaging Record Cortef CCFTK2	126
47	Order of Materials for Finger Flange Unit Correction	1
48	MNT-02996-2023 Correction for Plunger Rod Shafts	1
49	Photographs of cleaned compressor area	7
50	Photographs of cleaned walk-in fridge	5
51	MNT-02993-2023 Repair to E2 Door	1
52	Picture of Timeline	1

ATTACHMENTS

1. Form FDA 482, Notice of Inspection, issued on 01/09/2023 to Ms. Metzinger, 3 pages
2. Form FDA 483, Inspectional Observations, 4 pages

Digitally signed by Christina K. Theodorou -S
Date: 2023.02.28 17:18:21 +01'00'

Christina K. Theodorou, Investigator, Lead Investigator
ORA/OPQO/Division I/Investigations Branch 2

Wayne E. Seifert -S

Digitally signed by Wayne E. Seifert -S
Date: 2023.02.28 10:50:41 -05'00'

Wayne Seifert, Investigator
CDER/OPQ/OPMA/DBM/Biotechnology Manufacturing Branch 1

Brandy N. Lepage -S

Digitally signed by Brandy N. Lepage -S
Date: 2023.02.28 09:11:13 -05'00'

Brandy N. LePage, Investigator
ORA/OPQO/Division I/Investigations Branch 2

Bingchen Du -S

Digitally signed by Bingchen Du -S
Date: 2023.02.28 11:15:56 -05'00'

Ben Du, Staff Fellow
CDER/OPQ/OPMA/DBM/ Biotechnology Manufacturing Branch 1

An official website of the United States government Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

Search FDA.gov Menu

Home Drug Databases DECRS Search Result

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Drug Establishments Current Registration Site

New Search

Search Results for *Packaging Coordinators*

Showing 1 to 1 of 1 entry Show 50 entri

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Packaging Coordinators, LLC	1000522077	078525133	LABEL; PACK; REPACK; STERILIZE	3001 Red Lion Rd, Philadelphia, Pennsylvania (PA) 19114, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Thursday, May 15, 2025

New Search

pci
PHARMA SERVICES

LIST OF OFFICERS & OWNER FOR PCI

Name of Company Owner: Packaging Coordinators, Inc.
Percentage Owned: 100%
FEIN: 61-1683822
State of Incorporation: Delaware
Address: 3001 Red Lion Rd., Philadelphia PA 19114
Phone Number: 215.613.3600
Website Address: www.pci.com

Full Name: Salim Haffar
Title/Position: Chief Executive Officer
Business Address: 3001 Red Lion Rd., Philadelphia PA 19114
Phone Number: [redacted]
Email Address: Salim.Haffar@pci.com

Full Name: Tom Wim Frans De Weerdt
Title/Position: Chief Financial Officer
Business Address: 3001 Red Lion Rd., Philadelphia PA 19114
Phone Number: [redacted]
Email Address: Tom.DeWeerdt@pci.com

Full Name: Jeannie Metzinger
Title/Position: Chief Quality and Compliance Officer
Phone Number: [redacted]
Business Address: 3001 Red Lion Rd., Philadelphia PA 19114
Email Address: Jeannie.Metzinger@pci.com

Full Name: Brad Payne
Title/Position: Chief Operating Officer
Phone Number: [redacted]
Business Address: 3001 Red Lion Rd., Philadelphia PA 19114
Email Address: Brad.Payne@pci.com

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PACKAGING COORDINATORS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF JUNE, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PACKAGING COORDINATORS, LLC" WAS FORMED ON THE TWENTY-SEVENTH DAY OF APRIL, A.D. 2012.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203944305

Date: 06-13-25

5118926 8300

SR# 20253067829

You may verify this certificate online at corp.delaware.gov/authver.shtml

Certificate of Licensure

Certificate No. 8000002826
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Wholesaler/Distributor

Drug & Device Registration
2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

PACKAGING COORDINATORS, LLC
3001 RED LION ROAD
PHILADELPHIA, PA 19114

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: July 12, 2016
Expiration Date: The Last Day of July, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0428842	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-18-2025

PACKAGING COORDINATORS, LLC
3001 RED LION RD
PHILADELPHIA, PA 191141123

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0428842	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-18-2025

PACKAGING COORDINATORS, LLC
3001 RED LION RD
PHILADELPHIA, PA 191141123

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0428842	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-18-2025

PACKAGING COORDINATORS, LLC
3001 RED LION RD
PHILADELPHIA, PA 191141123

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
06/19/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Central, Inc.
Philadelphia PA Office
100 North 18th Street
15th Floor
Philadelphia PA 19103 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Federal Insurance Company	20281
INSURER B:	Illinois Union Insurance Company	27960
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Packaging Coordinators, Inc.
3001 Red Lion Road
Philadelphia PA 19114 USA

COVERAGES **CERTIFICATE NUMBER:** 570106526722 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			36055286	06/19/2024	06/19/2025	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$10,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$1,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$2,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	Excluded
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
A	X UMBRELLA LIAB X OCCUR			79837169	06/19/2024	06/19/2025	EACH OCCURRENCE	$15,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$15,000,000
	DED RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)		N/A				E.L. EACH ACCIDENT	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	
							E.L. DISEASE-POLICY LIMIT	
B	Products Liability			G71151864007 Claims Made SIR applies per policy terms & conditions	06/19/2024	06/19/2025	Each Occurrence Aggregate Limit	$10,000,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance

CERTIFICATE HOLDER

Packaging Coordinators and Subsidiaries
3001 Red Lion Road
Philadelphia PA 19114 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570106526722

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 2339435

Application/License No. _____

PACKAGING COORDINATORS, INC., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
3001 Red Lion Road Philadelphia, PA 19114, as
Address of Applicant/Principal
PRINCIPAL, and SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION, a
Surety Company
corporation organized under the laws of the state of MO
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1200 Main Street Suite 800 Kansas City, MO 64105-2478 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 16, 2024.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of October, 2024.

APPLICANT/PRINCIPAL
PACKAGING COORDINATORS, INC.

COMPANY

Authorized Representative

SURETY
SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION

Surety Company's Representative

Anne Potter, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Jacob Neerenberg

Witness Krista Laxton

SIGNED and SEALED in the presence of:

Witness Valorie Spates

Witness Sandra Diaz

Countersigned by:

Nevada Resident Agent N/A

Posted February 20, 2020

SWISS RE CORPORATE SOLUTIONS

SS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION ("SRCSAIC")
ISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION ("SRCSPIC")
/ESTPORT INSURANCE CORPORATION ("WIC")

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT SRCSAIC, a corporation duly organized and existing under laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, and SRCSPIC, a corporation organized and existing under the laws of the State of Missouri and having its principal office in the City of Kansas City, Missouri, and WIC, organized under the laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, each does hereby make, constitute and appoint:

SANDRA DIAZ, DEBRA A. DEMING, PETER HEALY, JENNIFER JAKAITIS, SUSAN A. WELSH, ANNE POTTER, FRANCESCA KAZMIERCZAK, FRANCES RODRIGUEZ, BEVERLY A. WOOLFORD, VALORIE SPATES, AKLIMA NOORHASSAN, PABLO GARCIA HORCAJO and VILMA GONZALEZ

JOINTLY OR SEVERALLY

Its true and lawful Attorney(s)-in-Fact, to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

ONE HUNDRED TWENTY FIVE MILLION ($125,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both SRCSAIC and SRCSPIC at meetings duly called and held on the 18th of November 2021 and WIC by written consent of its Executive Committee dated July 18, 2011.

"RESOLVED, that any two of the President, any Managing Director, any Senior Vice President, any Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is, authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Corporation bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Corporation; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Corporation may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Corporation when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION CORPORATE SEAL 1973 MISSOURI

SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION CORPORATE SEAL MISSOURI

By _____
Erik Janssens, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC & Senior Vice President of WIC

By _____
Gerald Jagrowski, Vice President of SRCSAIC & Vice President of SRCSPIC & Vice President of WIC

WESTPORT INSURANCE CORPORATION CORPORATE SEAL MISSOURI

IN WITNESS WHEREOF, SRCSAIC, SRCSPIC, and WIC have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers

this 29TH day of MARCH, 20 24

State of Illinois
County of Cook SS

Swiss Re Corporate Solutions America Insurance Corporation
Swiss Re Corporate Solutions Premier Insurance Corporation
Westport Insurance Corporation

On this 29TH day of MARCH, 20 24, before me, a Notary Public personally appeared Erik Janssens, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC and Senior Vice President of WIC and Gerald Jagrowski, Vice President of SRCSAIC and Vice President of SPCSPIC and Vice President of WIC, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

OFFICIAL SEAL
CHRISTINA MANISCO
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires March 28, 2026

Christina Manisco
Christina Manisco, Notary

I, Jeffrey Goldberg, the duly elected Senior Vice President and Assistant Secretary of SRCSAIC and SRCSPIC and WIC, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said SRCSAIC and SRCSPIC and WIC, which is still in full force and effect IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 18th day of October, 20 24.

Jeffrey Goldberg, Senior Vice President & Assistant Secretary of SRCSAIC and SRCSPIC and WIC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Packaging Coordinators, LLC dba PCI Pharma Services

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 3001 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 215-284-8661 Website: www.pci.com

Licensing Company Email: catherine.cabrera@pci.com

Section 2: Personal Information

First: Catherine Middle: Last: Cabrera

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Philadelphia State: PA Zip: [redacted]

Telephone: 215-284-8661 Email: catherine.cabrera@pci.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Carribbean University		1997-1999	
Address	**City**	**State**	**Zip**
Carretera 167 Km 21.2	Bayamón	PR	00960
Diploma/Degree obtained, if any			
Biology Curriculum			

School Name		From - To (MM/YY – MM/YY)	
Corps Barranquitas		1993 - 1997	
Address	**City**	**State**	**Zip**
5MWW+JVV	Barranquitas	PR	00794
Diploma/Degree obtained, if any			
Secretary			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2002 - Present	[redacted]	Philadelphia	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Packaging Coordinators, LLC			2002 - Present	
Business Address		**City**	**State**	**Zip**
3001 Red Lion Road		Philadelphia	PA	19114
Phone	**Title**		**Number of Employed Hours**	
215-284-8661	Director of Quality Systems		45,000+ Hours	
Description of Duties				
Responsible for: Internal Audits, Regulatory Audits, Customer Audits, monitoring DEA quotas. Oversight of: Supplier Management, Incoming quality assurance, complaints. Power of attorney for all regulatory registrations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

C. Coen
Original Signature (electronic, copies or stamps not accepted)

03/11/25
Date

I, Catherine Cabrera, **certify that as the designated representative for**

Packaging Coordinators, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CC I am at least 21 years of age;
3. CC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Catherine Cabrera

Print Name (First, Last)

C. Cabrera

Original Signature (electronic, copies or stamps not accepted)

03/11/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Catherine Cabrera

Print Name (First, Last)

C. Cabrera — 03/11/25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of PA, ss. County of Montgomery

I, Catherine Cabrera, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

C. Cabrera — 03/11/25

Original Signature — **Date**

Subscribed and Sworn to before me this 11 day of March 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Packaging Coordinators, LLC dba PCI Pharma Services

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 3001 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Mailing Address (if different from physical address): Same as above.

City: State: Zip:

Telephone: 215-284-8661 Website: www.pci.com

Licensing Company Email: compliance.PCIPharma@gmail.com

Section 2: Personal Information

First: Catherine Middle: Last: Cabrera

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Philadelphia State: PA Zip: [redacted]

Telephone: 215-284-8661 Email: catherine.cabrera@pci.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Carribbean University		1997-1999	
Address	**City**	**State**	**Zip**
Carretera 167 Km 21.2	Bayamón	PR	00960
Diploma/Degree obtained, if any			
Biology Curriculum			

School Name		From - To (MM/YY – MM/YY)	
Corps Barranquitas		1993 - 1997	
Address	**City**	**State**	**Zip**
5MWW+JVV	Barranquitas	PR	00794
Diploma/Degree obtained, if any			
Secretary			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2002 - Present	[redacted]	Philadelphia	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Packaging Coordinators, LLC			2002-Present
Business Address	**City**	**State**	**Zip**
3001 Red Lion Road	Philadelphia	PA	19114
Phone	**Title**		
215-284-8661	Director of Quality Systems		

Description of Duties

Responsible for: Internal Audits, Regulatory Audits, Customer Audits, monitoring DEA quotas. Oversight of: Supplier Management, Incoming quality assurance, complaints. Power of attorney for all regulatory registrations.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

C. C.

Original Signature (electronic, copies or stamps not accepted)

03/11/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Catherine Cabrera

Print Name (First, Last)

C. Cabrera — 03/11/25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Catherine Cabrera, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

C. Cabrera — 03/11/25

Original Signature — **Date**

Subscribed and Sworn to before me this 11 day of March 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Packaging Coordinators, LLC dba PCI Pharma Services

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 3001 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 215-613-3001 Website: www.pci.com

Licensing Company Email: compliance.PCIPharma@gmail.com

Section 2: Personal Information

First: Brad Middle: Last: Payne

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: ~~Bainbridge Island~~ Cape Coral State: ~~WA~~ FL Zip: ~~98110~~ [redacted]

Telephone: [redacted] Email: brad.payne@pci.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: University of Washington			From - To (MM/YY – MM/YY): 09/82 – 06/86	
Address: 3781 Okanogan Ln. NE.	City: Seattle		State: WA	Zip: 98105
Diploma/Degree obtained, if any: BS Chem Eng				
School Name: Shoreline H.S.			From - To (MM/YY – MM/YY): 09/78 – 06/82	
Address: 18560 1st Ave NE	City: Shoreline		State: WA	Zip: 98155
Diploma/Degree obtained, if any: H.S. Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/21 – 04/24	[redacted]	Bainbridge Island	WA	[redacted]
04/24 – 02/25		Cape Coral	FL	
02/25 – Present		Cape Coral	FL	
01/18 – 04/19		Philadelphia	PA	
04/19 – 01/21		Philadelphia	PA	
06/13 – 01/18		Nyon, Switzerland VD		
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Packaging Coordinators, Inc.	01/18 - Present

Business Address	City	State	Zip
3001 Red Lion Road	Philadelphia	PA	19114

Phone	Title
815-484-8900	Chief Operating Officer

Description of Duties: Chief Operating Officer, oversee 16 plants

Business Name	From - To (MM/YY – MM/YY)
Becton Dickinson	01/13 - 01/18

Business Address	City	State	Zip
Park-A4, Sàrl Terre Bonne Rt de Crassier	Eysins, Switzerland	VD	1262

Phone	Title
+41 21 556 30 00	SVP Operations

Description of Duties: Oversaw operations for Global drug delivery business.

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

March 31, 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brad Payne

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

March 31, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Pa, ss. County of Montgomery

I, Brad Payne, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/31/25

Date

Subscribed and Sworn to before me this 31 day of March, 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Packaging Coordinators, LLC dba PCI Pharma Services

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 3001 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 215-613-3001 Website: www.pci.com

Licensing Company Email: compliance.PCIPharma@gmail.com

Section 2: Personal Information

First: Jeannie Middle: Lynne Last: Metzinger

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Hudson State: MA Zip: [redacted]

Telephon[redacted] Email: jeannie.metzinger@pci.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Bishop McDevitt High School			9/71 - 6/75	
Address		City	State	Zip
125 Royal Ave		Wynecote	PA	19095
Diploma/Degree obtained, if any				
HS Diploma				

School Name			From - To (MM/YY – MM/YY)	
Holy Family University			9/75 - 5/79	
Address		City	State	Zip
9801 Frankford Ave		Phila	PA	19114
Diploma/Degree obtained, if any				
BS Biology				

School Name			From - To (MM/YY – MM/YY)	
Temple University			5/2005 - 12/2007	
Address		City	State	Zip
1801 N Broad St		Phila	PA	19122
Diploma/Degree obtained, if any				
MS Regulatory Affairs				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2022 - Now	[redacted]	Hudson	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Packaging Coordinators, Inc.				From - To (MM/YY – MM/YY):
Business Address: 3001 Red Lion Road		City: Philadelphia	State: PA	Zip: 19114
Phone: 815-484-8900	Title: Chief Quality and Compliance Officer			
Description of Duties: Responsible for quality assurance and quality control for all PCI				

Business Name: MERCK PHARMACEUTICALS				From - To (MM/YY – MM/YY): 7/2009 – 11/2012
Business Address: SUMNEY TOWN PIKE		City: WEST POINT	State: PA	Zip: 19486
Phone:	Title: Director Quality QMS			
Description of Duties: Responsible for implementing and maintaining Quality Systems for the site. This included all regulatory inspection				

Business Name: COLORCON				From - To (MM/YY – MM/YY): 7/1997 - 7/2008
Business Address: 420 MOYER BLVD		City: WEST POINT	State: PA	Zip: 19486
Phone: 215-699-7733	Title: DIRECTOR QA/QC NA			
Description of Duties: DIRECTOR QUALITY ASSURANCE AND QUALITY CONTROL NA - Responsible for Quality				

Business Name: Novartis (Rhone Poulenc Rorer)				From - To (MM/YY – MM/YY): 1984 – 7/~~20~~ 1997 gm
Business Address: 500 Virginia Drive		City: Ft Washington	State: PA	Zip: 19034
Phone: 215-628-6541	Title: Manager Quality			
Description of Duties: Responsible for all Quality Assurance and Quality Control for liquids and dermatological products				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Jeannie Fitzgerald

Original Signature (electronic, copies or stamps not accepted)

4 April 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeannie Metzinger

Print Name (First, Last)

Jeannie Metzinger

Original Signature (electronic, copies or stamps not accepted)

4 April 2025

Date

Please have this section completed in the presence of a Notary Public.

State of PA, ss. County of Montgom

I, Jeannie Metzinger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jeannie Metzinger

Original Signature

April 4, 2025

Date

Subscribed and Sworn to before me this 4 day of April.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Packaging Coordinators, LLC dba PCI Pharma Services

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 3001 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 215-613-3001 Website: www.pci.com

Licensing Company Email: compliance.PCIPharma@gmail.com

Section 2: Personal Information

First: Salim Middle: Last: Haffar

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address[redacted]

City: Manchester State: NH Zip [redacted]

Telephon[redacted] Email: salim.haffar@pci.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
McGill University		1992 - 1995	
Address	**City**	**State**	**Zip**
845 Sherbrooke Street west	Montreal	QC	H3A 0G4
Diploma/Degree obtained, if any			
Bachelor Chemical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]	Manchester	NH	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Packaging Coordinators, Inc.			
Business Address	**City**	**State**	**Zip**
3001 Red Lion Road	Philadelphia	PA	19114
Phone	**Title**		
845-282-2636	CEO		
Description of Duties	Strategic planning, relationship building, market expansion, oversees product innovation.		

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

3/20/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Salim Haffar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date 3/20/25

Please have this section completed in the presence of a Notary Public.

State of PA, ss. County of Montgomery

I, Salim Haffar, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature **Date** 3/20/25

Subscribed and Sworn to before me this 20 day of March 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Packaging Coordinators, LLC dba PCI Pharma Services

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 3001 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 215-613-3001 Website: www.pci.com

Licensing Company Email: compliance.PCIPharma@gmail.com

Section 2: Personal Information

First: Tom Middle: Wim Frans Last: De Weerdt

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: St Petersburg State: FL Zip: [redacted]

Telephone: [redacted] Email: tom.deweerdt@pci.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City St. Petersburg	State FL	[redacted]
From - To (MM/YY – MM/YY)		City St. Petersburg FL	State FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Packaging Coordinators, Inc.			
Business Address	**City**	**State**	**Zip**
3001 Red Lion Road	Philadelphia	PA	19114
Phone	**Title**		
815-484-8900	Chief Financial Officer		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

April 9, 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tom Wim Frans De Weerdt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

April 9, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Pa, ss. County of Montgomery

I, Tom Wim Frans De Weerdt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

April 9, 2025

Date

Subscribed and Sworn to before me this 9 day of April 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JESSICA M. WELDON, Notary Public
Montgomery County
My Commission Expires November 2, 2028
Commission Number 1384791

(Seal)

Full Legal Name
Aaliyah Joiner
Abdniel Francisco De Jesus Diaz
Abel Erazo
ABHISHEK PATEL
Abilio Goncalves
Abner Torruellas
Adam Dabkowski
Adam Santiago
Adelina S Paez Parejo
Adolphus Wesley
Agnes Baldwin
Ahmen Cleveland
Ahmet Gungor
Ahmir Rainford
Aida Vega
Ailla Bishop
Aiman Batool
Airin Choudhury
Ajmal Roshan Puthanpurayil Shamsuddin
Akiera McEachin
Akilah Keesee
Alain Louis
Albert Morris
Aleksandros Alaterezoglu
Alex George
Alex Kraus
Alex Mungo
ALEX ROSSOLOV
Alexander Jefferson
Alexander Morrow
Alexander Pappy
Alexander Perez

Alexander Smith
Alexandria Cintron
Alexandria R. Unchis
Alexandria Ziegler
Alexis Burton
Alexis P. Colomy
Aleyamma Varughese
Ali Zeineddine
Alicia Carranco
Alik Zhurbich
Alim Hussein
Alisha Lee
Allen Navilliat
Alvoree Wallace
Alysha Hayes
Alyssa Renee Hampton
Amanda Diaz
Amanda Lokayi
Amarilys Echevarria
Amaya Cintron
Amber Ellis
Amina Noory
Amisha Patel
Ammar Rangunwala
Amy Ing
Amy Schillig
Amya Miller
Amylie Iglesias
Ana Lora
Ana Milagros Echevarria
Ananka Rojas
Andre M. Mosley
Andre Vaughan

Andrea Davis
Andrea Scott
Andres Reyes
Andrew Alexandrou II
Andrew Brenner
Andrew Colomy-Wright
Andrew Jenkins
Andrew Puchalski Jr.
Andrew Turzanski
Andrey Lapin
Anecita Huber
Angel Arias
Angel Fuentes
Angel Lopez Jr.
Angel Rodriguez
Angela Dam
Angela Dyer
Angela Nicolette Tillman
Angelica Oscal
Angelina Hopkins
Angelique Glenn
Anil Stephen
Anissa Montanez
Anita Bangura
Aniya Burroughs
Anna L. Gray
Anna Torres
Annamaria Berger
Annamma Varghese
Annette Parks
Anthonia Adeyeye
Anthony Anderson
Anthony Green

Anthony Rue
Anthony Watkins
Antoinette Ervin
Antoinette Tyree
Antwoine Hunter
Anup Varghese
Anwar M. Levere
April West
Ariel Jaquez
Arif Chariwala
Arman Rowshan
Arnitha Barnes
ASHAIYAH BANKS
Ashley Colon Rivera
Ashley Ortiz
Asiyah Saud
Audrey Sell
Avery Jackson
Bahija Ahmida
Baltazar Cisneros-Berrios
Barbara lissbet Grullon Rosario
Barbara Sanderlin
Baron Roane
Barry Nash
BASSIROU DIENG
Benjamin Kim
Benjamin Mc Cann
Benjohnson B Louis
Betty Jackson
Bevis Vanterpool
Biju Varghese
Binika Hada
Bonita Morales

Brandy Kugler
Brea Jacobs
Brenda Derolf
Brenden Jackson
Brent Collins
BRETT RADZISZEWSKI
Brian Beers
Brian Kite
Brian Mooney
Brian William Mullin
Briana Rodrigues
Brianna Ali
Brianna jacobs
Brittany Allen
Bruce Craig
Bryan Bolds
Bryan Jones
Bryan K Bradley
Bryan Sims
Bryant Collins
Bryheem Jacobs
Caitlin Monahan
Caitlin Rose Mastropietro
Calvern Smith
Camille Sanchez
Camille Simpson-Pryce
Carisma Fisher
Carl D. Davis
Carl Elysee
Carlianys Oquendo
Carlos Alvarez
Carlos Ceballos
Carlos Deyne jr

Carlos J. Deyne
Carmel Nicolas
Carmelo Rodriguez
Carmen Arce
Carmen Rodriguez
Carmencita Minaya
CAROLYN HENSOR
Casey Koger
Catalina Duque
Catherine Cabrera
Catherine Shipton
Ceirra Williams
Champa Bardhan
Chanda Bhatti
Chandrikaben Brahmbhatt
Chanelle Clark
Chanyia Kirkland
Charlene Darrah
Charles Harris
Chenelle Stokes
Cherisse Russell
Cheryl D Wimberly-Perry
Cheryl Russell
Chester Venable Jr
CHIDINMA MAPP
Choudhury Jamy
Chris Chapluk
Christen Jones-Bryant
Christian Alejandro
CHRISTIAN AMARO
Christian Matos
Christina Giles
Christine Marie Aust

Christopher Adrian Durant
Christopher Borden
Christopher Gourdine
Christopher Harrison
Christopher Jackson
Christopher Kline
Christopher Lentz
CHRISTOPHER SANTIAGO
Christopher Selden
Christopher Steigerwalt
Cindy Figueroa
Claire Crawford
Clarence McCorkle
Claude Clark
Claudette Bernadel
Claudia Jervas
Cleveland Matthews
Cleveland Pickett
Cody Miller
Cody Saez
Colette Destin
Colleen Schmid
Connor Derolf
Constance M. Koerner
Coraly Melendez
Corbin Bradshaw
Corey Dailey
Courtney Burgess
Courtney Cahill
Craig Hughes
Cristopher Santiago Cabrera
Cyesha Burton
Cynthia Evans

Cynthia Lavorgna
Cynthia Trang
Cynthia Wells
Daemon Maguire
Dafna Karikari
Dagnela Meneus
Daiquan Haynesworth
Dalice Amore Carter
Dallas Salley
Damaris De Jesus
Damaris Rivera
Damien Pedrosa
Danessa Lopez
DANIEL RODRIGUEZ
Daniel Smith
Dante Orlando
Daren Burton Jr
Darlene Rodriguez
Darnell Grandy
Darnell Taylor
Darryl Stukes
Davena MCkenzie
Daveshu Patel
David Collacchi
David J. Burger
David Kountz
David Leach
David Miller
David Pabon
David Yeow
Deborah Booker
Deborah Duerstock
Deborah Howell

Deborah St Marie-Nuttall
Debra Sherrick
Deepa Kochukaleeckal Philemon
Delani Rivera
Delilah Lebron
DeLisa Hool
Demetrius Mann
Demetrius Porter
Demetrius Sutton
Denise Brach
Denise Garay
Denise Holmes
Denise Smith
Dennis Cliggett
Dennis Johnson
Dennis Mullen Jr
Denny Alex
Deon A. McKenzie
Derek Edward Still
Desiree Baldwin
Destiny Bell
Destiny Savage
Dewey Wakefield
Dezmand Davis
Diana Vegerano-Rodriguez
Diane Stoner
Dief Remonnette
Dieufait Morisset
Diocko Gandega
Dion Cottingham
Divya Tripathi
Dmitri Murray
Dolly Gladson

Dominiq Bass
Dominique Johnson
Donald Bowers
Donald Cliggett
Donald Rookstool
Donna Connor
Donna McCauley
Donna Sterling
Donnell Jackson
Dontae Dawson
Dontae Wilson
Dorian Douglass
Dorothy Harmon
Dwayne Divers
dwayne forman
Dweep Dey
Eboni Killing
Ebony Byrd
Edalys Maria Duran
Edgardo Albandoz
Ediberto Gonzalez-Portalatin
Edieca Perez
Edward B Rehl
Edward Coffin
Edward Kaye
Edward Szczepankiewicz
Edwige Chery
Edwin A. Bushey
Edwin Nicholas
Edwin Ortiz Mendez
Edwin Rafael Rosario
Efran Junior Maldonado JR Jr.
Efran Maldonado

Egbert Gordon
Eileen Echevarria
Elaine Jewell
Elaine Smith
Elaine Stirling
Eleasim Maisonet
Eleonora Rytsar
Elijah Munoz
Elizabeth Carcano
Elizabeth Colon
Elizabeth Crummy
Elizabeth Suarez
Ellis Gibbs
Elma Chowdhury
Elvira Roci
Elwood Dennis
Emely Santana Diaz
Emilson Mazile
Emmanuel Okendu
Entela Bileri
Erianna Marie Padua
Eric Bass
Eric Boafo
Eric Lilly
Eric Martin
Eric Silver-Folk
Erica Gabel
Erich Pollinger
Ertha Cineus Narcisse
Eseeta Reme Hossain
Esther Olmo
Ethewaldo Cribas Diaz
Eugene Groves

Eva Soto
Faatimah Hayes
Fabiola Bijou
Fakia Leake
Fanny Early
Farah Joseph
Farah Samuel
Farida Aly
Farida Barkas
Farran Haynes
Fatiha Berdaoui
Felicia Bynes
Felicia Kennard
Felix Melendez
Fernando Massillon
Fnu Sanju Sunny
Francis Schleinkofer
Franky Aponte
Freddie Gomez
Freddy Joy Joseph
Fuat Hyseneshi
Gabriel Figueroa
Gabrille Cunningham
Gail Wildonger
Gardy Eliser
Garry Teagle
Gelane Pratts
Genesis Burgos
George Garbrah
George Philip
George Thomas
George V George
Geyonna Jones

Giorgi Tsuladze
Giovanna Barbato
Giovanni Delhomme
Giovanny Mejias
Gloria M Feliciano
Grazyna Krengiel
Gregory Vutera
Guilherme De Faria Eisinger
Gulshan Toirjonova
Gulyara Karimova
Gwendolyn Williams
Haider Khan
Hannibal Collick
Harry Philizaire
Hassan Khan
Hazel Missimer
Hazera Munira
Heinrich Rost
Hendry Dominguez
Henrietta Fraley
Hilda Aviles
Hina Ishaq Khan
Holly Summers
Honesto I Nunez III
Hugo Colin Charles Pochart
Huy Ngo
Iang My
Ida Tender
Ikea Murray
Imran Khan
Irene Matthew
Irene Miriam George
Iris Bautista

Iris Gonzalez
Iris Roman
Isabel Gutenberger
Isabella Giordano
Isiah Golson
Israel Lugo
Isys Alexia Reese
IVAN OTAMAS
Ivan Valentin
Ivette Lopez
Ivette Mandes Gallardo
Ivy Smith
Iysis Holly
Jack Hastings
Jacob Seamon
Jacqueline Cupp
Jacqueline Faulcon - Harris
Jacqueline Reese
Jacqueline Schonewolf
Jahziar Johnson
Jakhi Hilton
Jala Williams
Jalen Graves-Lawimore
Jamaal Ford
Jamal Talukder
JAMAR WASHINGTON
Jamarr Jefferson
Jamel Harvey
James Affleck
James Edessaril
James Hurley
James Jacobs
James Jamison

James Johnson
James M Clark
James Montague
James Mooney
James Nuttall
James Reingruber
James Sanderlin
James Semler
James W. Miller
JAMES WEBB
Jameson Augustin
Jamie Burton
Jamie McGlone
Jamilka Rivera
Jamison Bullock
Janessa Washington
Janine Mayhew
Jaquan James
Jarred Spencer
Jarvis Lynch
Jasen Carroll
Jasmin Vasquez
Jasmine Bryant
Jasmine Williams
Jason Garcia
Jason Kuhns
Jason Lewis
Jason Piccone
Javier Celeste
Javonne Wilkinson
Jayda Mullins
Jayme Hopkins Allison
Jazmin Parrilla

Jean Augustin
Jean Elie Ostagne
Jean Gerald Similien
Jean-Michael Bowler
Jeffrey Charles Noak
Jeffrey Greate
Jeffrey L Schlesinger
Jeffrey Ming Tan
Jeffrey Rein
Jeffrey Wright
Jeiser Rodriguez
Jelani Carter
JENELLE R HOLLOMAN
Jenneh Wawood
Jennifer Aviles
Jennifer Bovack
Jennifer Carrion
Jennifer Celeste
Jennifer Dagnall
Jennifer Do
Jennifer Giacinto
Jennirose Graboskie
Jenny Garcia
Jeremiah Robinson
Jeremy Bennett
Jeremy Norwood
Jermaine Tillman
Jerome Thomas
JERYLL BALLESTEROS
Jesenia Camacho
Jesse Cartagena
Jessica Achecar
Jessica B Wolfenden

Jessica Dejesus
Jessica Khamphoumy
Jessie Pascual
Jettleen Carter
Jinny Samuel Thomas
Jn Francois Yves Nicolas Altag Lapierre
Joann Natchez
Joanna Philemon
Joanna Rosado
Joanne Valentine
Jobin Thomas
Joel Garcia
Joel Hartmann
Joel Mirabal
Joel Sutherlan
Johanna Maysonet-Hernandez
John Bates
John Bracey
John Davila
JOHN DOMINGUEZ
John Helverson
John Parankamoottil Mathew
John Redfain
John Stride
John Viaud
Johna Little
JOHNATHAN GLOVER
Johnathan Nowacki
JOHNNY HUA
Johnny Torres
Jonathan Girard
Jonathan Hill
Jonathan Mayanan

Jonathan Napper
Jordan Dyer
Jordan Lewis
Jordan Mormello
Jordan Stockage
Jorge Ivan Luciano Garcia
Jorge Vicent
Jorge Vicent
Jose K John
Jose Ortiz
Jose Soto
Jose Thomas
Jose Torres
JOSELINE MORALES
Joseph Annan
Joseph Badillo
Joseph Bisirri
Joseph Clark
Joseph Fedorowycz
Joseph Floody
Joseph Hettinger
Joseph Schnell
Joshua Jackson
Joshua Searle
Joshua Simmons
Joshua Subramani
Journn'i Flamer
Joy Browning
Juan Bonilla
Juana Gonzalez
Juanita Berry
Julia Bahamonde
Julian Cora

Juliet Vicent
Julio Ceasar Ferrer Mendez
Justin Michael Kravchuck
Justin Perez
Justin T Pollino
Kaday Mansaray
Kahri Haynesworth
Kaleb Llovet
Kalin Parham
Kalu Azuma
Kamaar Briggs
Kamari Reaves
Kameesha Reid
Kareem Edwards
Karen Hall
Karen Ryan
Kathleen Kafel
Katrena Bethel
Katrina Armstrong
Katrina Campbell
KAVANIA ROBINSON
Kellan Spencer
Kelli Zajdel
Kendal Morris
Kenneth Cave
Kenneth Kenneth Brown Sr.
Kenneth Ray
Kera Cathel
Kerolos Akraz
Kerry Harper
Keshia Richardson
Kevin Buzby
Kevin C. Bryant

Kevin Guerra
Kevin Hagler
Kevin Haxton
Kevin Lawrence
Kevin Mance
Kevin Wallace
Keving Nicolas
Keyra Torres
Keyvon Montague
Khalif Barrett
Khalil Gibson
Khayree Elliot
Kian Kinchloe
Kiana Simone Spratley
Kimball Eng
Kimberly Michele Wiggins
Kimberly Wiggins
Kimetha Reese
Kofi Ampofo
Koshy George
Kristen Paden
KWAMAIR RILEY
Kyle Felix
Kyle Josey
Kyle Prima
Kyshaun Hall
Lan Trinh
Lance Jordon
Lanlie America
Laronda Shanell Jones
Lashawn Hayes
LaTanya Turner
Latascha Seals

Latrese McLeod
Lauren Michelle Robinson
Laurie Cooper
Laverne Summers
Leena Thomas
Lemoryd Holmes
Leonora Garcia Wright
Leroy Hawkins
Leslie P. Langley
Liam Slavin
Libin Mathew Abraham
Libu Varghese
Lileana Cruz
Linda Candelaria
Linda Scull
Lisa Ann Sponheimer
Lisa Harley
Lisa Kiple
Lisa Martin
Lisa Scrimenti
Lisandra Gonzalez
Loretta Ramirez
Lorna Beal
Lorraine Daniels
Lorraine Marrow
Louis Stefanoni
Louise Bailey
Lourdes Deyne
Ludivico Perillo
Luis Bizaldi
Luis Galvan
Luis Rosario
Luke Growney

Luqman Abram
Luz De Jesus
Lynette Roman
Lynette Torres
Lyudmila Shubinsky
Ma teresa Garcia
Madison Maxwell Gummel
Mahbub Suny
Mahmad S Tai
Makir Henry
Malaejah Sample
Maleina Morales
Malik Young
Malika Pryor
Manasa Jaymon
Manisha Mathew
Manisha Morker
Manjula Littu
Marcelo R Romero Curbelo
Marcus C. Turner
Margaret Clark
Margaret Dooley
Margaret Huynh
Margareth Coriolan
Margaretta Carrecter
Maria Alarcon
Maria E Roberts
Maria Nunez
Maribel Cribas
Maribel Torres
Marie Claire Daphnee Casseus
Marie Rosenie Elysee Jeune
Marie Yobouet

Mariely Manan
Mario Victor Parlapiano
Mario Ward
Marion Banks
Marisol Torres
Maritza Lopez
Mark Jackson
Mark Kiple
Mark Ligato
Mark Tilley
Markeeta Price
Marlee Wuchter
Marlene Rijo
Marlisa Thomas
Marlon Bennett
Marquetta Woodlyn
Marquis McGill
Marsela Dosti
Martin Jakos
Marveenlee Pierre
Marvin Parker
Mary Curichiyil
Mary E Hendry
Mary Ortiz
Mary Sol Ramos
Maryam Hamza
Marzuwq Shamsid-Deen
Masiah Hurst
Massiel Cruz
Mastila Dosti
Mathew Kuttielavumkal
MATI ULLAH
Matthew Eroh

Matthew Gavenda
Matthew Glisson
matthew hanson
Matthew McDermott
Matthew Merriweather
Matthew Mullen
Matthew Sweet
Maurice Harmon
Maurice Hockaday
Maurice Miller
Maymary Huynh
md rahman
Md Sadequr Rahman
MD Shohidul Islam
Megan Monahan
Meghan Lacey Gallagher
Mehwish Shadab
Melanie Walker
Melisa Gunawan
Melissa Haynes
Melissa Montanez
Melody Achille
Melody Joiner
Melvin Anthony Maldonado Jr.
Mercy Mathew
Merida Colon
Michael Bradby
Michael Brennan
Michael Cheung
Michael Devanney
Michael Galinsky
Michael Guerrero
Michael H. Anderson

Michael Jacobs
Michael lockwood
Michael Luke
Michael Menaldi
Michael Menaldi
Michael Rubinstein
Michael Santiago
Michael Smith
Michael Thomas Trainor
Michael West
Michael Wood
Michelle Carrington
Michelle Perez
Michelle Pressley
Migdalia Rivera
Miguel A. Burgos
Miguel Rodriguez
Mihaela Tilica
Mikel Kararaj
Minerva Cardona
Mobisha Monachan
Mohamed Bangura
Mohammad Shah Imran
Mohammed Al-Bataineh
Mohammed Ali
Monica Rios
Monique Diane Phelps
Mosky Georges
Moussasrey Christian Bamba
Mr. Binu Thankachan
Mr. Enrique Ricardo Rodriguez
Mr. Marchello Kiheem Hancock
Mr. Rokeysh Jerell Lyde

Mr. Stanford Hill
Ms. Renette Mahotiere
Muggett Rivera
Mugguett Diaz
Muhammed Chariwala
Mukesh Mahida
Myeesha Walker
Myrnaliza Pierce
Mysha Maria
NADEEM IBRAHIM
Nadir Bryant
Nahid Akhtar
Nancy Arabinick
Nancy Dorr
Nancy Gonzalez
Nancy Hoffman
Nancy Sanchez
Naomi Crompton
Nashel Nazario Velez
Nashi Fussell-Smith
Nasir Sutton
Natalie Oberholtzer
Nathan Point-Dujour
Nathaniel McIntyre
Natia Drake
Nayana Patel
Naylenne Marrero
Neda Rahimi
NEIL WALLOP
Nelson Figueroa
Nettie Lawrence
Nevin Jaison
Neycha Davila-Hernandez

Nicholas Falconiero
Nicholas James Matyi
Nicola Hayes
Nicole Felicioni
Nicole Makin
Nicole Rosselli
Nikia Berry
Nikita Ben Patel
Nikunj J. Patel
Nilesh Shah
Nirzari Patel
Nishita Patel
Nithin Lalith
Nitza Lee Robles
Noah Brodecki
Noman Patel
Noorul Aain
Nora Lopez
Norma Hernandez
Norma Rodriguez
Nuon Tek
Nyasia Gonzalez
Nyire Dorsey
Nyree Walker
Olga Oyola
Olivia Boyd
Omar Hassouni
Osayogie D Osemwegie
Paris Hines
Parker Chen
Patrick Allen Jr
Patrick Heizman
Patrick J. Kelly

Paul Altidor
Paul Rodriguez
Pavel Mekhedav
Payal Patel
Pedro Ore
Pedro Rodriguez
Penny Burroughs
Peter Cona
Peter Jacuk
Peter Sinesi
Phanosha Sanders
Phara Juste
Philemon Kochukaleeckal
Philip Hughes
Philip Nemirovsky
Phillip O'Driscoll
Pierre Hermann Elysee
Pierre Ossoide Elysee
Pierre Similien
Praise Abraham
Prathish Kurian Abraham
Princemessiah Alexander
Quadir Fleming
Quaron Jainlett
Quincetta Moore
Rachel Zellars
Rafael Arroyo
Rafael Arroyo
Rafael Enrique Vazquez
Rafael L. Arroyo
Rafael Rivera
Rafael Soto
Raheem Holloway

Rahim Diggins
Rajendra Patel
Rajendra Prasad Krishnan
Ramire Jones
Randy Roberts
Ranxie Chen
Raquel Sprual
Rasahn McDuffie
Rashuan Antley
Raul A Velez Jr.
Raul Rodriguez
Raymond Walker
Regina Conly-Klampfer
Rehan Khanzada
Reis Hill
Reji John
Remona Spence
Renee Waters
Rexhina Struga
REXY THOMAS
Ricardo Moise
Ricardo Thomas
Ricci D'Andrea
Richard Canavera
Richard D Sterling
Richard Gowallis
Richard Rossi
RIMON ABOUSEIF
Rina Belaid
Rita Jacuk
Rita Pondexter
Rob Kramer
Robert Bailey

Robert Brown
Robert Bryan Cutler
Robert Costello
Robert Cristinziani
Robert Edelmann
Robert Groves
Robert Henry
Robert Kane
Robert Michael Groves
Robert V. Burger
Robert Viall
Robin Summers
Rock Eben Ezer Laguerre
Rod Coriolan
Rodger Hasty
Rohan Ekambaram
Rollen Malabuyoc
Rollie Palec
Romaire Tisoit
Ronald Daniel
Ronnie Darnell Reed Jr.
Ronnie Rollins
ROSA SILVA
Rosa Teran
Rosamma Sunny
Rosanne Dunn
Rose Franqui
Rose Peters
Rosita Torruella
Roy Thomas
Ruby Quindlen
Ruth Serrano
Ryan Burke

Ryan Kerr
Ryan Luu
Ryan Maguire
Ryan Meehan
Ryan Vogt
Rymone R Auld
Sabria Mason
sadir nobles
Sai Chandana Ventrapragada
Saida Berdaoui
Saige Williams
Sainath Vittal Dadiga
Sam Jones
Sam Laguerre
Samantha Lopez
Samantha Rishel
Samoda Smith
Samone Whittaker
Sampson Snottee Nyawkun
Samuel Mitchell
Samuel Pierre
Sandra Beckler
Sandra Eubanks-Spurgeon
Sandra Gabel
Sandy Burns
Sandy Colon
Santiago Ossa
Santiago Rose
Saquib Siddiq
Saymon Sondi
Schadrack Moise
Scott Griscom
Scott Pleune

Sean Walsh
Sean Whalen
Sebastian Anzalone
Sehar Luqa
Selina Sanderlin
Sena Tahoulan
Serenity Irvin
Shabresha Stover
Shaheed Afzal
Shahiyd Da'ood Tilghman Bullock
Shahzad Masih
Shaji John
Shamira Hurdle
Shamsun Jelly
Shanice Foster-White
Shanik Baxter
Shannon Buckley
Shantel Tomlin
Shaquor Walker
Sha-Rae Seals
Sharee Bentley
Sharon Sweeney
Shatika Jones
Shaun Stephenson
Shawn Webb
Shawneese Douglas
Shayem Shahriar
Sheena Anderson
Sheila Bivens
Shelley Roberson
Shirley A Simpson
Shirley Green
Shiven Patel

Shmill Northan
Siedah Neal
Siju John
Sokha Koy
Sonia I Torres
SONIA LAIFA
Sonia Montanez
Sonia Pascua
Sonia Rosa
Sonja Rhett
Sonya Marie Murray
Sophann Phat
Stacy Cosby
Stanley Sturgis
Stephanie Blackiston
Stephanie Coker
Stephanie M. Burroughs
Stephen John
Stephen Malicek
Stephen Walker
Steven Calhoun
Steven Daniels
Steven Gambrell
Steven Grullon
Steven Nicholson
Stivanson Tailor
Sudha Jose
Sunitha Mary Rays
Sunny Abraham
susan George
Susan Tobin
Susan Yannuzzi
Suzanne Gallagher

Sybil Jacob
Syed Ali
Tai Ong
Taira Saunders
Tajaii Mason
Tamara Leith
Tamia Burton
Tammy Gallinger
Tanajia Johnson
Tania Guerra
Tanimur Chowdhury
Tara Goncalves
Taras Scott
Taryn Jackson
Taslima Akter Rima
Tatyanna Washington
Tavis Wills
Tawanda Ware
Tawanna Clark
Taylor Hammond
Tealia Brown
Tejinder Singh
Terence Jefferys
Terrance Watson
Terrence McBride
Thaely Enid Montijo Rosado
Theresa Bailey
Theresa Barbardo
Thomas Alexander
Thomas Cliggett
Thomas Fasano
Thomas Mathew
Thomas Monefeldt

Tiaesha Randolph
Tiana Cintron
Tieisha Williams
Tiffaney W Quiles
Tiffany Logan
Tiffany Scott
Tigi Thomas
Tijo Parappully
Tim Jaison
Timisha Smith-Rafi
Timothy Martin
Timothy Thagnabouth
Todd O'Neal
Tohura Buyah
Toni Micciolo
Tonya Yao
Travis Cliggett
Tristyn Baumgartner
Trocon Kai
Troy Culver
Trung Trinh
Tucker Rinne
Twanda Jefferson
Twomelay Harding
Tyqua Murray
Tyree Payne
Tyren Booker
Umesh Patel
Urszula Pellegrino
Vadim Balibar
Valerie Ertell
Vanessa Carroll
Vanessa Ravenell

Varghese Littu
Varinder Dhaliwal
Varughese E Thevervelil
Vaughn Ricchini
Vickie Marshall
Victor Fernandez
Victor Manuel Pagan Jr.
Victoria Donadel
Victoria Miller
Victoria Nguyen
Vincent Manochio
Vincent Shaw
Vionnette Cruz
Vital CHATELIER
Vivian White Sardo
Walter Helm
Wayne Cooper
Wendy Dozier
Wilfredo Rivera
William Briggs
William Grogan
WILLIAM JOHNSON
William Joyce
William Kinton
William Prawl
William Proctor
WILLIAM RHIM
Xavier Rivera
Yamisley Colon
Yana Gonzalez
Yesenia Barada
Yi Xing Chen
Yimly Fong Diaz

Yin Leon Chan
Yolanda Hannah Maria Spruill
Yolinda Reyes
Yoly Rodriguez
Yonatan Celeste
Yudy Bernard
Yugkumar Patel
Yvette Rice
Zachary Galloway
Zachary Kane
Zachary M Derolf
Zakia LeVere
ZAKIA TAHIR
Zamear Ashrafali
Zayaini Dennis
Zoila Osorio Navarro
Zuri Parks
Zyhir Chandler

9B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH 01206	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Patterson Logistics Services, Inc.

Physical Address: 800 Monte Vista Drive

City: Dinuba State: CA Zip: 93618

Mailing Address (if different from physical address): 1031 Mendota Heights Road Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 559-595-1450 Website: www.pattersoncompanies.com

Name of Designated Representative (DR): Larry Murillo

Licensing Company Email: facilitylicensing@pattersoncompa DR Email: larry.murillo@pattersonvet.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class I/II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: universities/res.facilities		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01.22.2024		SC	Blythewood	Richland
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		District of South Carolina on behalf of Drug Enforcement Agency		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Patterson Logistics Services, Inc.				

Provide explanation below:

On January 22, 2024, Patterson Logistics Services, Inc. ("PLSI") entered into a Settlement Agreement with the United States Attorney's Office for the District of South Carolina ("DOJ"), acting on behalf of the Drug Enforcement Administration ("DEA"), in which PLSI agreed to pay a fine of $45,500 with no associated admission of liability or guilt by PLSI. The allegations of the DEA are related primarily to certain record-keeping and reporting violations of the Controlled Substance Act. The DOJ and the DEA were satisfied with Patterson's corrective action measures, such that the matter was settled with no associated Memorandum of Understanding or ongoing reporting requirement for PLSI.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into by and between the United States of America, acting through the United States Attorney's Office for the District of South Carolina, on behalf of the Drug Enforcement Administration ("DEA") (collectively, the "United States"), and Patterson Logistic Services Inc. ("Patterson") (together, "the Parties").

RECITALS

Patterson is currently registered with DEA Certificate of Registration #RP0349224 as a distributor authorized to handle controlled substances on Schedules II-V at its registered location, 925 Carolina Pines Boulevard, Suite B, Blythewood, South Carolina 29016 (the "Blythewood FC").

At all times relevant to this Agreement, Patterson was required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder, 21 C.F.R. Part 1300, *et seq.* (collectively "the CSA.")

Between January 31, 2023, and February 2, 2023, the DEA conducted an inspection at Blythewood FC. As a result of the inspection, the United States contends Patterson violated civil provisions of the CSA. Specifically, the United States contends that from January 31, 2021 through February 2, 2023, in regard to operations at Blythewood FC, Patterson violated certain suspicious order requirements, reporting requirements to ARCOS and order form and recordkeeping requirements pursuant to the CSA, specifically Title 21 Parts 1301, 1304, and 1305 of the CFR.

The conduct identified above at the Blythewood FC shall hereinafter be referred to as "Covered Conduct" and the identified time frame shall be referred to as "Covered Time Period."

The parties agree that this Agreement is not an admission of liability by Patterson, its

employees, or its agents for the Covered Conduct under the CSA nor a concession by the United States that its claims are not well-founded.

To avoid the uncertainty and expense of the adjudication of each claim, and of exhausting all administrative and legal remedies, the Parties desire to reach a mutual agreement that settles the above-referenced allegations without the United States filing a civil suit.

STIPULATIONS

In consideration of the foregoing and the mutual promises and obligations contained in this Agreement, the Parties agree and covenant as follows:

1. Patterson shall pay $45,500 (the "Settlement Amount") to the United States no later than 10 business days after counsel for Patterson receives the written electronic funds transfer instructions by the United States Attorney for the District of South Carolina.

2. By signing this Settlement Agreement, Patterson agrees to waive all rights to seek judicial review or to challenge or contest the validity of any terms or conditions of this Settlement Agreement.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Patterson's full payment of the Settlement Amount under this Agreement, the United States agrees to refrain from filing against Patterson any action for civil penalty claims under the CSA that is based on the Covered Conduct. In further consideration of Patterson's fulfillment of its obligations under this Agreement, expressly conditioned upon Patterson's timely paying the Settlement Amount and subject to the exceptions in Paragraph 5 (concerning excluded claims), below, the United States fully and finally releases Patterson and its parent, affiliates, insurers, agents, assigns, successors, predecessors, shareholders, principals, current and former employees,

management, officers, and directors from any civil or administrative claims the United States has, could have, or may assert in the future related to the Covered Conduct during the Covered Time Period.

4. Patterson fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including without limitation attorney's fees, costs, and expenses of every kind and however denominated) that Patterson has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, and servants, and agents related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Notwithstanding the release given in Paragraph 3 of this Settlement Agreement, or any other terms of this Agreement, the following claims of the United States are specifically reserved and not released:

a. Any liability arising under Title 26 of the United States Code;

b. Any criminal liability;

c. Any liability under the False Claims Act, 31 U.S.C. § 3729, or the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Except as explicitly stated in this Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;

f. Any liability based upon obligations created by this Agreement; and

g. Any liability of individuals except as expressly stated in Paragraph 3 of this Agreement.

6. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against Patterson

for violations of the CSA unrelated to the violations identified in the audit conducted between January 31, 2023 and February 2, 2023. Nothing in this Agreement, however, waives or limits Patterson's right or ability to raise any defenses to such an action.

7. The obligations imposed upon the United States and Patterson pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon each party pursuant to all applicable federal, state, and local laws and regulations, including, but not limited to the requirements in the CSA and its implementing regulations.

8. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

9. The Parties agree that any and all costs they have, will, or may incur, in connection with this matter—including payment of the Settlement Amount under this Agreement, attorneys' fees, costs of investigation, negotiation, past and future compliance efforts, and remedial action—shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVII and IXI of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

10. This Agreement is intended to be for the benefit of the Parties only. It does not provide any rights or benefits to third parties. The Parties do not release any claims against any other person or entity except as provided in Paragraph 15.

11. This Settlement Agreement may not be changed, altered, or modified except in writing signed by the parties hereto.

12. The Parties agree to bear their own respective costs and fees (including without

limitation attorneys' fees) incurred in connection with this matter, including those incurred in the preparation and performance of this Agreement.

13. The Parties acknowledge their promises in this Agreement are provided in exchange or valuable consideration provided by and through this Agreement.

14. The Parties consent to the United States' disclosure of this Agreement and information about this Agreement to the public.

15. This Settlement Agreement shall be binding upon and inure to the benefit of the assigns, successors-in-interest, or transferees of the Parties.

16. Each of the signatories to this Settlement Agreement represents and warrants that it/he/she has the full power and authority to enter into this Settlement Agreement on behalf of the person and entities indicated below, and further represents that it/he/she freely and voluntarily enters into this Agreement without any degree of duress or compulsion. Facsimiles of signatures and electronic transmissions of signatures (including transmittal and receipt of PDF versions of signatures) shall constitute acceptable, binding signatures for purposes of this Agreement.

17. The Settlement Agreement shall be final once signed by all parties below and shall be effective on the date the last signature is obtained. The Agreement may be executed in counterparts, each of which constitutes an original and all of which constitutes one and the same agreement.

18. This Settlement Agreement constitutes the complete agreement between the Parties with respect to the settlement of the United States' civil and administrative CSA claims against Patterson on the Covered Conduct from the Covered Time.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to the Agreement is the United States District Court for the District of South Carolina.

20. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

On behalf of Patterson Logistic Services Inc.

K. Reddy
Kirti Vaidya Reddy, Esq.
Quarles & Brady
(202) 372-9606
Kirti.Reddy@Quarles.com

January 18, 2024
Date

On behalf of the United States of America

ADAIR F. BOROUGHS
United States Attorney District of South Carolina

Beth Drake
Assistant United States Attorney

1/22/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054

Name: ADEC
Address: 2601 Crestview Drive City: Newberg State: OR Zip: 97132

Name: Solventum US LLC
Address: 2510 Conway Ave E Ste 75-6W City: Maplewood State: MN Zip: 55144

Name: Ivoclar North America Inc.
Address: 175 Pineview Drive City: Amherst State: NY Zip: 14228

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Patterson Dental Supply, Inc.
Corporation/Organization Name: Patterson Logistics Services, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651.686.1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Patterson Logistics Services, Inc.

Facility Name

Leslie B. Korsh

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/6/25

Date

Board Use Only	Date Received: 5/15/25	Amount: $1000.00

NABP ACCREDITED
DRUG DISTRIBUTOR

Patterson Logistics Services, Inc

located at

800 Monte Vista Dr, Dinuba, CA 93618

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/09/2024 - 04/08/2027
Period of Accreditation

PATTERSON

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Parent Company: Patterson Dental Supply, Inc.
Address: 1031 Mendota Heights Road
Saint Paul, MN 55120
Ownership: 100%
FEIN: 41-1833619

PATTERSON LOGISTICS SERVICES, INC. – Officer List

Corporate address: 1031 Mendota Heights Road
St. Paul, MN 55120
Phone Number: 651-686-1600
FEIN: 20-4404128
State of Incorporation: Minnesota - #1737876-2 (3/1/2006)

Robert Rajalingam **Chief Executive Officer**
Business Address: 1031 Mendota Heights Road
St. Paul, MN 55120
Business Phone: 651-686-1600
Email: Facilitylicensing@pattersoncompanies.com

Kevin Barry **Chief Financial Officer**
Business Address: 1031 Mendota Heights Road
St. Paul, MN 55120
Business Phone: 651-686-1600
Email: Facilitylicensing@pattersoncompanies.com

Leslie Korsh **Corporate Secretary**
Business Address: 1031 Mendota Heights Road
St. Paul, MN 55120
Business Phone: 651-686-1600
Email: Facilitylicensing@pattersoncompanies.com

Effective 10/13/2022

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Patterson Logistics Services, Inc.
Date Filed:	03/01/2006
File Number:	1737876-2
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota
This certificate has been issued on:	12/16/2024

Steve Simon
Secretary of State
State of Minnesota

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal License

Third-Party Logistics Provider

License No. TPL 1084
Receipt No. 00193504

Valid Until: 10/1/2025

PATTERSON LOGISTICS SERVICES INC
800 MONTE VISTA DR
DINUBA, CA 93618-9117

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Third-Party Logistics Provider License.

This license is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer(s) shareholder (more than 10 percent share change), manager, or responsible manager.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHTPL (09/30/19) TPL

CALIC100.RENWALR.07232024.61528.SEQID511

PATTERSON LOGISTICS SERVICES INC
800 MONTE VISTA DR
DINUBA, CA 93618-9117 511

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0372855	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
800 MONTE VISTA DRIVE
DINUBA, CA 93618

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0372855	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
800 MONTE VISTA DRIVE
DINUBA, CA 93618

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0372855	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
800 MONTE VISTA DRIVE
DINUBA, CA 93618

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/04/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 **FAX (A/C, No):** 212-948-5382
E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Starr Indemnity & Liability Company	38318
INSURER B : Starr Specialty Insurance Company	16109
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Patterson Companies, Inc.
and its subsidiaries and affiliates
1031 Mendota Heights Road
St. Paul, MN 55120

COVERAGES **CERTIFICATE NUMBER:** CHI-010950096-01 **REVISION NUMBER:** 4

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	0
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	10,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	4,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY			1000198195241 (AOS)	11/01/2024	11/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	3,000,000
A	X ANY AUTO			1000198196241 (MA)	11/01/2024	11/01/2025	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
A	X UMBRELLA LIAB X OCCUR			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	5,000,000
	DED X RETENTION $ 25,000							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			100 0005556 (AOS)	11/01/2024	11/01/2025	X PER STATUTE OTH-ER		
B	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N	N/A		100 0005558 (FL,MA)	11/01/2024	11/01/2025	E.L. EACH ACCIDENT	$	1,000,000
B	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			100 0005559 (WI)	11/01/2024	11/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence only

CERTIFICATE HOLDER

Patterson Companies, Inc.
1031 Mendota Heights Road
St. Paul, MN 55120

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

555 Double Eagle Court #1100
Reno, Nevada 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. KO8188865

Application/License No. _____

Patterson Logistics Services, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 800 Monte Vista Drive, Dinuba, CA 93618 (Address of Applicant/Principal), as PRINCIPAL, and Westchester Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1601 Chestnut Street, Philadelphia, PA 19101 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 29, 2008 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal

may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 29th day of September, 20 08.

APPLICANT/PRINCIPAL
Patterson Logistics Services, Inc.

Authorized Representative

SURETY COMPANY
Westchester Fire Insurance Company

Cynthia L. Hanak
Surety Company's Representative

Cynthia L. Hanak, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

JoAnn R. Frank
Witness

Linda L Ham
Witness

Countersigned by:

Michele Robertson
Nevada Resident Agent

Countersigned for Nevada By
Marsh USA, Inc.
Michele Robertson, Resident Agent

NEVADA STATE BOARD OF PHARMACY

555 Double Eagle Court #1100
Reno, Nevada 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. KO8188865

Application/License No. _____

Patterson Logistics Services, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
800 Monte Vista Drive, Dinuba, CA 93618, as
(Address of Applicant/Principal)
PRINCIPAL, and Westchester Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of New York
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1601 Chestnut Street, Philadelphia, PA 19101 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 29, 2008.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal

ACKNOWLEDGMENT BY SURETY

STATE OF Missouri }
County of St. Charles } ss.

On this 29th day of September, 2008, before me personally appeared Cynthia L. Hanak, known to me to be the Attorney-in-Fact of Westchester Fire Insurance Company, the corporation that executed the within instrument, and acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

Debra C. Schneider

Debra C. Schneider
Notary Public in the State of Missouri
County of St. Charles

My Commission Expires: November 5, 2011

(Seal)

DEBRA C. SCHNEIDER
Notary Public/Notary Seal
State of Missouri
St. Charles County
COMMISSION #07419088
My Commission Expires: 11/05/2011

S-0230/GEEF 2/98

Power of Attorney

324011

WESTCHESTER FIRE INSURANCE COMPANY 1261428

Know all men by these presents: That **WESTCHESTER FIRE INSURANCE COMPANY**, a corporation of the State of New York, having its principal office in the City of Atlanta, Georgia, pursuant to the following Resolution, adopted by the Board of Directors of the said Company on December 11, 2006, to wit:

"RESOLVED, that the following authorizations relate to the execution for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested.

FURTHER RESOLVED, that the Resolution of the Board of Directors of the Company adopted at the meeting held on November 8, 1999 relating to the authorization of certain persons to execute, for and on behalf of the Company, Written Commitments and appointments and delegations, is hereby rescinded."

Does hereby nominate, constitute and appoint PAMELA A. BEELMAN, HEIDI A. NOTHEISEN, CYNTHIA L. HANAK, DEBRA C. SCHNEIDER, JOANN R. FRANK, KAREN L. ROIDER and SANDRA L. HAM all of the City of Saint Louis, State of Missouri, each individually if there be more than one named, its true and lawful attorney-in-fact, to make, execute, seal and deliver on its behalf, and as its act and deed any and all bonds, undertakings, recognizances, contracts and other writings in the nature thereof in penalties not exceeding Twenty Million Dollars ($20,000,000) and the execution of such writings in pursuance of these presents shall be as binding upon said Company, as fully and amply as if they had been duly executed and acknowledged by the regularly elected officers of the Company at its principal office.

IN WITNESS WHEREOF, the said Stephen M. Haney, Vice-President, has hereunto subscribed his name and affixed the corporate seal of the said **WESTCHESTER FIRE INSURANCE COMPANY** this 30th day of May 2008.

WESTCHESTER FIRE INSURANCE COMPANY

Stephen M. Haney, Vice President

COMMONWEALTH OF PENNSYLVANIA
COUNTY OF PHILADELPHIA ss.

On this 30th day of May, A.D. 2008, before me, a Notary Public of the Commonwealth of Pennsylvania in and for the County of Philadelphia came Stephen M. Haney, Vice-President of the **WESTCHESTER FIRE INSURANCE COMPANY** to me personally known to be the individual and officer who executed the preceding instrument, and he acknowledged that he executed the same, and that the seal affixed to the preceding instrument is the corporate seal of said Company; that the said corporate seal and his signature were duly affixed by the authority and direction of the said corporation, and that Resolution, adopted by the Board of Directors of said Company, referred to in the preceding instrument, is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Philadelphia the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
KAREN E. BRANDT, Notary Public
City of Philadelphia, Phila. County
My Commission Expires September 26, 2010

Notary Public

I, the undersigned Assistant Secretary of **WESTCHESTER FIRE INSURANCE COMPANY**, do hereby certify that the original POWER OF ATTORNEY, of which the foregoing is a substantially true and correct copy, is in full force and effect.

In witness whereof, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of the Corporation, this 29th day of September 2008.

William L. Kelly, Assistant Secretary

THIS POWER OF ATTORNEY MAY NOT BE USED TO EXECUTE ANY BOND WITH AN INCEPTION DATE AFTER May 30, 2010.

THE BACK OF THIS DOCUMENT LISTS VARIOUS SECURITY FEATURES THAT WILL PROTECT AGAINST COPY COUNTERFEIT AND ALTERATION.

SURETY RIDER

To be attached to and form a part of

Bond No. KO8188865

dated effective September 29, 2008
(MONTH-DAY-YEAR)

executed by Patterson Logistics Services, Inc. , as Principal,
(PRINCIPAL)

and by Westchester Fire Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

The Bond Amount from:

One Hundred Thousand & 00/100 ($100,000.00)

To:

Twenty-Five Thousand & 00/100 ($25,000.00)

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective February 27, 2025
(MONTH-DAY-YEAR)

Signed and Sealed February 27, 2025
(MONTH-DAY-YEAR)

Patterson Logistics Services, Inc.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Westchester Fire Insurance Company
(SURETY)

By: Cynthia L. Choren
Cynthia L. Choren, Attorney-in-Fact
NV Non-Resident License No. 221080

S-0443/GEEF 10/99

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Cynthia L. Choren

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024.**

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this February 27, 2025

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903- 3493 Fax (908) 903- 3656 e-mail: surety@chubb.com

CHUBB

SURETY BOND CORPORATE SEAL NOTICE AND ADDENDUM

In an effort to facilitate the use of our respective corporate seals during the COVID-19 pandemic, WESTCHESTER FIRE INSURANCE COMPANY ("WESTCHESTER FIRE") has authorized its respective Attorneys-in-Fact to affix WESTCHESTER FIRE'S corporate seal to any surety bond executed on behalf of WESTCHESTER FIRE by any such Attorney-in-Fact by attaching this Notice and Addendum to said bond.

To the extent this Notice and Addendum is attached to a surety bond that is executed on behalf of WESTCHESTER FIRE by its Attorney-in-Fact, WESTCHESTER FIRE hereby agrees that the corporate seal below for WESTCHESTER FIRE shall be deemed affixed to said bond to the same extent as if its raised corporate seal was physically affixed to the face of the bond.

Dated this 30th day of March, 2020.

WESTCHESTER FIRE INSURANCE COMPANY

By: _____

Stephen M. Haney, Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Patterson Logistics Services, Inc. MDEG License # (if applicable): _____

Physical Address: 800 Monte Vista Drive

City: Dinuba State: CA Zip: 93618

Mailing Address (if different from physical address): 1031 Mendota Heights Road, Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 615-686-1957 Website: www.pattersoncompanies.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Larry Middle: _____ Last: Murillo

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Dinuba State: CA Zip: [redacted]

Telephon[redacted] Email: larry.murillo@pattersonvet.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State University, Fresno		2003-2005	
Address	**City**	**State**	**Zip**
5241 N Maple Ave	Fresno	CA	93740
Diploma/Degree obtained, if any			
Bachelor of Science in Business Administration with Emphasis in Organizational Leadership Management			

School Name		From - To (MM/YY – MM/YY)	
Reedley College		2000-2003	
Address	**City**	**State**	**Zip**
995 N. Reed Ave	Reedley	CA93654	
Diploma/Degree obtained, if any			
Associate of Science in General Business and Associate of Arts in General Studies			

School Name		From - To (MM/YY – MM/YY)	
Dinuba High School			
Address	**City**	**State**	**Zip**
340 E Kern Street	Dinuba	CA	93618
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/21 - present	[redacted]	Dinuba	CA	[redacted]
07/21 - 09/21		Dinuba	CA	
09/09 -07/21		Dinuba	CA	

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			05/09 - present	
Business Address		**City**	**State**	**Zip**
800 Monte Vista Drive		Dinuba	CA	93618
Phone	**Title**		**Number of Employed Hours**	
559-595-1450	Operations Manager		6000+	

Description of Duties

Lead and direct all operations. Ensure compliance and adherence to state and federal regulations regarding the receipt, storage, inventory, and shipping of prescription drugs, including controlled substances.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/23/2025
Date

I, Larry Murillo, **certify that as the MDEG Administrator for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements):

1. JM Have a high school diploma or its equivalent;
2. JM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Larry Murillo
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/23/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Patterson Logistics Services, Inc.

Pharmacy/Wholesaler License # (if applicable): WH01206

Physical Address: 800 Monte Vista Drive

City: Dinuba State: CA Zip: 93618

Mailing Address (if different from physical address): 1031 Mendota Heights Road Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 651.686.1957 Website: www.pattersoncompanies.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Larry Middle: Last: Murillo

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Dinuba State: CA Zip: [redacted]

Telephone: [redacted] Email: larry.murillo@pattersonvet.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State University, Fresno		2003-2005	
Address	**City**	**State**	**Zip**
5241 N. Maple Ave	Fresno	CA	93740
Diploma/Degree obtained, if any			
Bachelor of Science in Business Administration with Emphasis in Organizational Leadership Management			

School Name		From - To (MM/YY – MM/YY)	
Reedley College		2000-2003	
Address	**City**	**State**	**Zip**
995 N. Reed Ave	Reedley	CA	93654
Diploma/Degree obtained, if any			
Associate of Science in General Business and Associate of Arts in General Studies			

School Name		From - To (MM/YY – MM/YY)	
Dinuba High School			
Address	**City**	**State**	**Zip**
340 E Kern Street	Dinuba	CA	93618
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/21 - present	[redacted]	Dinuba	CA	[redacted]
07/21 - 09/21		Dinuba	CA	
09/09 - 07/21		Dinuba	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			05/09 - present	
Business Address		**City**	**State**	**Zip**
800 Monte Vista Drive		Dinuba	CA	93618
Phone	**Title**		**Number of Employed Hours**	
559-595-1450	Operations Manager		6000+	
Description of Duties				
Lead and direct all operations. Ensure compliance and adherence to state and federal regulations regarding the receipt, storage, inventory, and shipping of prescription drugs, including controlled substances.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date 4/28/25

I, Larry Murillo, **certify that as the designated representative for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Larry Murillo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/28/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Larry Murillo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/28/25

Date

Please have this section completed in the presence of a Notary Public.

State of Califania, ss. County of Tulare

I, Larry Murillo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/28/25

Date

Subscribed and Sworn to before me this 28 day of April.

Notary Public Signature

NELDA GONZALEZ
Notary Public - California
Tulare County
Commission # 2408899
My Comm. Expires Jun 23, 2026

(Seal)

PATTERSON LOGISTICS

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Patterson Logistics Services, Inc. (PLSI) Dinuba, CA – Employee List

Employee Name
Magarin-Pascua, Merla
Lucatero, Gerardo
Monje Blanco, Cecilio
Garcia, Omar
Peregrina, Cristobal T
Ponce, Dalila
Gutierrez-Zarate, Floriberto
Valenzuela, Carlos
Murillo, Javier
Trinidad, Christine
Solorio, Rafael
Schutz, Paul D
Garcia, Maria Adriana
Elenes, Marco Antonio
Murillo, Larry
Urzua, Natalia
Nunez Gutierrez, Ernesto
Gaytan, Enoel
Martinez Lopez, Guadalupe
Gonzalez, Nelda E
Uyeg, Lemuel H
Pantoja, Diego Emilio
Romero, John
Tapia, Jimmy Alfred
Cazares Garcia, Jose A. Alexis
Banda, Paz
Aguilera, Martin
Pantoja Sanchez, Jose Jesus
Alvarez, Petra
Castillo, Rosemarie
Gecha Jr, Macario Calma
Gecha, Zenaida Ylagan
Avilez, Miguel A
Villasenor, Evelyn M
Cardosa, Raul
Flores Cruz, Ricardo
Orosco, Luis Miguel
Izaola-bravo, Javier
Estigoy, John Michael

Chavez, Matthew Jonah
Castillo, Steven C
Solorio, Joaquin
Marmolejo, Jorge Luis
Uribe, Richard O
Guzman, Elizabeth
Wilson, Kristopher
Saldana, Amalia
Velasquez, Claudia Patricia
Carrillo, Mariela
Ortiz Sahagun, Jose Ricardo
Gaona, Rodolfo
Flores, Julian Alexander
Villagomez, Alejandra
Sandoval, Angela Denise
Ortega, Rebecca
Salazar, Jasmine N
Corpus, Angela Berenice
Aguilera, Felipe D
Ortega, Carlos
Perez Ramos, Joel
Mejia Alva, Richard R
Pasillas, Gigi
Gaona Martinez, Vanessa
Fernandez, Joseph
Araujo, Evelyn
Fennell, Isaiah Thomas
Mandrell, Donald
Hicks, Greg
Gonzalez, Clarissa Cherie
Corpus, Iliana L
Perea, Maria L
Orozco, Lilia Lilia
Alejandro, Nicolas James
Hernandez, Maria Del Refugio
Zepeda, Jonathan
Torres, Yadira
Renteria, Juan Manuel
Vela, Jake
Luna, Carlos Armando
Carlos, Jeralyn L

Meza, Alejandra
Tostado, Fatima Loza
Reyna, Jose L
Aviles, Ernesto
Aguila, Vicky
Meraz, Eva Angelina
Diaz, Miguel
Cervantes, Salvador
Carlos, Imelda C
Diaz, Rogelio G
Armenta, Cynthia L
Uribe, Tina M
Aguirre, Cristina G
Segura, Rangel
Orosco, Jesusita Elena
Rios Lopez, Melissa Ann
Ramos, Ricardo
Ramirez, Maria M
Diaz, Miguel Alejandro
Hernandez, Maria
Rocha, Michael S
Salazar, Jose Luis
Ponce, Gabriela V
Romero, Esther M
Mendoza, Espectacion
Teso, Tommy
Hernandez, Billy
House, Kenneth
Robles, Ivan
Velasquez, Jeffrey
Viveros, Orlando
Manzo, Sylvia
Cruz, Julian
Chavez, Yulisa
Garcia, Maria del Carmen
Maldonado Lopez, Destiny
Flores Duran, Claudia Guadalupe
Santos, Covina
Madrigal, Alejandro
Carrillo Godina, Joseline
Rodriguez, Samantha
Arreguin, Eric
Davila, Christian
Virgen, Beatriz

Garcia Vera, Mireya
Pureco Cortez, Christian
Juarez, Jesus
Pineiro, Yazmin
Sanchez, Eduardo
Galban Flores, Raymond
Gutierrez, Claudia
Martinez, Alejandro
Figueroa Zamora, Brian
Orosco, Arturo
Piceno, Jose
Brenes Cerpa, Daniel
Martinez, Antonio
Rojas, Agustin
Galindo, Noe
Reynosa, Mario
Gutierrez, Miguel
Barajas, Anthony
Guerra, Alejandro
Velasquez, Fernando
Valdez, Alexander
Tejeda, Matthew
Villagomez, Jovanny
Mingming, Nellie
Sanchez Trujillo, Francisco
Arzate, Jennifer
Rodriguez, Alejandro
Morales, Daniel
Montes Martinez, Anthony
Coria, Jackeline
Moreno Carrillo, Eduardo
Martinez, Daisy
Hernandez, Juan
Gutierrez, Nathan
Garcia, Gilberto

9C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 01221	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Patterson Logistics Services, Inc.

Physical Address: 1905 Lakewood Drive

City: Boone State: IA Zip: 50036

Mailing Address (if different from physical address): 1031 Mendota Heights Road Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 515-433-1700 Website: www.pattersoncompanies.com

Name of Designated Representative (DR): Jonathan Doss

Licensing Company Email: facilitylicensing@pattersoncompa DR Email: jon.doss@pattersondental.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class I/II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: universities/res.facilities		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01.22.2024		SC	Blythewood	Richland
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		District of South Carolina on behalf of Drug Enforcement Agency		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Patterson Logistics Services, Inc.				

Provide explanation below:

On January 22, 2024, Patterson Logistics Services, Inc. ("PLSI") entered into a Settlement Agreement with the United States Attorney's Office for the District of South Carolina ("DOJ"), acting on behalf of the Drug Enforcement Administration ("DEA"), in which PLSI agreed to pay a fine of $45,500 with no associated admission of liability or guilt by PLSI. The allegations of the DEA are related primarily to certain record-keeping and reporting violations of the Controlled Substance Act. The DOJ and the DEA were satisfied with Patterson's corrective action measures, such that the matter was settled with no associated Memorandum of Understanding or ongoing reporting requirement for PLSI.

Original Signature (electronic, copies or stamps not accepted)

Date

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into by and between the United States of America, acting through the United States Attorney's Office for the District of South Carolina, on behalf of the Drug Enforcement Administration ("DEA") (collectively, the "United States"), and Patterson Logistic Services Inc. ("Patterson") (together, "the Parties").

RECITALS

Patterson is currently registered with DEA Certificate of Registration #RP0349224 as a distributor authorized to handle controlled substances on Schedules II-V at its registered location, 925 Carolina Pines Boulevard, Suite B, Blythewood, South Carolina 29016 (the "Blythewood FC").

At all times relevant to this Agreement, Patterson was required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder, 21 C.F.R. Part 1300, *et seq.* (collectively "the CSA.")

Between January 31, 2023, and February 2, 2023, the DEA conducted an inspection at Blythewood FC. As a result of the inspection, the United States contends Patterson violated civil provisions of the CSA. Specifically, the United States contends that from January 31, 2021 through February 2, 2023, in regard to operations at Blythewood FC, Patterson violated certain suspicious order requirements, reporting requirements to ARCOS and order form and recordkeeping requirements pursuant to the CSA, specifically Title 21 Parts 1301, 1304, and 1305 of the CFR.

The conduct identified above at the Blythewood FC shall hereinafter be referred to as "Covered Conduct" and the identified time frame shall be referred to as "Covered Time Period."

The parties agree that this Agreement is not an admission of liability by Patterson, its

employees, or its agents for the Covered Conduct under the CSA nor a concession by the United States that its claims are not well-founded.

To avoid the uncertainty and expense of the adjudication of each claim, and of exhausting all administrative and legal remedies, the Parties desire to reach a mutual agreement that settles the above-referenced allegations without the United States filing a civil suit.

STIPULATIONS

In consideration of the foregoing and the mutual promises and obligations contained in this Agreement, the Parties agree and covenant as follows:

1. Patterson shall pay $45,500 (the "Settlement Amount") to the United States no later than 10 business days after counsel for Patterson receives the written electronic funds transfer instructions by the United States Attorney for the District of South Carolina.

2. By signing this Settlement Agreement, Patterson agrees to waive all rights to seek judicial review or to challenge or contest the validity of any terms or conditions of this Settlement Agreement.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Patterson's full payment of the Settlement Amount under this Agreement, the United States agrees to refrain from filing against Patterson any action for civil penalty claims under the CSA that is based on the Covered Conduct. In further consideration of Patterson's fulfillment of its obligations under this Agreement, expressly conditioned upon Patterson's timely paying the Settlement Amount and subject to the exceptions in Paragraph 5 (concerning excluded claims), below, the United States fully and finally releases Patterson and its parent, affiliates, insurers, agents, assigns, successors, predecessors, shareholders, principals, current and former employees,

management, officers, and directors from any civil or administrative claims the United States has, could have, or may assert in the future related to the Covered Conduct during the Covered Time Period.

4. Patterson fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including without limitation attorney's fees, costs, and expenses of every kind and however denominated) that Patterson has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, and servants, and agents related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Notwithstanding the release given in Paragraph 3 of this Settlement Agreement, or any other terms of this Agreement, the following claims of the United States are specifically reserved and not released:

a. Any liability arising under Title 26 of the United States Code;

b. Any criminal liability;

c. Any liability under the False Claims Act, 31 U.S.C. § 3729, or the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Except as explicitly stated in this Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;

f. Any liability based upon obligations created by this Agreement; and

g. Any liability of individuals except as expressly stated in Paragraph 3 of this Agreement.

6. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against Patterson

for violations of the CSA unrelated to the violations identified in the audit conducted between January 31, 2023 and February 2, 2023. Nothing in this Agreement, however, waives or limits Patterson's right or ability to raise any defenses to such an action.

7. The obligations imposed upon the United States and Patterson pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon each party pursuant to all applicable federal, state, and local laws and regulations, including, but not limited to the requirements in the CSA and its implementing regulations.

8. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

9. The Parties agree that any and all costs they have, will, or may incur, in connection with this matter—including payment of the Settlement Amount under this Agreement, attorneys' fees, costs of investigation, negotiation, past and future compliance efforts, and remedial action—shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVII and IX1 of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

10. This Agreement is intended to be for the benefit of the Parties only. It does not provide any rights or benefits to third parties. The Parties do not release any claims against any other person or entity except as provided in Paragraph 15.

11. This Settlement Agreement may not be changed, altered, or modified except in writing signed by the parties hereto.

12. The Parties agree to bear their own respective costs and fees (including without

limitation attorneys' fees) incurred in connection with this matter, including those incurred in the preparation and performance of this Agreement.

13. The Parties acknowledge their promises in this Agreement are provided in exchange or valuable consideration provided by and through this Agreement.

14. The Parties consent to the United States' disclosure of this Agreement and information about this Agreement to the public.

15. This Settlement Agreement shall be binding upon and inure to the benefit of the assigns, successors-in-interest, or transferees of the Parties.

16. Each of the signatories to this Settlement Agreement represents and warrants that it/he/she has the full power and authority to enter into this Settlement Agreement on behalf of the person and entities indicated below, and further represents that it/he/she freely and voluntarily enters into this Agreement without any degree of duress or compulsion. Facsimiles of signatures and electronic transmissions of signatures (including transmittal and receipt of PDF versions of signatures) shall constitute acceptable, binding signatures for purposes of this Agreement.

17. The Settlement Agreement shall be final once signed by all parties below and shall be effective on the date the last signature is obtained. The Agreement may be executed in counterparts, each of which constitutes an original and all of which constitutes one and the same agreement.

18. This Settlement Agreement constitutes the complete agreement between the Parties with respect to the settlement of the United States' civil and administrative CSA claims against Patterson on the Covered Conduct from the Covered Time.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to the Agreement is the United States District Court for the District of South Carolina.

20. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

On behalf of Patterson Logistic Services Inc.

K. Reddy
Kirti Vaidya Reddy, Esq.
Quarles & Brady
(202) 372-9606
Kirti.Reddy@Quarles.com

January 18, 2024
Date

On behalf of the United States of America

ADAIR F. BOROUGHS
United States Attorney District of South Carolina

Beth Drake
Assistant United States Attorney

1/22/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054
Name: ADEC
Address: 2601 Crestview Drive City: Newberg State: OR Zip: 97132
Name: Solventum US LLC
Address: 2510 Conway Ave E Ste 75-6W City: Maplewood State: MN Zip: 55144
Name: Ivoclar North America Inc.
Address: 175 Pineview Drive City: Amherst State: NY Zip: 14228

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Patterson Dental Supply, Inc.
Corporation/Organization Name: Patterson Logistics Services, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651.686.1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Patterson Logistics Services, Inc.

Facility Name

Leslie B. Korsh

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Date

Board Use Only	Date Received: 5/15/25	Amount: $1000

NABP ACCREDITED
DRUG DISTRIBUTOR

Patterson Logistics Services, Inc

located at

1905 Lakewood Drive, Boone, IA 50036

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

05/11/2024 - 05/10/2027
Period of Accreditation

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Parent Company:	Patterson Dental Supply, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-1833619

PATTERSON LOGISTICS SERVICES, INC. – Officer List

Corporate address:	1031 Mendota Heights Road St. Paul, MN 55120
Phone Number:	651-686-1600
FEIN:	20-4404128
State of Incorporation:	Minnesota - #1737876-2 (3/1/2006)

Robert Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Kevin Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Leslie Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Effective 10/13/2022

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Patterson Logistics Services, Inc.
Date Filed:	03/01/2006
File Number:	1737876-2
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 12/16/2024

Steve Simon
Secretary of State
State of Minnesota

IOWA BOARD OF PHARMACY
6200 PARK AVENUE, SUITE 100
DES MOINES, IA 50321-1270
515/281-5944 FAX 515/281-4609
https://pharmacy.iowa.gov

2026

Third-Party Logistics Provider License No.80002

ISSUED 02/05/2025

EXPIRES 03/31/2026

LICENSE STATUS: Current/Active

MAILING ADDRESS
Patterson Logistics Services Inc
Attn: Regulatory Licensing
1031 Mendota Heights Rd
St Paul,MN 55120

LICENSED LOCATION
Patterson Logistics Services Inc
1905 Lakewood Dr
Boone, IA 50036

Facility Manager: Jonathan David Doss

IOWA BOARD OF PHARMACY
6200 PARK AVENUE, SUITE 100
DES MOINES, IA 50321-1270
515/281-5944 FAX 515/281-4609
https://pharmacy.iowa.gov

CSA 2027

CERTIFICATE OF REGISTRATION
IOWA CONTROLLED SUBSTANCES ACT

REGISTRATION NUMBER 2210301
DRUG SCHEDULES REGISTERED 33N45

REGISTRATION ISSUED 02/05/2025
REGISTRATION EXPIRES 03/31/2027
REGISTRATION STATUS: Current/Active

NAME, MAILING ADDRESS
Patterson Logistics Services Inc
Attn: Regulatory Licensing
1031 Mendota Heights Rd
St Paul MN 55120

NAME, REGISTERED LOCATION
Patterson Logistics Services Inc
1905 Lakewood Dr
Boone IA 50036

Distributor

COUNTY 8

Jonathan David Doss, Responsible Individual

DEA REGISTRATION NO. RP0380523

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0380523	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
1905 LAKEWOOD DRIVE
BOONE, IA 500367604

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0380523	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
1905 LAKEWOOD DRIVE
BOONE, IA 500367604

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0380523	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
1905 LAKEWOOD DRIVE
BOONE, IA 500367604

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/04/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 **FAX (A/C, No):** 212-948-5382
E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Starr Indemnity & Liability Company	38318
INSURER B : Starr Specialty Insurance Company	16109
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Patterson Companies, Inc.
and its subsidiaries and affiliates
1031 Mendota Heights Road
St. Paul, MN 55120

COVERAGES **CERTIFICATE NUMBER:** CHI-010950096-01 **REVISION NUMBER:** 4

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	0
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	10,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	4,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY			1000198195241 (AOS)	11/01/2024	11/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	3,000,000
A	X ANY AUTO			1000198196241 (MA)	11/01/2024	11/01/2025	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
A	X UMBRELLA LIAB X OCCUR			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	5,000,000
	DED X RETENTION $ 25,000							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			100 0005556 (AOS)	11/01/2024	11/01/2025	X PER STATUTE / OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? N	N/A		100 0005558 (FL,MA)	11/01/2024	11/01/2025	E.L. EACH ACCIDENT	$	1,000,000
B	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			100 0005559 (WI)	11/01/2024	11/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence only

CERTIFICATE HOLDER

Patterson Companies, Inc.
1031 Mendota Heights Road
St. Paul, MN 55120

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. **K41888489**

Application/License No. _____

Patterson Logistics Services, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is **1905 Lakewood Drive, Boone, IA 50036** (Address of Applicant/Principal), as PRINCIPAL, and **Federal Insurance Company** (Surety Company), a corporation organized under the laws of the state of **Indiana** (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is **202B Halls Mill Road, Whitehouse Station, NJ 08889-3454** (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on **February 25, 2025** (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25th day of February, 2025.

APPLICANT/PRINCIPAL
Patterson Logistics Services, Inc.

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY
Federal Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness JoAnn R. Frank

Witness Brittany D. Stuckel

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Cynthia L. Choren

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024.**

Rupert HD Swindells Assistant Secretary

Warren Eichhorn Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this February 25, 2025

Rupert HD Swindells Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903- 3493 Fax (908) 903- 3656 e-mail: surety@chubb.com

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Patterson Logistics Services, Inc. MDEG License # (if applicable): _____

Physical Address: 1905 Lakewood Drive

City: Boone State: IA Zip: 50036

Mailing Address (if different from physical address): 1031 Mendota Heights Road, Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 515-433-1700 Website: www.pattersoncompanies.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Jonathan Middle: David Last: Doss

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Boone State: IA Zip: [redacted]

Telephone: [redacted] Email: jon.doss@pattersoncompanies.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Des Moines Area Community College			
Address	City	State	Zip
1300 Des Moines	Des Moines	IA	50309
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
Madrid High School			
Address	City	State	Zip
8** N Kennedy Avenue	Madrid	IA	50156
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2008 - present	[redacted]	Boone	IA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.		08/2018 - present	
Business Address	**City**	**State**	**Zip**
1905 Lakewood Drive	Boone	IA	50036
Phone	**Title**	**Number of Employed Hours**	
515-433-1700	Operations Manager	6000+	
Description of Duties			
Lead and direct all operations. Ensure compliance and adherence to state and federal regulations regarding the receipt, storage, inventory, and shipping of prescription drugs, including controlled substances.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Jonathan Doss
Original Signature (electronic, copies or stamps not accepted)

5/27/25
Date

I, Jonathan Doss, **certify that as the MDEG Administrator for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements):

1. JD Have a high school diploma or its equivalent;
2. JD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Doss
Print Name (First, Last)

Jonathan Doss
Original Signature (electronic, copies or stamps not accepted)

5/27/25
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Patterson Logistics Services, Inc.

Pharmacy/Wholesaler License # (if applicable): WH01221

Physical Address: 1905 Lakewood Drive

City: Boone State: IA Zip: 50036

Mailing Address (if different from physical address): 1031 Mendota Heights Road Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 515-433-1700 Website: www.pattersoncompanies.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Jonathan Middle: David Last: Doss

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Boone State: IA Zip: [redacted]

Telephon: [redacted] Email: jon.doss@pattersoncompanies.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Des Moines Area Community College			
Address	**City**	**State**	**Zip**
1300 Des Moines Street	Des Moines	IA	50309
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
Madrid High School			
Address	**City**	**State**	**Zip**
599 N Kennedy Avenue	Madrid	IA	50156
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/08-present	[redacted]	Boone	IA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services Inc.			08/18-present	
Business Address		**City**	**State**	**Zip**
1905 Lakewood Drive		Boone	IA	50036
Phone	**Title**		**Number of Employed Hours**	
515-433-1700	Operations Manager		6000+	
Description of Duties				
Lead and direct all operations. Ensure compliance and adherence to state and federal regulations regarding the receipt, storage, inventory, and shipping of prescription drugs, including controlled substances.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Jonathan Doss
Original Signature (electronic, copies or stamps not accepted)

4/24/25
Date

I, Jonathan Doss, **certify that as the designated representative for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JD I am at least 21 years of age;
3. JD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jonathan Doss

Print Name (First, Last)

Jonathan Doss

Original Signature (electronic, copies or stamps not accepted)

4/24/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Doss

Print Name (First, Last)

Jonathan Doss

Original Signature (electronic, copies or stamps not accepted)

4/24/25

Date

Please have this section completed in the presence of a Notary Public.

State of Iowa, ss. County of Boone

I, Jonathan Doss, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jonathan Doss

Original Signature

4/24/25

Date

Subscribed and Sworn to before me this 24 day of April.

Tina Marie Myers

Notary Public Signature

NOTARIAL SEAL IOWA

TINA MARIE MYERS
Commission Number 815823
My Commission Expires
March 15, 2028

(Seal)

PATTERSON LOGISTICS

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Patterson Logistics Services, Inc. (PLSI) Boone, IA – Employee List

Employee Name
Hiles, Cory
Treganza, Nathan M
Wickman, Christopher Thomas
Laughlin, Douglas
Elsner, Edwin Jacob
Morgan, Luke
Kimrey, Jackson Timothy
Doss, Jonathan
Titus, Sharon L
Swan, Jason Michael
Miller, Cody Allen
Myers, Tina M
Green, Ashley
Myers, Kaleb I
Burke, Cameron Mitchel
Haleen, Andrew
Jones, Angela
Hilsabeck, Hillary Rose Marie
Fitzpatrick, Michael D
Kluender, Karl Ronald
Irvine, Joshua Thomas
Myers, Laura Esther
Caskey, Jennifer
Smith, Marcie
Dasilva, Moises
Munson, Jamin
Clayton, Traci R
Wilkening, Colton E
Jensen, Chris M
Marks, Danny R
Knapp, Kaylin
Grimes, Jonah
Rhoades, Sandra Kay
Reynolds, Manuela Judy
Brogden, Kallie Maia
Thornton, Kerrigan Anne Clara
Crook, Tyler Lee
Lee, Jenny
Wingert, Scott Edward
Browning, Neyma Edith
Duncan, Shawn

Luzadder, Teresa Marie
Newbold, Brady
Ertz, Jennifer
Anderson, Michael
Outersky, Frank W
Good, Aaron Thompson
Erb, Douglas M
Peterson, Ryioko S
Rampton, Tyler
Kinnetz, Austin
Miller, Caldwell
Nation, Hilary
Witt, Timothy J
Wildt, Stephen
Tilley, Carrie Marie
Dotzler, Colby
Sloter, Caleb
Sloter, Isaac
Purscell, Mackenzie
Roberts, Ezra
Hodge, Adelfa
Crook, Jakob
Honkomp, Hunter
Boothroyd, Ty
Elsberry, Creeda
Wilkening, Halle
Rather, Deana
Gordon, Rowena
Davis, Jaelyn
Johnson, Kjersti
Hernandez, Jose
Jones, Coltin
Nardini, Nicole
Searcy, Cameron
Anderson, Bryce
Kahler, Brandon

9D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
■ Ownership Change*	WH 01483	■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)		☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Patterson Logistics Services, Inc.

Physical Address: 925 Carolina Pines Blvd., Suite B

City: Blythewood State: SC Zip: 29016

Mailing Address (if different from physical address): 1031 Mendota Heights Rd. Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 803-691-2202 Website: www.pattersoncompanies.com

Name of Designated Representative (DR): Richard Easler

Licensing Company Email: facilitylicensing@pattersoncompa DR Email: richard.easler@pattersoncompanies.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class I and Class II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: universities/res.facilities		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01.22.2024		SC	Blythewood	Richland
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		District of South Carolina on behalf of Drug Enforcement Agency		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Patterson Logistics Services, Inc.				

Provide explanation below:

On January 22, 2024, Patterson Logistics Services, Inc. ("PLSI") entered into a Settlement Agreement with the United States Attorney's Office for the District of South Carolina ("DOJ"), acting on behalf of the Drug Enforcement Administration ("DEA"), in which PLSI agreed to pay a fine of $45,500 with no associated admission of liability or guilt by PLSI. The allegations of the DEA are related primarily to certain record-keeping and reporting violations of the Controlled Substance Act. The DOJ and the DEA were satisfied with Patterson's corrective action measures, such that the matter was settled with no associated Memorandum of Understanding or ongoing reporting requirement for PLSI.

Original Signature (electronic, copies or stamps not accepted)

5/14/2025
Date

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into by and between the United States of America, acting through the United States Attorney's Office for the District of South Carolina, on behalf of the Drug Enforcement Administration ("DEA") (collectively, the "United States"), and Patterson Logistic Services Inc. ("Patterson") (together, "the Parties").

RECITALS

Patterson is currently registered with DEA Certificate of Registration #RP0349224 as a distributor authorized to handle controlled substances on Schedules II-V at its registered location, 925 Carolina Pines Boulevard, Suite B, Blythewood, South Carolina 29016 (the "Blythewood FC").

At all times relevant to this Agreement, Patterson was required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder, 21 C.F.R. Part 1300, *et seq.* (collectively "the CSA.")

Between January 31, 2023, and February 2, 2023, the DEA conducted an inspection at Blythewood FC. As a result of the inspection, the United States contends Patterson violated civil provisions of the CSA. Specifically, the United States contends that from January 31, 2021 through February 2, 2023, in regard to operations at Blythewood FC, Patterson violated certain suspicious order requirements, reporting requirements to ARCOS and order form and recordkeeping requirements pursuant to the CSA, specifically Title 21 Parts 1301, 1304, and 1305 of the CFR.

The conduct identified above at the Blythewood FC shall hereinafter be referred to as "Covered Conduct" and the identified time frame shall be referred to as "Covered Time Period."

The parties agree that this Agreement is not an admission of liability by Patterson, its

employees, or its agents for the Covered Conduct under the CSA nor a concession by the United States that its claims are not well-founded.

To avoid the uncertainty and expense of the adjudication of each claim, and of exhausting all administrative and legal remedies, the Parties desire to reach a mutual agreement that settles the above-referenced allegations without the United States filing a civil suit.

STIPULATIONS

In consideration of the foregoing and the mutual promises and obligations contained in this Agreement, the Parties agree and covenant as follows:

1. Patterson shall pay $45,500 (the "Settlement Amount") to the United States no later than 10 business days after counsel for Patterson receives the written electronic funds transfer instructions by the United States Attorney for the District of South Carolina.

2. By signing this Settlement Agreement, Patterson agrees to waive all rights to seek judicial review or to challenge or contest the validity of any terms or conditions of this Settlement Agreement.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Patterson's full payment of the Settlement Amount under this Agreement, the United States agrees to refrain from filing against Patterson any action for civil penalty claims under the CSA that is based on the Covered Conduct. In further consideration of Patterson's fulfillment of its obligations under this Agreement, expressly conditioned upon Patterson's timely paying the Settlement Amount and subject to the exceptions in Paragraph 5 (concerning excluded claims), below, the United States fully and finally releases Patterson and its parent, affiliates, insurers, agents, assigns, successors, predecessors, shareholders, principals, current and former employees,

management, officers, and directors from any civil or administrative claims the United States has, could have, or may assert in the future related to the Covered Conduct during the Covered Time Period.

4. Patterson fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including without limitation attorney's fees, costs, and expenses of every kind and however denominated) that Patterson has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, and servants, and agents related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Notwithstanding the release given in Paragraph 3 of this Settlement Agreement, or any other terms of this Agreement, the following claims of the United States are specifically reserved and not released:

a. Any liability arising under Title 26 of the United States Code;

b. Any criminal liability;

c. Any liability under the False Claims Act, 31 U.S.C. § 3729, or the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Except as explicitly stated in this Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;

f. Any liability based upon obligations created by this Agreement; and

g. Any liability of individuals except as expressly stated in Paragraph 3 of this Agreement.

6. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against Patterson

for violations of the CSA unrelated to the violations identified in the audit conducted between January 31, 2023 and February 2, 2023. Nothing in this Agreement, however, waives or limits Patterson's right or ability to raise any defenses to such an action.

7. The obligations imposed upon the United States and Patterson pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon each party pursuant to all applicable federal, state, and local laws and regulations, including, but not limited to the requirements in the CSA and its implementing regulations.

8. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

9. The Parties agree that any and all costs they have, will, or may incur, in connection with this matter—including payment of the Settlement Amount under this Agreement, attorneys' fees, costs of investigation, negotiation, past and future compliance efforts, and remedial action—shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVII and IXI of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

10. This Agreement is intended to be for the benefit of the Parties only. It does not provide any rights or benefits to third parties. The Parties do not release any claims against any other person or entity except as provided in Paragraph 15.

11. This Settlement Agreement may not be changed, altered, or modified except in writing signed by the parties hereto.

12. The Parties agree to bear their own respective costs and fees (including without

limitation attorneys' fees) incurred in connection with this matter, including those incurred in the preparation and performance of this Agreement.

13. The Parties acknowledge their promises in this Agreement are provided in exchange or valuable consideration provided by and through this Agreement.

14. The Parties consent to the United States' disclosure of this Agreement and information about this Agreement to the public.

15. This Settlement Agreement shall be binding upon and inure to the benefit of the assigns, successors-in-interest, or transferees of the Parties.

16. Each of the signatories to this Settlement Agreement represents and warrants that it/he/she has the full power and authority to enter into this Settlement Agreement on behalf of the person and entities indicated below, and further represents that it/he/she freely and voluntarily enters into this Agreement without any degree of duress or compulsion. Facsimiles of signatures and electronic transmissions of signatures (including transmittal and receipt of PDF versions of signatures) shall constitute acceptable, binding signatures for purposes of this Agreement.

17. The Settlement Agreement shall be final once signed by all parties below and shall be effective on the date the last signature is obtained. The Agreement may be executed in counterparts, each of which constitutes an original and all of which constitutes one and the same agreement.

18. This Settlement Agreement constitutes the complete agreement between the Parties with respect to the settlement of the United States' civil and administrative CSA claims against Patterson on the Covered Conduct from the Covered Time.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to the Agreement is the United States District Court for the District of South Carolina.

20. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

On behalf of Patterson Logistic Services Inc.

K. Reddy
Kirti Vaidya Reddy, Esq.
Quarles & Brady
(202) 372-9606
Kirti.Reddy@Quarles.com

January 18, 2024
Date

On behalf of the United States of America

ADAIR F. BOROUGHS
United States Attorney District of South Carolina

Beth Drake
Assistant United States Attorney

1/22/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054

Name: A-dec
Address: 2601 Crestview Drive City: Newberg State: OR Zip: 97132

Name: Solventum US LLC
Address: 2510 Conway Ave. E Ste 75-6W City: Maplewood State: MN Zip: 55144

Name: Ivoclar North America Inc.
Address: 175 Pineview Drive City: Amherst State: NY Zip: 14228

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Patterson Dental Supply,Inc.
Corporation/Organization Name: Patterson Logistics Services, Inc.
Mailing Address: 1031 Mendota Heights Rd.
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Patterson Logistics Services, Inc.

Facility Name

Leslie B. Korsh

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/14/2025

Date

Board Use Only	Date Received: 5/15/25	Amount: $1000.00

NABP ACCREDITED
DRUG DISTRIBUTOR

Patterson Logistics Services, Inc

located at

925 Carolina Pines Blvd, Ste B, Blythewood, SC 29016

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

11/16/2023 -11/15/2026
Period of Accreditation

PATTERSON

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Parent Company:	Patterson Dental Supply, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-1833619

PATTERSON LOGISTICS SERVICES, INC. – Officer List

Corporate address:	1031 Mendota Heights Road St. Paul, MN 55120
Phone Number:	651-686-1600
FEIN:	20-4404128
State of Incorporation:	Minnesota - #1737876-2 (3/1/2006)

Robert J. Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Kevin M. Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Leslie B. Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Effective 10/13/2022

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Patterson Logistics Services, Inc.
Date Filed:	03/01/2006
File Number:	1737876-2
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota
This certificate has been issued on:	12/16/2024



Steve Simon
Secretary of State
State of Minnesota

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

PATTERSON LOGISTICS SERVICES, INC.

925 CAROLINA PINES BLVD SUITE B
BLYTHEWOOD, SC 29016

PY .16417 PTP

Third Party Logistics Provider

License Expires on
06/30/2025

Heather C. Harris

Heather C. Harris, Board Chair

Archie "Artie" McKnight, Vice Chair

Effective Date
06/17/2024

Traci Collier

Traci Collier, Board Administrator

To verify current license status, go to http://verify.llronline.com/LicLookup/LookupMain.aspx

License must be displayed publicly.

SOUTH CAROLINA DEPARTMENT OF PUBLIC HEALTH Back to Drug Control DPH Home

Controlled Substances Registration Verification

Welcome to the SC DPH Bureau of Drug Control Verification page. All fields are not required.

Enter search criteria.

Registration Number 40-16417 **City** Enter city...

Name (last, first) Enter name **County** Select county...

Company Name Enter company name... **State** Select state...

Search Clear Form Print Listing

Registration Number	Name/Address	County	Issuance Date	Expiration Date	Schedules
4016417	PATTERSON LOGISTICS SERVICES, INC 925 CAROLINA PINES BLVD STE B BLYTHEWOOD, SC 29016	RICHLAND	2/15/2007	4/1/2026	22N33N45

Showing 1 to 1 of 1 entries

The maximum number of results is limited to 25. If you are unable to view the data you are looking for, please refine your search.
Verification Disclaimer: This is to attest to the accuracy of the information contained on the website and to verify that the information is updated at least daily.
The information on this site is primary source verification, and is non-modifiable by outside entities.

For additional information, contact: (803) 896-0636 Fax (803) 896-0627

© 2025 South Carolina Department of Public Health. All Rights Reserved. 2100 Bull Street, Columbia, SC 29201 (803) 896-3432
DPH.SC.gov

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0349224	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES INC
925 CAROLINA PINES BLVD
STE B
BLYTHEWOOD, SC 290167926

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0349224	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES INC
925 CAROLINA PINES BLVD
STE B
BLYTHEWOOD, SC 290167926

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
06/04/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400	**CONTACT NAME:** Marsh | U.S. Operations & Technology **PHONE (A/C, No, Ext):** 866-966-4664 **FAX (A/C, No):** 212-948-5382 **E-MAIL ADDRESS:** Minneapolis.CertRequest@marsh.com	
	INSURER(S) AFFORDING COVERAGE	**NAIC #**
	INSURER A : Starr Indemnity & Liability Company	38318
INSURED Patterson Companies, Inc. and its subsidiaries and affiliates 1031 Mendota Heights Road St. Paul, MN 55120	**INSURER B :** Starr Specialty Insurance Company	16109
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** CHI-010950096-01 **REVISION NUMBER:** 4

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	2,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	0
							PERSONAL & ADV INJURY	$	2,000,000
							GENERAL AGGREGATE	$	10,000,000
							PRODUCTS - COMP/OP AGG	$	4,000,000
								$	
A	**AUTOMOBILE LIABILITY**			1000198195241 (AOS)	11/01/2024	11/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	3,000,000
A	X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			1000198196241 (MA)	11/01/2024	11/01/2025	BODILY INJURY (Per person)	$	
							BODILY INJURY (Per accident)	$	
							PROPERTY DAMAGE (Per accident)	$	
								$	
A	X **UMBRELLA LIAB** X OCCUR **EXCESS LIAB** CLAIMS-MADE DED X RETENTION $ 25,000			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	5,000,000
							AGGREGATE	$	5,000,000
								$	
B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y / N			100 0005556 (AOS)	11/01/2024	11/01/2025	X PER STATUTE OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N / A		100 0005558 (FL,MA)	11/01/2024	11/01/2025	E.L. EACH ACCIDENT	$	1,000,000
B	**(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below			100 0005559 (WI)	11/01/2024	11/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence only.

CERTIFICATE HOLDER

Patterson Companies, Inc.
1031 Mendota Heights Road
St. Paul, MN 55120

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. **K41888507**

Application/License No. _____

Patterson Logistics Services, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is **925 Carolina Pines Blvd., Suite B, Blythewood, SC 29016** (Address of Applicant/Principal), as PRINCIPAL, and **Federal Insurance Company** (Surety Company), a corporation organized under the laws of the state of **Indiana** (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is **202B Halls Mill Road, Whitehouse Station, NJ 08889-3454** (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on **February 25, 2025** (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25th day of February, 2025.

APPLICANT/PRINCIPAL
Patterson Logistics Services, Inc.

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY
Federal Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness JoAnn R. Frank

Witness Brittany D. Stuckel

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Cynthia L. Choren

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024.**

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this February 25, 2025

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

Combined: FED-VIG-PI-WFIC-AAIC (rev. 11-19)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Patterson Logistics Services, Inc. MDEG License # (if applicable):
Physical Address: 925 Carolina Pines Blvd, Suite B
City: Blythewood State: SC Zip: 29016
Mailing Address (if different from physical address): 1031 Mendota Heights Road, Attn: Regulatory Licensing
City: Saint Paul State: MN Zip: 55120
Telephone: 803-691-2202 Website: www.pattersoncompanies.com
Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Richard Middle: Keith Last: Easler
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X
Mailing Addres: [redacted]
City: Leesville State: SC Zip: [redacted]
Telephon: [redacted] Email: richard.easler@pattersoncompanies.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Saluda High School		09/1987 - 05/1990	
Address	**City**	**State**	**Zip**
160 Ivory Key Road	Saluda	SC	29138
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2024 - Present	[redacted]	Leesville	SC	[redacted]
05/1995 - 04/2024		Leesville	SC	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			07/2001 - Present	
Business Address		**City**	**State**	**Zip**
925 Carolina Pines Blvd, Suite B		Blythewood	SC	29016
Phone	**Title**		**Number of Employed Hours**	
803-691-2202	Department Manager		6000+	
Description of Duties				
Trains and develops all employees for an understanding in State and Federal Regulations. Manages and supervises inventory to contain pharmaceutical and controlled substance to achieve 100% cycle count effectiveness each quarter.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Richard Easler, **certify that as the MDEG Administrator for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements):

1. RE Have a high school diploma or its equivalent;
2. RE Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RE Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RE Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard Easler
Print Name (First, Last)

Richard Easler
Original Signature (electronic, copies or stamps not accepted)

5/23/25
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Patterson Logistics Services, Inc.

Pharmacy/Wholesaler License # (if applicable): WH01483

Physical Address: 925 Carolina Pines Blvd., Suite B

City: Blythewood State: SC Zip: 29016

Mailing Address (if different from physical address): 1031 Mendota Heights Rd. Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 803-691-2202 Website: www.pattersoncompanies.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Richard Middle: Keith Last: Easler

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Leesville State: SC Zip: [redacted]

Telephon[redacted] Email: richard.easler@pattersoncompanies.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Saluda High School		09/1987 - 05/1990	
Address	**City**	**State**	**Zip**
160 Ivory Key Road	Saluda	SC	29138
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2024 - Present	[redacted]	Leesville	SC	[redacted]
05/1995 - 04/2024		Leesville	SC	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			07/2001-Present	
Business Address		**City**	**State**	**Zip**
925 Carolina Pines Blvd., Suite B		Blythewood	SC	29016
Phone	**Title**		**Number of Employed Hours**	
803-691-2202	Department Manager		6000+	
Description of Duties				
Trains and develops all employees for an understanding in State and Federal Regulations. Manages and supervises inventory to contain pharmaceutical and controlled substance to achieve 100% cycle count effectiveness each quarter.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Richard Eagles
Original Signature (electronic, copies or stamps not accepted)

5/2/25
Date

I, Richard Easler, **certify that as the designated representative for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RE I am at least 21 years of age;
3. RE I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RE I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RE I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RE I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RE I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Richard Easler

Print Name (First, Last)

Richard Easler

Original Signature (electronic, copies or stamps not accepted)

5/2/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard Easler

Print Name (First, Last)

Richard Easler

Original Signature (electronic, copies or stamps not accepted)

5/2/25

Date

Please have this section completed in the presence of a Notary Public.

State of South Carolina, ss. County of Richland

I, Richard Easler, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Richard Easler

Original Signature

5/2/25

Date

Subscribed and Sworn to before me this 2nd day of May 2025

Rashode Addison

Notary Public Signature

(Seal)

PATTERSON LOGISTICS

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Patterson Logistics Services, Inc.
Bythewood, SC – Employee List

Employee List
Easler, Richard Keith
Robinson, Pamela
Coleman, Stanley
Hopkins, Eugene
Miller, Enos J
Herrmann, Troy Joseph
Sapp, Corinthia
Jackson, Jacob B
Carter, Jerry L
Worzalla, Ashley R
Roberts, Tracey M
Donald, Charlene Denise
Addison, Rasheda D
Cox, Anthony Dwayne
Stewart, Roosevelt J
Brazell, Glenda F
Stokes, Emiliano T
Hammett, Kendrix
Lewis, Willie
Keo, Rachana Chhom
Stack, Angelo
Sawmadal, Loretta Maxwell
Benjamin, Charles Alonzo
Miller, Melisa
Hudson Jr, Nathaniel
Simmons, Jernell Nixon
Springman, Angela N
Bratton, Stephanie
Leneau, Chanell Tatiana
Burton, Andrea W
Johnson, Chesica Vernita
McKnight, Jacqueline Sabrina
Glover, Quintera Kyanna
Glover, Willie Derion
Shiver, Kelan
Maple, Naialah Jhanel
Burton, Jacqueline Geneva
Cokely, Deanya
Drayton Jr, Leroy
Stewart, Michael Eric
Clegg, Amy
Reynolds, Audrey T
Cole, JoAnn

Garner, Christopher R
Daniels, Toduario Antione
Lewis, Christyn
Sampson, Kimberly Dawn
Lee, Jerred
Jones, Jakira
Lee-Burns, Shanelle
Lawhorn, Jordan
Urena, Jose
Golson, Angelique
Carraway, Dewayne
Gary, Janelle
Tobon Sr, Jason
White, Terri
Williams, Robert
Eison, Demarcus
Roberts, Abigail
Tobon, Amy
Daniels, Shadaria
Patton, Bahsil
Smith, William
Lacy, Bernard
Dalloul, Ramzi
Outen, Maggie
Harris, Ricky
Roberts, Lesley
Hall, Valorie
Sherman, El-Amin
Stewart, Chasity
Moulton, April
Sampson, Latisha
Watson, Marissa
Pardo, Ameriya
Benbow, Lindee
Ancrum, Zaylan
Shakur, Mahoni
Patterson, Iesha
Samuels, Kyree
Leysath, Herbert
Jackson, Javonte
McMillan, A'lasha
Douglas, Alexander
Luna, Mark
Ransome, Darrin
Pridgeon, Justin
Burdett, Quinn
Crawford jr, Fernando
Scott, Steven

Benbow, Jabrandis
Patterson, Jayla
Huling, Terry James
Ashford, Cameryn
Robinson, Angel

9E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH 01239	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Patterson Logistics Services, Inc.

Physical Address: 6419 South 228th Street, Suite 101

City: Kent State: WA Zip: 98032

Mailing Address (if different from physical address): 1031 Mendota Heights Rd. Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 803-691-2202 Website: www.pattersoncompanies.com

Name of Designated Representative (DR): John Benson

Licensing Company Email: facilitylicensing@pattersoncompa DR Email: john.benson@pattersoncompanies.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class I and Class II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: universities/res.facilities		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01.22.2024		SC	Blythewood	Richland
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		District of South Carolina on behalf of Drug Enforcement Agency		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Patterson Logistics Services, Inc.				

Provide explanation below:

On January 22, 2024, Patterson Logistics Services, Inc. ("PLSI") entered into a Settlement Agreement with the United States Attorney's Office for the District of South Carolina ("DOJ"), acting on behalf of the Drug Enforcement Administration ("DEA"), in which PLSI agreed to pay a fine of $45,500 with no associated admission of liability or guilt by PLSI. The allegations of the DEA are related primarily to certain record-keeping and reporting violations of the Controlled Substance Act. The DOJ and the DEA were satisfied with Patterson's corrective action measures, such that the matter was settled with no associated Memorandum of Understanding or ongoing reporting requirement for PLSI.

Original Signature (electronic, copies or stamps not accepted)

5/14/2025
Date

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into by and between the United States of America, acting through the United States Attorney's Office for the District of South Carolina, on behalf of the Drug Enforcement Administration ("DEA") (collectively, the "United States"), and Patterson Logistic Services Inc. ("Patterson") (together, "the Parties").

RECITALS

Patterson is currently registered with DEA Certificate of Registration #RP0349224 as a distributor authorized to handle controlled substances on Schedules II-V at its registered location, 925 Carolina Pines Boulevard, Suite B, Blythewood, South Carolina 29016 (the "Blythewood FC").

At all times relevant to this Agreement, Patterson was required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder, 21 C.F.R. Part 1300, *et seq.* (collectively "the CSA.")

Between January 31, 2023, and February 2, 2023, the DEA conducted an inspection at Blythewood FC. As a result of the inspection, the United States contends Patterson violated civil provisions of the CSA. Specifically, the United States contends that from January 31, 2021 through February 2, 2023, in regard to operations at Blythewood FC, Patterson violated certain suspicious order requirements, reporting requirements to ARCOS and order form and recordkeeping requirements pursuant to the CSA, specifically Title 21 Parts 1301, 1304, and 1305 of the CFR.

The conduct identified above at the Blythewood FC shall hereinafter be referred to as "Covered Conduct" and the identified time frame shall be referred to as "Covered Time Period."

The parties agree that this Agreement is not an admission of liability by Patterson, its

employees, or its agents for the Covered Conduct under the CSA nor a concession by the United States that its claims are not well-founded.

To avoid the uncertainty and expense of the adjudication of each claim, and of exhausting all administrative and legal remedies, the Parties desire to reach a mutual agreement that settles the above-referenced allegations without the United States filing a civil suit.

STIPULATIONS

In consideration of the foregoing and the mutual promises and obligations contained in this Agreement, the Parties agree and covenant as follows:

1. Patterson shall pay $45,500 (the "Settlement Amount") to the United States no later than 10 business days after counsel for Patterson receives the written electronic funds transfer instructions by the United States Attorney for the District of South Carolina.

2. By signing this Settlement Agreement, Patterson agrees to waive all rights to seek judicial review or to challenge or contest the validity of any terms or conditions of this Settlement Agreement.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Patterson's full payment of the Settlement Amount under this Agreement, the United States agrees to refrain from filing against Patterson any action for civil penalty claims under the CSA that is based on the Covered Conduct. In further consideration of Patterson's fulfillment of its obligations under this Agreement, expressly conditioned upon Patterson's timely paying the Settlement Amount and subject to the exceptions in Paragraph 5 (concerning excluded claims), below, the United States fully and finally releases Patterson and its parent, affiliates, insurers, agents, assigns, successors, predecessors, shareholders, principals, current and former employees,

management, officers, and directors from any civil or administrative claims the United States has, could have, or may assert in the future related to the Covered Conduct during the Covered Time Period.

4. Patterson fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including without limitation attorney's fees, costs, and expenses of every kind and however denominated) that Patterson has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, and servants, and agents related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Notwithstanding the release given in Paragraph 3 of this Settlement Agreement, or any other terms of this Agreement, the following claims of the United States are specifically reserved and not released:

a. Any liability arising under Title 26 of the United States Code;

b. Any criminal liability;

c. Any liability under the False Claims Act, 31 U.S.C. § 3729, or the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Except as explicitly stated in this Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;

f. Any liability based upon obligations created by this Agreement; and

g. Any liability of individuals except as expressly stated in Paragraph 3 of this Agreement.

6. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against Patterson

for violations of the CSA unrelated to the violations identified in the audit conducted between January 31, 2023 and February 2, 2023. Nothing in this Agreement, however, waives or limits Patterson's right or ability to raise any defenses to such an action.

7. The obligations imposed upon the United States and Patterson pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon each party pursuant to all applicable federal, state, and local laws and regulations, including, but not limited to the requirements in the CSA and its implementing regulations.

8. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

9. The Parties agree that any and all costs they have, will, or may incur, in connection with this matter—including payment of the Settlement Amount under this Agreement, attorneys' fees, costs of investigation, negotiation, past and future compliance efforts, and remedial action—shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVII and IXI of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

10. This Agreement is intended to be for the benefit of the Parties only. It does not provide any rights or benefits to third parties. The Parties do not release any claims against any other person or entity except as provided in Paragraph 15.

11. This Settlement Agreement may not be changed, altered, or modified except in writing signed by the parties hereto.

12. The Parties agree to bear their own respective costs and fees (including without

limitation attorneys' fees) incurred in connection with this matter, including those incurred in the preparation and performance of this Agreement.

13. The Parties acknowledge their promises in this Agreement are provided in exchange or valuable consideration provided by and through this Agreement.

14. The Parties consent to the United States' disclosure of this Agreement and information about this Agreement to the public.

15. This Settlement Agreement shall be binding upon and inure to the benefit of the assigns, successors-in-interest, or transferees of the Parties.

16. Each of the signatories to this Settlement Agreement represents and warrants that it/he/she has the full power and authority to enter into this Settlement Agreement on behalf of the person and entities indicated below, and further represents that it/he/she freely and voluntarily enters into this Agreement without any degree of duress or compulsion. Facsimiles of signatures and electronic transmissions of signatures (including transmittal and receipt of PDF versions of signatures) shall constitute acceptable, binding signatures for purposes of this Agreement.

17. The Settlement Agreement shall be final once signed by all parties below and shall be effective on the date the last signature is obtained. The Agreement may be executed in counterparts, each of which constitutes an original and all of which constitutes one and the same agreement.

18. This Settlement Agreement constitutes the complete agreement between the Parties with respect to the settlement of the United States' civil and administrative CSA claims against Patterson on the Covered Conduct from the Covered Time.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to the Agreement is the United States District Court for the District of South Carolina.

20. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

On behalf of Patterson Logistic Services Inc.

K. Reddy

Kirti Vaidya Reddy, Esq.
Quarles & Brady
(202) 372-9606
Kirti.Reddy@Quarles.com

January 18, 2024
Date

On behalf of the United States of America

ADAIR F. BOROUGHS
United States Attorney District of South Carolina

Beth Drake
Assistant United States Attorney

1/22/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054

Name: A-dec
Address: 2601 Crestview Drive City: Newberg State: OR Zip: 97132

Name: Solventum US LLC
Address: 2510 Conway Ave. E Ste 75-6W City: Maplewood State: MN Zip: 55144

Name: Ivoclar North America Inc.
Address: 175 Pineview Drive City: Amherst State: NY Zip: 14228

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Patterson Dental Supply,Inc.
Corporation/Organization Name: Patterson Logistics Services, Inc.
Mailing Address: 1031 Mendota Heights Rd.
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Patterson Logistics Services, Inc.

Facility Name

Leslie B. Korsh

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/14/2025

Date

Board Use Only	Date Received: 5/15/25	Amount: $1000cc

NABP ACCREDITED
DRUG DISTRIBUTOR

Patterson Logistics Services, Inc

located at

6419 South 228th Street, Suite 101, Kent, WA 98032

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

11/05/2023 - 11/04/2026
Period of Accreditation

PATTERSON

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Parent Company: Patterson Dental Supply, Inc.
Address: 1031 Mendota Heights Road
Saint Paul, MN 55120
Ownership: 100%
FEIN: 41-1833619

PATTERSON LOGISTICS SERVICES, INC. – Officer List

Corporate address: 1031 Mendota Heights Road
St. Paul, MN 55120
Phone Number: 651-686-1600
FEIN: 20-4404128
State of Incorporation: Minnesota - #1737876-2 (3/1/2006)

Robert J. Rajalingam **Chief Executive Officer**
Business Address: 1031 Mendota Heights Road
St. Paul, MN 55120
Business Phone: 651-686-1600
Email: Facilitylicensing@pattersoncompanies.com

Kevin M. Barry **Chief Financial Officer**
Business Address: 1031 Mendota Heights Road
St. Paul, MN 55120
Business Phone: 651-686-1600
Email: Facilitylicensing@pattersoncompanies.com

Leslie B. Korsh **Corporate Secretary**
Business Address: 1031 Mendota Heights Road
St. Paul, MN 55120
Business Phone: 651-686-1600
Email: Facilitylicensing@pattersoncompanies.com

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Patterson Logistics Services, Inc.
Date Filed:	03/01/2006
File Number:	1737876-2
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota
This certificate has been issued on:	12/16/2024

Steve Simon
Secretary of State
State of Minnesota

Washington State Department of Health

This organization

Patterson Logistics Services

is authorized by RCW 18.64 to have a

Pharmaceutical Wholesaler License

Operated by: **Patterson Logistics Services Inc**

Controlled Substance

Located at: **6419 S 228th St Ste 101**
Kent, WA 98032-1874

Secretary

Status
ACTIVE

Credential Number
PHWH.FX.00058990

Effective Date
10/01/2024

Expiration Date
09/30/2025

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0351736	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
6419 SOUTH 228 STREET
SUITE 101
KENT, WA 98032

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
6419 SOUTH 228 STREET
SUITE 101
KENT, WA 98032

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Form DEA-223 (9/2016)

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
06/04/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400	**CONTACT NAME:** Marsh | U.S. Operations & Technology **PHONE (A/C, No, Ext):** 866-966-4664 **FAX (A/C, No):** 212-948-5382 **E-MAIL ADDRESS:** Minneapolis.CertRequest@marsh.com	
	INSURER(S) AFFORDING COVERAGE	**NAIC #**
	INSURER A : Starr Indemnity & Liability Company	38318
INSURED Patterson Companies, Inc. and its subsidiaries and affiliates 1031 Mendota Heights Road St. Paul, MN 55120	**INSURER B :** Starr Specialty Insurance Company	16109
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** CHI-010950096-01 **REVISION NUMBER:** 4

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	2,000,000 1,000,000 0 2,000,000 10,000,000 4,000,000
A A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			1000198195241 (AOS) 1000198196241 (MA)	11/01/2024 11/01/2024	11/01/2025 11/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	3,000,000
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 25,000			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE AGGREGATE	$ $	5,000,000 5,000,000
B B B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		100 0005556 (AOS) 100 0005558 (FL,MA) 100 0005559 (WI)	11/01/2024 11/01/2024 11/01/2024	11/01/2025 11/01/2025 11/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence only.

CERTIFICATE HOLDER

Patterson Companies, Inc.
1031 Mendota Heights Road
St. Paul, MN 55120

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. **K41888490**

Application/License No. _____

Patterson Logistics Services, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is **6419 South 228th Street, Suite 101, Kent, WA 98032** (Address of Applicant/Principal), as PRINCIPAL, and **Federal Insurance Company** (Surety Company), a corporation organized under the laws of the state of **Indiana** (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is **202B Halls Mill Road, Whitehouse Station, NJ 08889-3454** (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on **February 25, 2025** (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25th day of February, 2025.

APPLICANT/PRINCIPAL
Patterson Logistics Services, Inc.

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY
Federal Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness JoAnn R. Frank

Witness Brittany D. Stuckel

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Cynthia L. Choren

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024.**

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this February 25, 2025

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Patterson Logistics Services, Inc. MDEG License # (if applicable):
Physical Address: 6419 South 228th Street, Suite 101
City: Kent State: WA Zip: 98032
Mailing Address (if different from physical address): 1031 Mendota Heights Road, Attn: Regulatory Licensing
City: Saint Paul State: MN Zip: 55120
Telephone: 253-850-4200 Website: www.pattersoncompanies.com
Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: John Middle: Carlton Last: Benson
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X
Mailing Address: [redacted]
City: Puyallup State: WA Zip: [redacted]
Telephone: [redacted] Email: John.Benson@pattersoncompanies.com
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Enumclaw High School		05/2010 - 09/2014	
Address	**City**	**State**	**Zip**
226 Semanski St S	Enumclaw	WA	98022
Diploma/Degree obtained, if any			
Graduated			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2020 - present	[redacted]	Puyallup	WA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
10/2017 - 03/2020		Kent	WA	
From - To (MM/YY – MM/YY)		City	State	
06/2013 - 10/2017		Enumclaw	WA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			05/2022 - Present	
Business Address		**City**	**State**	**Zip**
6419 South 228th Street, Suite 101		Kent	WA	98032
Phone	**Title**		**Number of Employed Hours**	
253-850-422	Department Manager		6000+	
Description of Duties				
Trains and develops all employees for an understanding in State and Federal Regulations. Manages and supervises inventory to contain pharmaceutical and controlled substance to achieve 100% cycle count effectiveness each quarter.				

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			09/2016 - 05/2022	
Business Address		**City**	**State**	**Zip**
6419 South 228th Street, Suite 101		Kent	WA	98032
Phone	**Title**		**Number of Employed Hours**	
253-850-4200	Supervisor		6000+	
Description of Duties				
Trains and develops all employees for an understanding in State and Federal Regulations. Manages and supervises inventory to contain pharmaceutical and controlled substance to achieve 100% cycle count effectiveness each quarter.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5-23-2025
Date

I, John Benson, **certify that as the MDEG Administrator for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements):

1. JB Have a high school diploma or its equivalent;
2. JB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Benson
Print Name (First, Last)

JB
Original Signature (electronic, copies or stamps not accepted)

5-23-2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Patterson Logistics Services, Inc.

Pharmacy/Wholesaler License # (if applicable): WH01239

Physical Address: 6419 South 228th Street, Suite 101

City: Kent State: WA Zip: 98032

Mailing Address (if different from physical address): 1031 Mendota Heights Rd. Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 253-850-4200 Website: www.pattersoncompanies.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: John Middle: Carlton Last: Benson

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Puyallup State: WA Zip: [redacted]

Telephone: [redacted] Email: John.Benson@pattersoncompanies.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Enumclaw High School		May/2010 - 09/2014	
Address	**City**	**State**	**Zip**
226 Semanski St S	Enumclaw	WA	98022
Diploma/Degree obtained, if any			
Graduated			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2020 - present	[redacted]	Puyallup	WA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
10/17 - 03/20		Kent	WA	
From - To (MM/YY – MM/YY)		City	State	
06/13 - 10/17		Enumclaw	WA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			05/22 - present	
Business Address		**City**	**State**	**Zip**
6419 South 228th Street, Suite 101		Kent	WA	98032
Phone	**Title**		**Number of Employed Hours**	
253-850-4200	Department Manager		6000+	
Description of Duties				
Trains and develops all employees for an understanding in State and Federal Regulations. Manages and supervises inventory to contain pharmaceutical and controlled substance to achieve 100% cycle count effectiveness each quarter.				

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			09/16 - 05/22	
Business Address		**City**	**State**	**Zip**
6419 South 228th Street, Suite 101		Kent	WA	98032
Phone	**Title**		**Number of Employed Hours**	
253-850-4200	Supervisor		6000+	
Description of Duties				
Trains and develops all employees for an understanding in State and Federal Regulations. Manages and supervises inventory to contain pharmaceutical and controlled substance to achieve 100% cycle count effectiveness each quarter.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4-25-2025
Date

I, John Benson, **certify that as the designated representative for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JB I am at least 21 years of age;
3. JB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

John Benson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4-25-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Benson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4-29-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Washington, ss. County of King

I, John Benson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4-29-2025

Date

Subscribed and Sworn to before me this 29 day of April, 2025.

Notary Public Signature

BECKY ANDERSON
Notary Public
State of Washington
Commission # 23031439
My Comm. Expires Oct 6, 2027

(Seal)

PATTERSON LOGISTICS

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Patterson Logistics Services, Inc.
Kent, WA – Employee List

Employee Name
Bassi, Virender K
Parr, Alysia Dawn
Mironov, Andrey Yuryevich
Cartwright, Dan C
Simmons, Jessica L
Tili, Elaine Faafouina
Benson, John C
Luther, Jodi L
Bueling, Julie A
Clark, Sammy D
Patterson, Errold
Perez-Gomez, Corina
McDowell, Rory
Ramos, Roxanne Rosalie
Alokoa, Ketty D
Heminna, Mohamed
Daniel, Gary
Guitron, Maricela
Tab, Chhoeub
Neneiya, Jane
Skilling, Tulpe
Funaki, Lupeau Pualani
Hassan, Mohamed Abdi
Rodriguez, Steve Vecino
Atonio, Peleiupu Samantha
Fili, Melepaea
Martin, Amelia Tonga
Kong, Veronica Chan
Hogan, Clifford
Mongkeya, Shra Chalsey
Anderson, Rebecca
de Vera, Roger
Nonan, Elsie
Ned, Lucy
Nithan, Ikaika-Brett
Ned, Luna-ladiva
Martin, Patrick
Star, Shania
Fili, Semisi
William, Robert
Brooks, Kathleen R
Zapata, Jorge

Searles, Austin
Nena, Billy
Altamirano, Edson
Rodriguez-Andrade, Elio
Carmona, Alexis
Galletch, Quinn
Phillip, Erica
Taulung, AJ

9F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 01744	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Patterson Logistics Services, Inc.

Physical Address: 7055 Cleveland Road

City: South Bend State: IN Zip: 46628

Mailing Address (if different from physical address): 1031 Mendota Heights Road Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 574-472-5800 Website: www.pattersoncompanies.com

Name of Designated Representative (DR): Kevin Mock

Licensing Company Email: facilitylicensing@pattersoncompa DR Email: kevin.mock@pattersondental.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Class I/II Medical Devices	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: universities/res.facilities		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01.22.2024		SC	Blythewood	Richland
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		District of South Carolina on behalf of Drug Enforcement Agency		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Patterson Logistics Services, Inc.				

Provide explanation below:

On January 22, 2024, Patterson Logistics Services, Inc. ("PLSI") entered into a Settlement Agreement with the United States Attorney's Office for the District of South Carolina ("DOJ"), acting on behalf of the Drug Enforcement Administration ("DEA"), in which PLSI agreed to pay a fine of $45,500 with no associated admission of liability or guilt by PLSI. The allegations of the DEA are related primarily to certain record-keeping and reporting violations of the Controlled Substance Act. The DOJ and the DEA were satisfied with Patterson's corrective action measures, such that the matter was settled with no associated Memorandum of Understanding or ongoing reporting requirement for PLSI.

Original Signature (electronic, copies or stamps not accepted)

5/6/25
Date

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into by and between the United States of America, acting through the United States Attorney's Office for the District of South Carolina, on behalf of the Drug Enforcement Administration ("DEA") (collectively, the "United States"), and Patterson Logistic Services Inc. ("Patterson") (together, "the Parties").

RECITALS

Patterson is currently registered with DEA Certificate of Registration #RP0349224 as a distributor authorized to handle controlled substances on Schedules II-V at its registered location, 925 Carolina Pines Boulevard, Suite B, Blythewood, South Carolina 29016 (the "Blythewood FC").

At all times relevant to this Agreement, Patterson was required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder, 21 C.F.R. Part 1300, *et seq.* (collectively "the CSA.")

Between January 31, 2023, and February 2, 2023, the DEA conducted an inspection at Blythewood FC. As a result of the inspection, the United States contends Patterson violated civil provisions of the CSA. Specifically, the United States contends that from January 31, 2021 through February 2, 2023, in regard to operations at Blythewood FC, Patterson violated certain suspicious order requirements, reporting requirements to ARCOS and order form and recordkeeping requirements pursuant to the CSA, specifically Title 21 Parts 1301, 1304, and 1305 of the CFR.

The conduct identified above at the Blythewood FC shall hereinafter be referred to as "Covered Conduct" and the identified time frame shall be referred to as "Covered Time Period."

The parties agree that this Agreement is not an admission of liability by Patterson, its

employees, or its agents for the Covered Conduct under the CSA nor a concession by the United States that its claims are not well-founded.

To avoid the uncertainty and expense of the adjudication of each claim, and of exhausting all administrative and legal remedies, the Parties desire to reach a mutual agreement that settles the above-referenced allegations without the United States filing a civil suit.

STIPULATIONS

In consideration of the foregoing and the mutual promises and obligations contained in this Agreement, the Parties agree and covenant as follows:

1. Patterson shall pay $45,500 (the "Settlement Amount") to the United States no later than 10 business days after counsel for Patterson receives the written electronic funds transfer instructions by the United States Attorney for the District of South Carolina.

2. By signing this Settlement Agreement, Patterson agrees to waive all rights to seek judicial review or to challenge or contest the validity of any terms or conditions of this Settlement Agreement.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Patterson's full payment of the Settlement Amount under this Agreement, the United States agrees to refrain from filing against Patterson any action for civil penalty claims under the CSA that is based on the Covered Conduct. In further consideration of Patterson's fulfillment of its obligations under this Agreement, expressly conditioned upon Patterson's timely paying the Settlement Amount and subject to the exceptions in Paragraph 5 (concerning excluded claims), below, the United States fully and finally releases Patterson and its parent, affiliates, insurers, agents, assigns, successors, predecessors, shareholders, principals, current and former employees,

management, officers, and directors from any civil or administrative claims the United States has, could have, or may assert in the future related to the Covered Conduct during the Covered Time Period.

4. Patterson fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including without limitation attorney's fees, costs, and expenses of every kind and however denominated) that Patterson has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, and servants, and agents related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Notwithstanding the release given in Paragraph 3 of this Settlement Agreement, or any other terms of this Agreement, the following claims of the United States are specifically reserved and not released:

a. Any liability arising under Title 26 of the United States Code;

b. Any criminal liability;

c. Any liability under the False Claims Act, 31 U.S.C. § 3729, or the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Except as explicitly stated in this Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;

f. Any liability based upon obligations created by this Agreement; and

g. Any liability of individuals except as expressly stated in Paragraph 3 of this Agreement.

6. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against Patterson

for violations of the CSA unrelated to the violations identified in the audit conducted between January 31, 2023 and February 2, 2023. Nothing in this Agreement, however, waives or limits Patterson's right or ability to raise any defenses to such an action.

7. The obligations imposed upon the United States and Patterson pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon each party pursuant to all applicable federal, state, and local laws and regulations, including, but not limited to the requirements in the CSA and its implementing regulations.

8. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

9. The Parties agree that any and all costs they have, will, or may incur, in connection with this matter—including payment of the Settlement Amount under this Agreement, attorneys' fees, costs of investigation, negotiation, past and future compliance efforts, and remedial action—shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVII and IXI of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

10. This Agreement is intended to be for the benefit of the Parties only. It does not provide any rights or benefits to third parties. The Parties do not release any claims against any other person or entity except as provided in Paragraph 15.

11. This Settlement Agreement may not be changed, altered, or modified except in writing signed by the parties hereto.

12. The Parties agree to bear their own respective costs and fees (including without

limitation attorneys' fees) incurred in connection with this matter, including those incurred in the preparation and performance of this Agreement.

13. The Parties acknowledge their promises in this Agreement are provided in exchange or valuable consideration provided by and through this Agreement.

14. The Parties consent to the United States' disclosure of this Agreement and information about this Agreement to the public.

15. This Settlement Agreement shall be binding upon and inure to the benefit of the assigns, successors-in-interest, or transferees of the Parties.

16. Each of the signatories to this Settlement Agreement represents and warrants that it/he/she has the full power and authority to enter into this Settlement Agreement on behalf of the person and entities indicated below, and further represents that it/he/she freely and voluntarily enters into this Agreement without any degree of duress or compulsion. Facsimiles of signatures and electronic transmissions of signatures (including transmittal and receipt of PDF versions of signatures) shall constitute acceptable, binding signatures for purposes of this Agreement.

17. The Settlement Agreement shall be final once signed by all parties below and shall be effective on the date the last signature is obtained. The Agreement may be executed in counterparts, each of which constitutes an original and all of which constitutes one and the same agreement.

18. This Settlement Agreement constitutes the complete agreement between the Parties with respect to the settlement of the United States' civil and administrative CSA claims against Patterson on the Covered Conduct from the Covered Time.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to the Agreement is the United States District Court for the District of South Carolina.

20. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

On behalf of Patterson Logistic Services Inc.

K. Reddy

Kirti Vaidya Reddy, Esq.
Quarles & Brady
(202) 372-9606
Kirti.Reddy@Quarles.com

January 18, 2024
Date

On behalf of the United States of America

ADAIR F. BOROUGHS
United States Attorney District of South Carolina

Beth Drake

Beth Drake
Assistant United States Attorney

1/22/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054

Name: ADEC
Address: 2601 Crestview Drive City: Newberg State: OR Zip: 97132

Name: Solventum US LLC
Address: 2510 Conway Ave E Ste 75-6W City: Maplewood State: MN Zip: 55144

Name: Ivoclar North America Inc.
Address: 175 Pineview Drive City: Amherst State: NY Zip: 14228

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Patterson Dental Supply, Inc.
Corporation/Organization Name: Patterson Logistics Services, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651.686.1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Patterson Logistics Services, Inc.

Facility Name

Leslie B. Korsh

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/6/25

Date

Board Use Only	Date Received: 5/15/25	Amount: $660.00

NABP ACCREDITED
DRUG DISTRIBUTOR

Patterson Logistics Services, Inc

located at

7055 Cleveland Rd, South Bend, IN 46628

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

12/06/2022 - 12/05/2025
Period of Accreditation

4893

PATTERSON

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Parent Company:	Patterson Dental Supply, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-1833619

PATTERSON LOGISTICS SERVICES, INC. – Officer List

Corporate address:	1031 Mendota Heights Road St. Paul, MN 55120
Phone Number:	651-686-1600
FEIN:	20-4404128
State of Incorporation:	Minnesota - #1737876-2 (3/1/2006)

Robert Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Kevin Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Leslie Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	Facilitylicensing@pattersoncompanies.com

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Patterson Logistics Services, Inc.
Date Filed:	03/01/2006
File Number:	1737876-2
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota
This certificate has been issued on:	12/16/2024

Steve Simon
Secretary of State
State of Minnesota

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000063A	09/30/2026

Patterson Logistics Services Inc
7055 Cleveland Road
South Bend IN 46628

Eric J. Holcomb
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000063A	**09/30/2026**

Patterson Logistics Services Inc

Signature

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

CSR

Registration Number	Expire Date
61101371B	12/31/2025

DRUG SCHEDULES

1	2	2N	3	3N	4	5
			Yes	Yes	Yes	Yes

Patterson Logistics Services Inc
7055 Cleveland Road
South Bend IN 46628

Eric J. Holcomb
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

CSR

Registration Number	Expire Date
61101371B	**12/31/2025**

Patterson Logistics Services Inc

Signature

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0414146	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
7055 CLEVELAND ROAD
SOUTH BEND, IN 466287724

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0414146	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
7055 CLEVELAND ROAD
SOUTH BEND, IN 466287724

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0414146	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES, INC.
7055 CLEVELAND ROAD
SOUTH BEND, IN 466287724

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/04/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 **FAX (A/C, No):** 212-948-5382
E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Starr Indemnity & Liability Company	38318
INSURER B : Starr Specialty Insurance Company	16109
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Patterson Companies, Inc.
and its subsidiaries and affiliates
1031 Mendota Heights Road
St. Paul, MN 55120

COVERAGES **CERTIFICATE NUMBER:** CHI-010950096-01 **REVISION NUMBER:** 4

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	0
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$	2,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$	10,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$	4,000,000
								$	
A	AUTOMOBILE LIABILITY			1000198195241 (AOS)	11/01/2024	11/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	3,000,000
A	X ANY AUTO			1000198196241 (MA)	11/01/2024	11/01/2025	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
A	X UMBRELLA LIAB X OCCUR			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	5,000,000
	DED X RETENTION $ 25,000							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			100 0005556 (AOS)	11/01/2024	11/01/2025	X PER STATUTE OTH-ER		
B	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A		100 0005558 (FL,MA)	11/01/2024	11/01/2025	E.L. EACH ACCIDENT	$	1,000,000
B	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			100 0005559 (WI)	11/01/2024	11/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence only

CERTIFICATE HOLDER
Patterson Companies, Inc.
1031 Mendota Heights Road
St. Paul, MN 55120

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. **K41888477**

Application/License No. _____

Patterson Logistics Services, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is **7055 Cleveland Road, South Bend, IN 46628** (Address of Applicant/Principal), as PRINCIPAL, and **Federal Insurance Company** (Surety Company), a corporation organized under the laws of the state of **Indiana** (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is **202B Halls Mill Road, Whitehouse Station, NJ 08889-3454** (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on **February 25, 2025** (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25th day of February, 2025.

APPLICANT/PRINCIPAL
Patterson Logistics Services, Inc.

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY
Federal Insurance Company

Cynthia L. Choren
Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

JoAnn R. Frank
Witness JoAnn R. Frank

Brittany D. Stuckel
Witness Brittany D. Stuckel

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Cynthia L. Choren

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024**.

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22, 2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this February 25, 2025

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Patterson Logistics Services, Inc. MDEG License # (if applicable):

Physical Address: 7055 Cleveland Road

City: South Bend State: IN Zip: 46628

Mailing Address (if different from physical address): 1031 Mendota Heights Road Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 651-686-1957 Website: www.pattersoncompanies.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Kevin Middle: Willis Last: Mock

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI[redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addres[redacted]

City: Berrien Springs State: MI Zip[redacted]

Telephon[redacted] Email: kevin.mock@pattersondental.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Siena Heights University		09/07-08/08	
Address	**City**	**State**	**Zip**
1247 E Siena Heights Drive	Adrian	MI	49921
Diploma/Degree obtained, if any			
Bachelors in Accounting			

School Name		From - To (MM/YY – MM/YY)	
Lake Michigan College		08/04-05/07	
Address	**City**	**State**	**Zip**
2755 E. Napier Avenue	Benton Harbor	MI	49022
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
Southwestern Michigan College		08/95-12/01	
Address	**City**	**State**	**Zip**
58900 Cherry Grove Road	Dowagiac	MI	49047
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Berrien Springs High School		09/91-05/95	
Address	**City**	**State**	**Zip**
201 Sylvester Avenue	Berrien Springs	MI	49103
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/04 - present	[redacted]	Berrien Springs	MI	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			05/22 - present	
Business Address		**City**	**State**	**Zip**
7055 Cleveland Road		South Bend	IN	46628
Phone	**Title**		**Number of Employed Hours**	
574-472-5794	Operations Manager		6000+	
Description of Duties				
Lead and direct all operations. Ensure compliance and adherence to state and federal regulations regarding the receipt, storage, inventory, and shipping of prescription drugs, including controlled substances.				

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			02/14 - 05/22	
Business Address		**City**	**State**	**Zip**
7055 Cleveland Road		South Bend	IN	46628
Phone	**Title**		**Number of Employed Hours**	
574-472-5794	Department Manager		6000+	
Description of Duties				
Trains and develops all employees for an understanding in State and Federal Regulations. Manages and supervises inventory to contain pharmaceutical and controlled substance to achieve 100% cycle count effectiveness each quarter.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

23 May 2025
Date

I, Kevin Mock, **certify that as the MDEG Administrator for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements):

1. KM Have a high school diploma or its equivalent;
2. KM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Mock
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

23 May 2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Patterson Logistics Services, Inc.

Pharmacy/Wholesaler License # (if applicable): WH01744

Physical Address: 7055 Cleveland Road

City: South Bend State: IN Zip: 46628

Mailing Address (if different from physical address): 1031 Mendota Heights Road Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 651.686.1957 Website: www.pattersoncompanies.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Kevin Middle: Willis Last: Mock

Alias(es, nicknames, name changes, etc.)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Berrien Springs State: MI Zip: [redacted]

Telephone: [redacted] Email: kevin.mock@pattersondental.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Siena Heights University			
Address	**City**	**State**	**Zip**
1247 E Siena Heights Drive	Adrian	MI	49921
Diploma/Degree obtained, if any			
Bachelors in Accounting			

School Name		From - To (MM/YY – MM/YY)	
Berrien Springs High School			
Address	**City**	**State**	**Zip**
201 Sylvester Avenue	Berrien Springs	MI	49103
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/04 - present	[redacted]	Berrien Springs	MI	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			05/22 - present	
Business Address		**City**	**State**	**Zip**
7055 Cleveland Road		South Bend	IN	46628
Phone	**Title**		**Number of Employed Hours**	
574-472-5794	Operations Manager		6000+	
Description of Duties				
Lead and direct all operations. Ensure compliance and adherence to state and federal regulations regarding the receipt, storage, inventory, and shipping of prescription drugs, including controlled substances.				

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			02/14 - 05/22	
Business Address		**City**	**State**	**Zip**
7055 Cleveland Road		South Bend	IN	46628
Phone	**Title**		**Number of Employed Hours**	
574-472-5794	Department Manager		6000+	
Description of Duties				
Trains and develops all employees for an understanding in State and Federal Regulations. Manages and supervises inventory to contain pharmaceutical and controlled substance to achieve 100% cycle count effectiveness each quarter.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A



Original Signature (electronic, copies or stamps not accepted)

29 APRIL 2025

Date

I, Kevin Mock, **certify that as the designated representative for**

Patterson Logistics Services, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KM I am at least 21 years of age;
3. KM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kevin Mock

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

29 APRIL 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Mock

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

29 April 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of St Joseph

I, Kevin Mock, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

29 April 2025

Date

Subscribed and Sworn to before me this 29th day of April 2025

Notary Public Signature

SANA MANSOUR
Notary Public
St Joseph County - State of Indiana
Commission Number NP0760799
My Commission Expires Jan 7, 2033

(Seal)

PATTERSON LOGISTICS

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Patterson Logistics Services, Inc. (PLSI) South Bend, IN – Employee List

Employee Name
Smeltzer, Chad
Lea, Jeffrey Jacob
Sult, Michael
Gorbitz, Emory Joseph
Tomaszewski, William Allen
Meiszberg, Brett
Roach, Clinton Lee
Mock, Kevin W
Kohler, Matthew
Giacherio, David John
Clayton, Brandon A
Wirebaugh, Jeremy D
Poorman, John E
Daly, Peter L
Vantornhout, Jeffrey
Booker, Laura J
Nelson, Lisa
Laurence, Adam A
Ford, Cherie J
Walz, Richard S
Ruess, Andrew Douglas
Barker, Joel A
Robinson, Matthew
Kelly, David A
Robinson, Kenneth Morgan
Treash, Lauren
Jackson, Chance
Lentz, Steven
Marshall, Andrew
Brown, Edward
Howard, Richard W
Kucharski, David
Austin, Nicolas
Williams, Joshua
Cabanaw, Shannon Renee
Green, William Robert
Hawkins, Willie I
Treash, Wendy R
Wirebaugh, Katherine Ann
Kowalski, Catherine Ann
Johnson, Crystal L
Schonbok, Debra
Marvin, Todd
Meyers, McKay

Sniadecki, David
Frisz, Scott J
Page, Jarrell L
Macri, Craig A
Vicsek, Angel J
Mullen, Leaha R
Dampier, Myron D
Taylor, Zachary B
Lopez, Marcos
Luccki, Angela Marie
Lopez, Christopher A
Piekarski, Patrick Michael
Dodge, Jody Ann
Metcalf, Annette
Kalu, Adrian
Kilberts, Alona D
Jacinto, Jack C
Adams, Jeffrey T
Spells, Lekia Mitsha
McLean, Lisa Marie
Lambert, Jason Wade
Wallace, Brittany Colleen
Howard, Ronald
Eiland, Jacquelyn Alexas
Davis, Michael C
Jackson, Johnathan R
Willard-Cantrell, Heidi Marie
Cowham, Blake Alan
Fussell, Tyler Zachary
Walton, Kyle
Clark, Kathleen
Fischer, Timothy
Collier, Nailah A
Smith, Darren M
Jordanek, Adam Joseph
Fischer, Eric
Watchorn, Travis
Austin, Steven
Beaty, Samuel Isaac
Nowicki, Dominic
Crawford, Chykeem
Douglass, Melissa
Williams, George
Fischer, Jennifer
Coy, Jennifer Ann
Kasprzak, Jasmin
Brazier, Sheila

Vivero, Erika
Horvath, Kyle
Hillring, Tracy
Viramontes, Mario
Ortega, Jesus
DeLaurelle, Siyara
Vargas, Oscar
Hix, Jordan
Terrones, Joshua
Martinez, Giselle
Jimenez, Sebastian
Miramontes, Sebastian
Jimenez, Jaime
Maxie, Dalvin Bryant
DeLuna, Isaac
Schmidtke, Aliyah
Causevic, Belmin
Trindade, Adrianna
Anderson, Will
Guzman, Javier
Coria, Andres
Mendoza, Luis
Pacheco, Alexis
Flores, Daniel
Semak, Brandon
Sanchez, Kevin
Johnson, Jonah
Spodnick, Caleb
Geates, Aiden
Petersen, Daniel
Ortega Diaz, Jose
Schmidtke, Evan
Ruiz, Alvaro
Young, Travis
Trancoso, Adrian
Miramontes, Ricardo

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	■ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 01236	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Patterson Dental Supply, Inc.

Physical Address: 6555 S Tenaya Way, #100

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): Attn: Regulatory Licensing, 1031 Mendota Heights Road

City: Saint Paul State: MN Zip: 55120

Telephone: 702-731-4267 Website: www.pattersoncompanies.com

Name of Designated Representative (DR): Jessica Jacob

Licensing Company Email: faciltiylicensing@pattersoncompa DR Email: jessie.jacob@pattersondental.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Medical Class I and Medical Class II devices.	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Universities/Research		■ Others: Virtual Wholesaler - No product onsite.

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Kristin L. Dingler

Original Signature (electronic, copies or stamps not accepted)

5/14/2025

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: ADEC
Address: 2601 Crestview Drive City: Newberg State: OR Zip: 97132
Name: Solventum US, LLC
Address: 2510 Conway Avenue, Ste 75-6W City: Maplewood State: MN Zip: 55144
Name: Ivoclar North America
Address: 175 Pineview Drive City: Amherst State: NY Zip: 14228
Name: Sirona Dental Systems, LLC
Address: 13320-B, Ballantyne Corporate Place City: Charlotte State: NC Zip: 28277

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Patterson Dental Holdings, Inc.
Corporation/Organization Name: Patterson Dental Supply, Inc.
Mailing Address: Attn: Regulatory Licensing, 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Patterson Dental Supply, Inc.

Facility Name

Kristin L. Dietzler

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5.14-2025

Date

Board Use Only	Date Received: 5/19/25	Amount: $1000-cc

Maria Herrera

From: Facility Licensing <facilitylicensing@pattersoncompanies.com>
Sent: Wednesday, May 28, 2025 2:12 PM
To: Maria Herrera
Cc: Karau, Kelley
Subject: RE: Nevada Out-of-State Wholesaler Application-Patterson Dental Supply, Inc.
Attachments: PDSI - Salt Lake City - NV(WS) - WH01542 - MDEG (Mortensen-signed) - CHOW.pdf; PDSI - Roseville - NV(WS) - WH01358 - MDEG (Montoya-signed) - CHOW.pdf; PDSI - Mesa - NV(WS) - WH02259 - MDEG (Tyler-signed) - CHOW.pdf; PDSI - Las Vegas - NV(WS) - WH01236 - MDEG (Jacob-signed) - CHOW.pdf; Patterson - COI - General Liability - Exp 11.01.2025 .pdf; PDSI - Mesa - NV(WS) - WH02259 - MDEG (Tyler-signed) - CHOW.pdf; NV - KO7562019 Las Vegas NV 432.pdf; PDSI - Roseville - NV(WS) - WH01358 - Cara Montoya DR Applic Signed.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Ms. Herrera, in response to your deficiency email below for Patterson Dental Supply, Inc. - please find the following:

For all applications, WH01542 (SLC,UT), WH01358 (Roseville, CA), WH02259 (Mesa, AZ), & WH01236 (Las Vegas, NV)

- The completed MDEG Administrator applications for each of the Licenses identified above.
- A copy of the Patterson Companies, Inc. – COI that covers all subsidiaries of Patterson Companies, Inc.
- Confirming FDA Labeler code for Patterson Dental Supply, Inc. as: Labeler DUNS is: 006962500

WH02259 – Patterson Dental Supply, Inc. – DR Tyler Banks

- An updated Designated Representative application that includes a completed Section 6.

WH01236 – Patterson Dental Supply, Inc. (Las Vegas NV)

- An updated Surety Bond #KO7562019 with required signatures.

WH01358 – Patterson Dental Supply, Inc. (Roseville CA – DR Cara Montoya)

- Please note: The DR application for Cara Montoya has an incorrect email address listed on page 2. Please update email to: cara.montoya@pattersondental.com
- An updated copy of the Designated Rep application for Cara Montoya is attached.

An official website of the United States government Here's how you know

FDA

Current through May 22, 2025

You have searched Finished drug products

Search Results: *'50227'*

Back to Search Page

Showing 1 to 1 of 1 entries (filtered from 14 total entries) Show 50 entr

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product N
Mepivacaine	50227-1080-5	30mg/mL	INJECTION, SOLUTION	SUBMUCOSAL	ANDA088387	Patterson Dental Supply, Inc.	50227-108

Previous 1 Next

PATTERSON

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Parent Company:	Patterson Dental Holdings, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	20-3380268
State of Incorporation:	Minnesota

PATTERSON DENTAL SUPPLY, INC. – Officer List

Corporate Address:	1031 Mendota Heights Road, St. Paul, MN 55120
Phone Number:	651-686-1600
FEIN:	41-1833619
State of Incorporation:	Minnesota - #9C-524 (3/22/1996)

Robert J. Rajalingam	**Chief Executive Officer**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	FacilityLicensing@Pattersoncompanies.com

Kristin L. Dietzler	**President**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	FacilityLicensing@Pattersoncompanies.com

Kevin M. Barry	**Chief Financial Officer**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	FacilityLicensing@Pattersoncompanies.com

Leslie B. Korsh	**Corporate Secretary**
Business Address:	1031 Mendota Heights Road St. Paul, MN 55120
Business Phone:	651-686-1600
Email:	FacilityLicensing@Pattersoncompanies.com

Effective 4/22/2025

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Patterson Dental Supply, Inc.
Date Filed:	03/22/1996
File Number:	9C-524
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota
This certificate has been issued on:	12/30/2024

Steve Simon
Secretary of State
State of Minnesota

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/04/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 FAX (A/C, No): 212-948-5382
E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Starr Indemnity & Liability Company	38318
INSURER B : Starr Specialty Insurance Company	16109
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Patterson Companies, Inc.
and its subsidiaries and affiliates
1031 Mendota Heights Road
St. Paul, MN 55120

COVERAGES **CERTIFICATE NUMBER:** CHI-010950096-01 **REVISION NUMBER:** 4

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			1000100137241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	0
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	10,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	4,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY			1000198195241 (AOS)	11/01/2024	11/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	3,000,000
A	X ANY AUTO			1000198196241 (MA)	11/01/2024	11/01/2025	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
A	X UMBRELLA LIAB X OCCUR			1000589674241	11/01/2024	11/01/2025	EACH OCCURRENCE	$	5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	5,000,000
	DED X RETENTION $ 25,000							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			100 0005556 (AOS)	11/01/2024	11/01/2025	X PER STATUTE OTH-ER		
B	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N: N	N / A		100 0005558 (FL,MA)	11/01/2024	11/01/2025	E.L. EACH ACCIDENT	$	1,000,000
B	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			100 0005559 (WI)	11/01/2024	11/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
B	Workers Compensation			100 0005557 (AK,AZ,CT,IA,NJ,NY,NC,TX,VT)	11/01/2024	11/01/2025	Limits		See Above

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence only.

CERTIFICATE HOLDER
Patterson Companies, Inc.
1031 Mendota Heights Road
St. Paul, MN 55120

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

555 Double Eagle Court #1100
Reno, Nevada 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K07562019

Application/License No. WH01236

Patterson Dental Supply Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 6555 S. Tenaya Way, Suite 100, Las Vegas, NV 89113 (Address of Applicant/Principal), as PRINCIPAL, and Westchester Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 525 W. Monroe, Chicago, IL 60661 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 1 2006 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal

may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 2nd day of October, 20 06

APPLICANT/PRINCIPAL
Patterson Dental Supply Inc.

Authorized Representative

SURETY COMPANY
Westchester Fire Insurance Company

Surety Company's Representative

Cynthia L. Hanak, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent 10/3/06
Countersigned for Nevada By
Marsh USA, Inc.
Michele Robertson, Resident Agent

ACKNOWLEDGMENT BY SURETY

STATE OF Missouri }
City of St. Louis } ss.

On this 2nd day of October, 2006, before me personally appeared Cynthia L. Hanak, known to me to be the Attorney-in-Fact of Westchester Fire Insurance Company, the corporation that executed the within instrument, and acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

My Commission Expires: November 15, 2009.

(Seal) KAREN L. ROIDER
NOTARY PUBLIC - NOTARY SEAL
STATE OF MISSOURI, ST. LOUIS CITY
MY COMMISSION EXPIRES 11-15
COMMISSION #05401551

Karen L. Roider
Notary Public in the State of Missouri
City of St. Louis

S-0230/GEEF 2/98

Power of Attorney

WESTCHESTER FIRE INSURANCE COMPANY

1143373

324011

Know all men by these presents: That **WESTCHESTER FIRE INSURANCE COMPANY**, a corporation of the State of New York, having its principal office in the City of Atlanta, Georgia, pursuant to the following Resolution, adopted by the Board of Directors of the said Company on November 8, 1999, to wit:

"RESOLVED, that the following Rules shall govern the execution for the Company of bonds, undertakings, recognizances, contracts and other writings in the nature thereof.

(1) That the President, any Senior Vice President, any Vice President, and Assistant Vice President, or any Attorney-in-Fact, may execute for and on behalf of the Company any and all bonds, undertakings, recognizances, contracts and other writings in the nature thereof, the same to be attested when necessary by the Corporate Secretary, or any Assistant Corporate Secretary, and the seal of the Company affixed thereto; and that the President, any Senior Vice President, any Vice President or any Assistant Vice President may appoint and authorize any other Officer (elected or appointed) of the Company, as Attorneys-In-Fact to so execute or attest to the execution of all such writings on behalf of the Company and to affix the seal of the Company thereto.

(2) Any such writing executed in accordance with these Rules shall be as binding upon the Company in any case as though signed by the President and attested to by the Corporate Secretary.

(3) The signature of the President, or a Senior Vice President, or a Vice President, or an Assistant Vice President and the seal of the Company may be affixed by facsimile on any power of attorney granted pursuant to this Resolution, and the signature of a certifying Officer and the seal of the Company may be affixed by facsimile to any certificate of any such power, and any such power or certificate bearing such facsimile signature and seal shall be valid and binding on the Company.

(4) Such other Officers of the Company, and Attorneys-In-Fact shall have authority to certify or verify copies of this Resolution, the By-Laws of the Company, and any affidavit or record of the Company necessary to the discharge of their duties.

(5) The passage of this Resolution does not revoke any earlier authority granted by Resolutions of the Board of Directors."

Does hereby nominate, constitute and appoint PAMELA A. BEELMAN, HEIDI A. NOTHEISEN, CYNTHIA L. HANAK, DEBRA C. SCHNEIDER, JOANN R. FRANK, KAREN L. ROIDER and SANDRA L. HAM all of the City of Saint Louis, State of Missouri, each individually if there be more than one named, its true and lawful attorney-in-fact, to make, execute, seal and deliver on its behalf, and as its act and deed any and all bonds, undertakings, recognizances, contracts and other writings in the nature thereof in penalties not exceeding Ten Million Dollars ($10,000,000) and the execution of such writings in pursuance of these presents shall be as binding upon said Company, as fully and amply as if they had been duly executed and ackowledged by the regularly elected officers of the Company at its principal office.

IN WITNESS WHEREOF, the said Stephen M. Haney, Vice-President, has hereunto subscribed his name and affixed the corporate seal of the said **WESTCHESTER FIRE INSURANCE COMPANY**, this 17th day of March, 2006.

WESTCHESTER FIRE INSURANCE COMPANY

Stephen M. Haney, Vice President

COMMONWEALTH OF PENNSYLVANIA
COUNTY OF PHILADELPHIA ss.

On this 17th day of March, A.D. 2006, before me, a Notary Public of the Commonwealth of Pennsylvania in and for the County of Philadelphia, came Stephen M. Haney, Vice-President of the **WESTCHESTER FIRE INSURANCE COMPANY** to me personally known to be the individual and officer who executed the preceding instrument, and he acknowledged that he executed the same, and that the seal affixed to the preceding instrument is the corporate seal of said Company; that the said corporate seal and his signature were duly affixed by the authority and direction of the said corporation, and that Resolution, adopted by the Board of Directors of said Company, referred to in the preceding instrument, is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Philadelphia the day and year first above written.

NOTARIAL SEAL
Kathleen Tirri, Notary Public
Philadelphia, Philadelphia County
My commission expires September 22, 2007

Notary Public

I, the undersigned Secretary of **WESTCHESTER FIRE INSURANCE COMPANY**, do hereby certify that the original POWER OF ATTORNEY, of which the foregoing is a substantially true and correct copy, is in full force and effect.

In witness whereof, I have hereunto subscribed my name as Secretary, and affixed the corporate seal of the Corporation, this 2nd day of October 2006

George D. Mulligan, Secretary

THIS POWER OF ATTORNEY MAY NOT BE USED TO EXECUTE ANY BOND WITH AN INCEPTION DATE AFTER March 17, 2008

FORM NO. 8905

THIS DOCUMENT LISTS VARIOUS SECURITY FEATURES THAT WILL PROTECT AGAINST COPY COUNTERFEIT AND ALTERATION.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Patterson Dental Supply, Inc. MDEG License # (if applicable): _____

Physical Address: 6555 S Tenaya Way, #100

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): Attn: Regulatory Licensing, 1031 Mendota Heights Road

City: Saint Paul State: MN Zip: 55120

Telephone: 702-731-4267 Website: www.pattersoncompanies.com

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Jessica Middle: Johana Last: Jacob

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Addres: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Valley View High School		09/1990 - 09/1994	
Address	**City**	**State**	**Zip**
13135 Nason St	Moreno Valley	CA	92555
Diploma/Degree obtained, if any			
Graduated			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2005 - Ongoing	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Patterson Dental Supply, Inc.			06/2021 - Ongoing	
Business Address		**City**	**State**	**Zip**
6555 S Tenaya Way, #100		Las Vegas	NV	89113
Phone	**Title**		**Number of Employed Hours**	
701-731-4267	TechEdge Services Coordinator		6000+	
Description of Duties				
Manages TechEdge technicians and service order life-cycle, ensuring prompt and effective service scheduling, optimizing operational efficiency. Actively aware of daily operations of wholesaler.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

05/23/2025
Date

I, Jessica Jacob, **certify that as the MDEG Administrator for**

Patterson Dental Supply, Inc.,

that I (initial that you have read and meet the following requirements):

1. _____ Have a high school diploma or its equivalent;
2. _____ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. _____ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. _____ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Jacob

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/23/2025

Date

Board Use Only	Date Received: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Patterson Dental Supply, Inc.

Pharmacy/Wholesaler License # (if applicable) WH01236

Physical Address 6555 S Tenaya Way, #100

City Las Vegas State NV Zip 89113

Mailing Address (if different from physical address) Attn: Regulatory Licensing, 1031 Mendota Heights Road

City Saint Paul State MN Zip 55120

Telephone 702-731-4267 Website www.pattersoncompanies.com

Licensing Company Email facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First Jessica Middle Johana Last Jacob

Alias(es, nicknames, name changes, etc.) _____

Date of Birt[redacted] SSN or ITI[redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip[redacted]

Telephone[redacted] Email jessie.jacob@pattersondental.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Valley View High School		09/1990 - 09/1994	
Address	**City**	**State**	**Zip**
13135 Nason St	Moreno Valley	CA	92555
Diploma/Degree obtained, if any			
Graduated			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2005 - Ongoing	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Patterson Dental Supply, Inc.			06/2021 - Ongoing	
Business Address		**City**	**State**	**Zip**
6555 S. Tenaya Way, #100		Las Vegas	NV	89113
Phone	**Title**		**Number of Employed Hours**	
701-731-4267	TechEdge Services Coordinator		6000+	
Description of Duties				
Manages TechEdge technicians and service order life-cycle, ensuring prompt and effective service scheduling, optimizing operational efficiency. Actively aware of daily operations of wholesaler.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

04/23/2025
Date

I, Jessica Jacob, **certify that as the designated representative for**

Patterson Dental Supply, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jessica Jacob

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/23/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Jacob

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/23/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Jessica Jacob, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04/24/2025

Date

Subscribed and Sworn to before me this 24 day of April 2025.

Notary Public Signature

Notary Public - State of Nevada
COUNTY OF CLARK
LILITH LAUZURICA
(Seal)
My Appointment Expires
No. 25-1330-01 FEBRUARY 17, 2029

PATTERSON DENTAL

1031 Mendota Heights Road

Saint Paul, MN 55120

Patterson Dental Supply, Inc.
Las Vegas NV – Employee List

Legal Name
Kankelborg, Ryan J
Aird, John R
Castro, Vincent J
Jacob, Jessica Johana
Johnson, Justin Paul
Mays, Stanley Calvin
Lamoure, Jennifer A
Winfield, Kirsten
Tipper, Kyle
Grelecki, Michael

11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Y.

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☑ Schedule II ☐ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: Eric Middle: Colburn Last: Disbrow

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone [redacted] Email: [redacted]

Degree: MD Practitioner License #: 24369 Specialty: F.P.

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Student Outreach Clinic

Practice Address: 740 W. Moana Ln Suite #:

City: Reno State: NV Zip: 89509

Telephone: Fax: Email:

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? ?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/16/2021	3/30/2022	Ca	Atwater, Ca	Merced
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
800-2018-045589	Attorney General California			
Reason/Charge				
Inappropriate prescribing of controlled Substances				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Erica Dizbrow		Mediation		
Name of Business/Industry/Entity				
Atwater Medical Group				

Provide explanation below:

see pg 2, p. 3

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/27/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Eric Dubrow — Print Name (First, Last)

5/27/25 — Date

[redacted] — Original Signature (electronic, copies or stamps not accepted)

5/27/25 — Date

Board Use Only: Date Processed: 6/3/25 Amount: $200 CC

Eric Colburn Disbrow

License Number:
24369

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Sep-18-2023

Expiration Date:
Jun-30-2027

Public Address:
[redacted]

Public City:
Reno

Public State:
Nevada

Public ZIP Code:
[redacted]

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Family Medicine
Family Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
Albany Medical College	Medical Doctor Degree	Sep-08-1966	May-28-1970

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
University of California Davis Health Program	Internship	Surgery,General	Jul-01-1970	Jun-30-1971
University of California Davis Health Program	Residency	Surgery,General	Jul-01-1971	Jun-30-1972

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

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Memo of explanation to Nevada State Board of Pharmacy 5/22/2025

Regarding public reprimand for Eric C. Disbrow MD

I was served by the Medical Board of California with the accusation on June 16, 2021. I hired Dr. Firestone MD JD to defend me. On March 11, 2022 a settlement conference was convened. Ms. Lynette Hecker MD for the board, Dr. Marvin Firestone, MD JD, myself and a judge, mediated the accusation. The result (see attachment number 1 an email from Ms. Hecker to Dr. Firestone) was that the original accusation was amended alleging only documentation/record keeping departures. It should be noted that the "factual allegations" on page 6-12 of the 1st amended accusation were not supported, there was no inappropriate prescribing, and except for the record keeping, "the factual allegations" were not pursued by Ms. Hecker. Pag 12-14 of the 1st amended accusation reflects only record keeping issues. (See attachment 2). On page 4 of the stipulated settlement paragraph A I was given a public reprimand for record keeping (see attachment 3). My initial reaction was to continue the fight; but then reality set in! My defense had already cost me $60,000. My attorney informed me that to take this to a hearing would cost another $50-$100,00. He also stated the state always takes their "pound of flesh" and that this was a good outcome. My license to practice in California and my DEA license were in no way restricted and I was free to continue to practice medicine with no restrictions. Indeed, on June 22, 2022 my DEA license was renewed until June 30, 2025 and my California license was renewed until January 1, 2025 and renewed again until 1/31/2027. My Nevada license was issued 9/18/2023 and was recently renewed and expires on 6/30/2027. The fact that there were no limitations placed on my California license, my Nevada license, and DEA license underscores the fact there was no inappropriate prescribing.

Respectfully submitted,

[redacted]

Eric C. Disbrow, MD

See attached pages and documents:

Page 1 Email from Lynette Hecker to MR. Firestone

Page 2 First amended accusation

Page 3 Stipulated settlement and disciplinary order

Page 4 California Medical License

Page 5 Nevada Medical License renewal

Page 1 Email from Lynette Hecker to MR. Firestone

Page 2 First amended accusation

Page 3 Stipulated settlement and disciplinary order

Page 4 California Medical License

Page 5 Nevada Medical License renewal

From: Marvin H. Firestone [redacted]
Subject: FW: Amended Accusation & Stip - Eric Disbrow, MD
Date: Mar 25, 2022 at 12:18:38 PM
To: Eric Disbrow [redacted]

FYI

From: Lynette Hecker [redacted]
Sent: Friday, March 25, 2022 12:12 PM
To: Marvin H. Firestone [redacted]
Subject: Amended Accusation & Stip - Eric Disbrow, MD
Importance: High

Greetings Mr. Firestone,

You are welcome! My goal and that of the Board's is to always strive for accuracy and fairness.

We have accounted for the information you provided yesterday. The Accusation is being amended to allege only documentation/recordkeeping departures (attached). It will likely not be singed and served until next week as Mr. Prasifka is out of the office this afternoon.

For your convenience, I've also attached the Stip. Please return signature pages once you and Dr. Disbrow have signed and dated accordingly. I will thereafter sign and submit it to OAH to have the hearing taken off calendar.

As always, please do not hesitate to contact me if you have any questions or wish to discuss anything regarding this matter in further detail. Take care and stay safe!

Very truly yours,

Lynette D. Hecker
Deputy Attorney General
Health Quality Enforcement Section
Civil Division, Attorney General's Office
California Department of Justice
[redacted]

CONFIDENTIALITY NOTICE: This communication with its contents may contain confidential and/or legally privileged information. It is solely for the use of the intended recipient(s). Unauthorized

ROB BONTA
Attorney General of California
STEVE DIEHL
Supervising Deputy Attorney General
LYNETTE D. HECKER
Deputy Attorney General
State Bar No. 182198
California Department of Justice
2550 Mariposa Mall, Room 5090
Fresno, CA 93721
Telephone: (559) 705-2320
Facsimile: (559) 445-5106
Attorneys for Complainant

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **Eric Colburn Disbrow, M.D.** [redacted] **Atwater, CA** [redacted] **Physician's and Surgeon's Certificate No. G 21038,** Respondent.	Case No. 800-2018-045589 **FIRST AMENDED ACCUSATION**

PARTIES

1. William Prasifka (Complainant) brings this First Amended Accusation solely in his official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On or about August 9, 1971, the Medical Board issued Physician's and Surgeon's Certificate Number G 21038 to Eric Colburn Disbrow, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2023, unless renewed.

///

///

JURISDICTION

3. This First Amended Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 2227 of the Code states:

> (a) A licensee whose matter has been heard by an administrative law judge of the Medical Quality Hearing Panel as designated in Section 11371 of the Government Code, or whose default has been entered, and who is found guilty, or who has entered into a stipulation for disciplinary action with the board, may, in accordance with the provisions of this chapter:
>
> (1) Have his or her license revoked upon order of the board.
>
> (2) Have his or her right to practice suspended for a period not to exceed one year upon order of the board.
>
> (3) Be placed on probation and be required to pay the costs of probation monitoring upon order of the board.
>
> (4) Be publicly reprimanded by the board. The public reprimand may include a requirement that the licensee complete relevant educational courses approved by the board.
>
> (5) Have any other action taken in relation to discipline as part of an order of probation, as the board or an administrative law judge may deem proper.
>
> (b) Any matter heard pursuant to subdivision (a), except for warning letters, medical review or advisory conferences, professional competency examinations, continuing education activities, and cost reimbursement associated therewith that are agreed to with the board and successfully completed by the licensee, or other matters made confidential or privileged by existing law, is deemed public, and shall be made available to the public by the board pursuant to Section 803.1.

5. Section 2234 of the Code, states:

> The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:
>
> (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
>
> (b) Gross negligence.
>
> (c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

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(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

(d) Incompetence.

(e) The commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon.

(f) Any action or conduct that would have warranted the denial of a certificate.

(g) The failure by a certificate holder, in the absence of good cause, to attend and participate in an interview by the board. This subdivision shall only apply to a certificate holder who is the subject of an investigation by the board.

6. Section 2266 of the Code states: The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct.

COST RECOVERY

7. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case[1], with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DEFINITIONS

8. Acetaminophen and hydrocodone bitartrate (Vicodin® and Norco®) is a combination of two medicines used to treat moderate to severe pain. Hydrocodone is an opioid pain medication, commonly referred to as a narcotic. Acetaminophen is a less potent pain reliever that

[1] As of November 18, 2021, Section 125.3 of the Code has been amended to remove subsection (k), which precluded the Board from collecting costs. The Board may collect investigation, prosecution, and other costs incurred for a disciplinary proceeding against a licensee beginning January 1, 2022.

increases the effects of hydrocodone. Hydrocodone has a high potential for abuse. Hydrocodone is a Schedule II controlled substance and narcotic as defined by section 11055, subdivision (b)(1) of the Health and Safety Code, and a Schedule II controlled substance as defined by Section 1308.12 (b)(1) of Title 21 of the code of Federal Regulations and a dangerous drug as defined in Business and Professions Code section 4022.

9. Alprazolam (Xanaz®) is in the class of benzodiazepine medications. It affects chemicals in the brain that may be unbalanced in people with anxiety. Xanax is used to treat anxiety disorders, panic disorders, and anxiety caused by depression. Xanax has the potential for abuse. Xanax is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions Code section 4022.

10. Arthralgia is pain in one or more of a person's joints. The pain may be described as sharp, dull, stabbing, burning or throbbing, and may range in intensity from mild to severe. There are many causes of arthralgia, including injury, infection, arthritis, and other ailments.

11. Cervicalgia is a common term used to describe neck pain -- often referred to as a "crick in the neck." General neck pain can arise from various causes including poor posture, muscle fatigue from overuse or even from poor sleeping positions.

12. Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease that causes obstructed airflow from the lungs. Symptoms include breathing difficulty, cough, mucus (sputum) production and wheezing.

13. Fentanyl transdermal (Duragesic®) patches are a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (c), and a dangerous drug pursuant to Business and Professions Code section 4022. Fentanyl transdermal system is a means for conveyance of fentanyl to the patient via a patch that adheres to the skin, releasing the substance via absorption, over time. When properly prescribed and indicated fentanyl transdermal patches are indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long term opioid treatment and for which alternative treatment options are inadequate. The FDA has issued several black box warnings about fentanyl

transdermal patches including, but not limited to, the risks of addiction, abuse and misuse; life threatening respiratory depression; accidental exposure; neonatal opioid withdrawal syndrome; and the risks associated with the concomitant use with benzodiazepines or other CNS depressants.

14. Klonopin® (clonazepam), a benzodiazepine, is a centrally acting hypnotic-sedative that is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions Code section 4022. When properly prescribed and indicated, it is used to treat seizure disorders and panic disorders. Concomitant use of Klonopin® with opioids "may result in profound sedation, respiratory depression, coma, and death." The Drug Enforcement Administration (DEA) has identified benzodiazepines, such as Klonipin®, as drug of abuse. (Drugs of Abuse, DEA Resource Guide (2011 Edition), at p. 53.) Klonopin® has a half-life of 20-50 hours such that twice daily dosing is usually sufficient to prevent a build-up of bioavailable medication. Caution is advised when prescribed in combination with hydromorphone due to an increased risk of respiratory depression.

15. Methadone is an opioid medication that has a high potential for abuse. It is a dangerous drug as defined in section 4022 and a Schedule II controlled substance and narcotic as defined by section 11055 of the Health and Safety Code. Methadone is used as a pain reliever and as part of drug addiction detoxification and maintenance programs. It may cause a prolonged QT interval (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death).

16. Myalgia describes muscle aches and pain, which can involve ligaments, tendons and fascia, the soft tissues that connect muscles, bones and organs. Injuries, trauma, overuse, tension, certain drugs and illnesses can all bring about myalgia.

17. Naprosyn is a prescription medicine used to treat the symptoms of pain or inflammation caused by arthritis, ankylosing spondylitis, tendinitis, bursitis, gout or menstrual cramps. Naprosyn may be used alone or with other medications. Naprosyn is a nonsteroidal anti-inflammatory medication (NSAID) and is not a controlled substance.

18. Oxycodone is an opioid pain medication, commonly referred to as a narcotic. Oxycodone has a high potential for abuse. Oxycodone is a Schedule II controlled substance and narcotic as defined by section 11055, subdivision (b)(1) of the Health and Safety Code, and a

Schedule II controlled substance as defined by Section 1308.12 (b)(1) of Title 21 of the code of Federal Regulations and a dangerous drug as defined in Business and Professions Code section 4022. Oxycodone should be used with caution and started in a reduced dosage (1/3 to 1/2 of the usual dosage) in patients who are concurrently receiving other central nervous system depressants including sedatives or hypnotics, general anesthetics, phenothiazines, other tranquilizers, and alcohol. The Drug Enforcement Administration ("DEA") has identified opioids, such as oxycodone, as a drug of abuse. (Drugs of Abuse, DEA Resource Guide (2011 Edition), at p. 41.) Respiratory depression is the chief hazard from all opioid agonist preparations.

19. Peripheral neuropathy refers to the conditions that result when nerves that carry messages to and from the brain and spinal cord from and to the rest of the body are damaged or diseased. The peripheral nerves make up an intricate network that connects the brain and spinal cord to the muscles, skin, and internal organs.

20. Stenosis, which means narrowing, can cause pressure on the spinal cord or the nerves that go from the spinal cord to muscles. Spinal stenosis can happen in any part of the spine but is most common in the lower back. This part of your spine is called the lumbar area.

21. Trigger finger is a condition in which a finger gets stuck in a bent position. The finger may bend or straighten with a snap — like a trigger being pulled and released. Trigger finger is also known as stenosing tenosynovitis because it is caused by a narrowing of the structures around the affected tendon.

FACTUAL ALLEGATIONS[2]

22. Respondent is Board-Certified in family practice and geriatric medicine. Respondent works approximately three days a week at Atwater Medical Clinic and attends to nursing homes the rest of the week. All five of the patients whose care and treatment is the subject of this case came under Respondent's care at Atwater Medical Clinic.

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[2] Events prior to May 2014 are beyond the statute of limitations and are included for background purposes only.

CIRCUMSTANCES RELATED TO PATIENT A[3]

23. Patient A is a 57-year-old male with a history of anxiety, COPD, depression, fatigue, high cholesterol, lumbar disc disease, obstructive sleep apnea, osteoarthritis of the ankle, multiple ankle surgeries, and peripheral neuropathy. Patient A presented to Respondent approximately once a month, or every other month from on or about September 1, 2011, through on or about August 7, 2018, for routine health care for his chronic medical problems, including refills for his Norco and Xanax medications.

24. Respondent's medical records consistently reflect similar and at times identical verbiage in the history of present illness section when describing Patient A's ankle pain. Respondent consistently characterized Patient A's ankle pain as "constant and severe; aggravated with weight bearing; denies ankle instability, numbness, swelling and weakness."

25. The only aspect Respondent documented of Patient A's musculoskeletal condition related to his ankle is "no edema or significant varicosities, gait: affected by limp." Further, while Respondent noted that Patient A was sent for diagnostic imaging studies for his chronic ankle issues, and referred to an orthopedic specialist in or around 2014, Respondent failed to document make any attempts to decrease or otherwise prescribe any non-controlled substances for Patient A. There was insufficient basis documented to support the ongoing prescribing of Norco and Xanax for Patient A.

26. Respondent's records for Patient A variously reflect inconsistencies or lack specific details. For example, in the progress note for a visit on or about July 7, 2015, Patient A was noted to have presented for anxiety and for refills of Norco and Xanax. The history of present illness discusses Patient A's anxiety. However, in the review of systems portion of the progress note, under "psychiatric" the patient was noted as "negative for anxiety and depression."

27. From on or about September of 2012, through on or about August of 2018, Respondent failed to document a specific treatment plan and objectives with discussion of potential side effects of continued prescribing of controlled substances and documentation of

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[3] To protect the privacy of patients, individual names are not identified in this Accusation.

periodic review of the treatment plan based on a clearly documented, problem specific focused history and physical examination which did not have documented inconsistencies for Patient A.

CIRCUMSTANCES RELATED TO PATIENT B

28. Patient B was a 46-year-old female, with a history of chronic pain syndrome, acquired trigger finger, and cervicalgia. From the period of on or about October of 2012, through on or about January of 2019, Patient B presented to Respondent approximately once a month and he consistently prescribed Methadone HCl for Patient B.

29. Respondent utilized similar and at times identical verbiage in the history of present illness section when describing Patient B's shoulder pain. Respondent consistently characterized her pain as "moderate in severity, constant, dull and aching and relieved with Methadone and Naprosyn; aggravated with weight bearing; discomfort increased with repetitive motion . . . ."

30. Additionally, Respondent continuously documented the musculoskeletal portion of the physical examination as "tone and strength 5/5 L, 4/5 R biceps" and for the neurological portion "sensation, hypoesthesia in the bilateral median nerve distribution." Respondent did not clearly document attempts to taper or decrease the prescribed controlled substances for Patient B. There was insufficient basis documented to support Respondent's ongoing prescribing of Methadone for Patient B. Respondent's medical records for Patient B from on or about October of 2012, to on or about January of 2019, do not contain documentation of any treatment plans, nor did Respondent have and document any clear plan or objectives with discussion of potential side effects for the ongoing prescribing of controlled substances for Patient B. Despite this, Respondent repeatedly refilled Patient B's Methadone prescription.

CIRCUMSTANCES RELATED TO PATIENT C

31. Patient C is a male with a history of spinal stenosis, COPD, chronic pain syndrome, colon cancer, osteoporosis, generalized anxiety disorder, lumbar region radiating pain (sciatica), gout, and chronic kidney disease. Respondent saw Patient C approximately monthly and consistently prescribed Alprazolam, hydrocodone, and oxycodone for Patient C from on or about February 12, 2018, through on or about February 3, 2019.

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32. Respondent noted consistently similar, if not identical verbiage in the history of present illness section when describing Patient C's chronic pain conditions at his visits. Respondent's records for Patient C also contain inconsistencies of the documentation within the progress notes. For example, as to Patient C's visit on or about April 4, 2019, Respondent documented that Patient C presented with worsening symptoms of spinal stenosis in the lumbar region. He was noted as complaining of stiffness and paravertebral muscle spasm with reports of constant pain. However, Respondent documented in the musculoskeletal section that Patient C was negative for arthralgias, joint stiffness, and myalgias. Respondent did not clearly document a specific and focused examination of Patient C's spine despite the fact that the patient returned for controlled substances for management of lumbar pain and spinal stenosis and the neurological examination was merely noted as "grossly intact."

33. Further, Respondent failed to clearly document any attempts to decrease Patient C's controlled substances or attempts to prescribe non-controlled substances for Patient C. There was insufficient documentation by Respondent to support the ongoing prescribing of controlled substances to Patient C.

34. From in or about February of 2012, through in or about February of 2019, documentation in the plan of care for Patient C noted his prescribed controlled substances were refilled. However, there is no documentation of any treatment plans, nor did Respondent document any clear plan or objectives with discussion of potential side effects for the ongoing prescribing of controlled substances for Patient C. Respondent's records lacked medical indication for the controlled medications prescribed to Patient C over a period of approximately seven years.

CIRCUMSTANCES RELATED TO PATIENT D

35. Patient D was a male patient with a medical history that included low back pain, generalized anxiety disorder, lumbar disc disease, chronic pain syndrome, and major depressive disorder. Respondent consistently prescribed Oxycodone, Clonazepam, Narcan, and Duragesic transdermal patches for Patient D from in or about February of 2015, through in or about 2019.

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Though Respondent saw Patient D occasionally in or about 2015, 2016, and 2017, he saw Patient D at least monthly in or about 2018 and 2019.

36. Throughout those years, Respondent repeatedly noted consistently similar, if not identical verbiage in the history of present illness section when describing Patient D's chronic pain condition. Respondent's documentation contains inconsistencies. On or about February 7, 2019, Respondent noted Patient D presented with evaluation for low back pain with associated symptoms of "stiffness, radicular right leg pain, and sharp pain going down the leg." However, in the review of systems section, in the musculoskeletal section, Patient D was noted as "negative for arthralgias, joint stiffness, and myalgias." Additionally, Respondent did not consistently document a specific and focused examination of Patient D's spine despite the fact that he was returning for a medical visit for controlled substances for management of the pain in his lower back. Respondent documented on the musculoskeletal portion of the physical examination of this visit "grossly normal tone and muscle strength," but there is no documentation that Respondent performed a neurological examination.

37. On or about January 16, 2019, Respondent's progress note indicated that Patient D presented for treatment of anxiety, which had increased. Yet in the review of systems section of the progress note, Respondent documented that Patient D was "negative for anxiety and depression." Respondent failed to attempt to decrease his prescribing of controlled substances for Patient D. Respondent's records lacked sufficient documentation to support ongoing prescribing of controlled substances to Patient D.

38. From in or about February of 2015, through in or about March of 2019, documentation in the plan of care for Patient D noted his prescribed controlled substances were refilled. However, there is no documentation of any treatment plans, nor did Respondent document any clear plan or objectives with discussion of potential side effects for the ongoing prescribing of controlled substances for Patient D. Respondent's records lacked documented indication for the controlled medications prescribed for Patient D over a period of approximately four years.

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CIRCUMSTANCES RELATED TO PATIENT E

39. Patient E was a female patient with a medical history that included hypertension, morbid obesity, spinal stenosis, low back pain, and generalized muscle weakness. Respondent consistently prescribed Methadone and oxycodone for Patient E from in or about October of 2012, through in or about July of 2019. During this period, Patient E presented to Respondent approximately once a month.

40. Through those years, Respondent repeatedly noted consistently similar, if not identical verbiage in the history of present illness section when describing Patient E's chronic pain condition. Additionally, Respondent's documentation contains inconsistencies. On or about June 26, 2019, Respondent documented that Patient E presented with low back pain with associated stiffness, radicular leg pain, numbness in the right buttock, weakness in the upper legs, and right lower leg swelling. However, in the review of systems section of the progress note, Respondent documented in the musculoskeletal section that the patient was negative for arthralgias, joint stiffness, and myalgias and was negative in the neurological section for weakness and gait disturbance. Additionally, Respondent failed to consistently document a specific and focused examination of the patient's lumbar spine and lower extremities in spite of the fact that she was returning for controlled substances for management of low back pain. Respondent failed to document a focused examination of the lumbar region, though he documented under the musculoskeletal examination that the patient had normal gait with grossly normal tone and muscle strength. Further, Respondent failed to document any attempts to decrease Patient E's controlled substance prescriptions or attempt to prescribe any non-controlled substances for Patient E. There was insufficient documentation by Respondent to support the ongoing prescribing of controlled substances to Patient E.

41. From in or about October of 2012, through in or about July of 2019, documentation in the plan of care for Patient E noted her prescribed controlled substances were refilled. However, there is no documentation of any specific treatment plan, nor did Respondent have and document any clear plan or objectives with discussion of potential side effects for the ongoing prescribing of

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controlled substances for Patient E. Respondent's records lacked medical indication for the controlled substances prescribed for Patient E over approximately six years.

FIRST CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

42. Respondent has subjected his Physician's and Surgeon's Certificate No. G 21038, to disciplinary action under sections 2227 and 2234, as defined by section 2234, subdivision (c), in that he engaged in repeated acts of negligence in his documentation practices as to Patient A, Patient B, Patient C, Patient D, and Patient E. The circumstances are set forth in paragraphs 22 through 41, above, which are incorporated here by reference as if fully set forth.

43. The standard of care requires a medical history and physical exam, which includes an assessment of the patient's pain, including physical and psychological status and function; substance abuse history; history of prior pain treatments and assessment of any other underlying or co-existing conditions. Finally, it should include documentation of recognized medical indications for the use of controlled substances.

44. Regarding Patient A, Respondent's documentation of consistently similar if not identical verbiage in the history of present illness, and the inconsistencies in the medical records constitute negligence. Respondent's lack of sufficient documentation in the medical records to support the ongoing prescribing of Norco and Xanax to Patient A over a period of multiple years constitutes negligence.

45. Regarding Patient B, Respondent's documentation of consistently similar if not identical verbiage in the history of present illness constitute negligence. Respondent's lack of sufficient documentation in the medical records to support the ongoing prescribing of a controlled substance to Patient B over a period of multiple years constitutes negligence.

46. Regarding Patient C, Respondent's documentation of consistently similar if not identical verbiage in the history of present illness constitute negligence. Respondent's lack of sufficient documentation in the medical records to support the ongoing prescribing of controlled substances to Patient C over a period of multiple years constitutes negligence.

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47. Regarding Patient D, Respondent's documentation of consistently similar if not identical verbiage in the history of present illness, and the inconsistencies in the medical records constitute negligence. Respondent's lack of sufficient documentation in the medical records to support the ongoing prescribing of controlled substances to Patient D over a period of multiple years constitutes negligence.

48. Regarding Patient E, Respondent's documentation of consistently similar if not identical verbiage in the history of present illness, and the inconsistencies in the medical records constitute negligence. Respondent's lack of sufficient documentation in the medical records to support the ongoing prescribing of controlled substances to Patient E over a period of multiple years constitutes negligence.

49. The standard of care requires the medical records contain stated objectives that may include relief of pain or relief of the medical condition requiring controlled substances and/or improved physical or psychological function or ability to perform certain tasks or activities of daily living. This should also include any plans for further diagnostic evaluations and treatments, such as rehabilitation programs.

50. Respondent's failure to document a specific treatment plan for Patient A constitutes negligence. Respondent's lack of documentation of a specific treatment plan, aside from refilling of controlled substances, in Patient A's records from in or about September of 2011, through in or about August of 2018, constitutes negligence.

51. Respondent's failure to document a specific treatment plan for Patient B constitutes negligence. Respondent's lack of documentation of a specific treatment plan, aside from refilling of controlled substances, in Patient B's records from in or about October of 2012, through in or about January of 2019, constitutes negligence.

52. Respondent's failure to document a specific treatment plan for Patient C constitutes negligence. Respondent's lack of documentation of a specific treatment plan, aside from refilling of controlled substances, in Patient C's records from in or about February of 2018, through in or about February of 2019, constitutes negligence.

53. Respondent's failure to document a specific treatment plan for Patient D constitutes

negligence. Respondent's lack of documentation of a specific treatment plan, aside from refilling of controlled substances, in Patient D's records from in or about February of 2015, through in or about March of 2019, constitutes negligence.

54. Respondent's failure to document a specific treatment plan for Patient E constitutes negligence. Respondent's lack of documentation of a specific treatment plan, aside from refilling of controlled substances, in Patient E's records from in or about October of 2021, through in or about July of 2019, constitutes negligence.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Medical Records)

55. Respondent has further subjected his Physician's and Surgeon's Certificate No. G 21038 to disciplinary action under sections 2227 and 2234, as defined by section 2266, in that he failed to maintain adequate and accurate medical records in his care and treatment of Patient A, Patient B, Patient C, Patient D, and Patient E. The circumstances are set forth in paragraphs 22 through 41, above, which are incorporated here by reference as if fully set forth.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate Number G 21038, issued to Eric Colburn Disbrow, M.D.;

2. Revoking, suspending or denying approval of Eric Colburn Disbrow, M.D.'s authority to supervise physician assistants and advanced practice nurses;

3. Ordering Eric Colburn Disbrow, M.D., to pay the Board the reasonable costs of the enforcement of this case incurred beginning on January 1, 2022, and if placed on probation, to pay the Board the costs of probation monitoring; and

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4. Taking such other and further action as deemed necessary and proper.

DATED: APR 0 5 2022

WILLIAM PRASIFKA
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

FR2020304777

ROB BONTA
Attorney General of California
STEVE DIEHL
Supervising Deputy Attorney General
LYNETTE D. HECKER
Deputy Attorney General
State Bar No. 182198
California Department of Justice
2550 Mariposa Mall, Room 5090
Fresno, CA 93721
Telephone: (559) 705-2320
Facsimile: (559) 445-5106
Attorneys for Complainant

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **ERIC COLBURN DISBROW, M.D.** [redacted] **Atwater, CA** [redacted] **Physician's and Surgeon's Certificate No. G 21038** Respondent.	Case No. 800-2018-045589 OAH No. 2021100436 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Medical Board of California of the Department of Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the First Amended Accusation.

PARTIES

1. William Prasifka (Complainant) is the Executive Director of the Medical Board of California (Board). He brought this action solely in his official capacity and is represented in this

matter by Rob Bonta, Attorney General of the State of California, by Lynette D. Hecker, Deputy Attorney General.

2. Eric Colburn Disbrow, M.D. (Respondent) is represented in this proceeding by attorney Marvin Firestone, MD, JD, whose address is: 1700 South El Camino Real, Ste. 408, San Mateo, CA 94402.

3. On or about August 9, 1971, the Board issued Physician's and Surgeon's Certificate No. G 21038 to Respondent. The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 800-2018-045589, and will expire on January 31, 2023, unless renewed.

JURISDICTION

4. First Amended Accusation No. 800-2018-045589 was filed before the Board, and is currently pending against Respondent. The original Accusation and all other statutorily required documents were properly served on Respondent on June 16, 2021. Respondent timely filed his Notice of Defense contesting the Accusation. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on April 5, 2022. This stipulation shall serve as Respondent's Notice of Defense pursuant to Government Code section 11506, subdivision (a)(4).

5. A copy of the First Amended Accusation No. 800-2018-045589 is attached as "Exhibit A" and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 800-2018-045589. Respondent has also carefully read, fully discussed with his counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the

production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in First Amended Accusation No. 800-2018-045589, if proven at a hearing, constitute cause for imposing discipline upon his Physician's and Surgeon's Certificate.

10. Respondent does not contest that, at an administrative hearing, Complainant could establish a *prima facie* case or factual basis with respect to the charges and allegations in First Amended Accusation, that he has thereby subjected his Physician's and Surgeon's Certificate, No. G 21038 to disciplinary action, and Respondent hereby gives up his right to contest those charges. Respondent agrees that if in any future case he ever petitions for early termination or modification of probation, or if the Board ever petitions for revocation of probation, all of the charges and allegations contained in First Amended Accusation No. 800-2018-045589 shall be deemed true, correct, and fully admitted by Respondent for purposes of that proceeding or any other licensing proceeding involving Respondent in the State of California.

11. Respondent agrees that his Physician's and Surgeon's Certificate is subject to discipline and he agrees to be bound by the Board's imposition of discipline as set forth in the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Medical Board of California. Respondent understands and agrees that counsel for Complainant and the staff of the Medical Board of California may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails

to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or opportunity to be heard by the Respondent, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

A. PUBLIC REPRIMAND

IT IS HEREBY ORDERED that Respondent Eric Colburn Disbrow, M.D., Physician's and Surgeon's Certificate No. G 21038, shall be and is hereby Publicly Reprimanded pursuant to California Business and Professions Code section 2227, subdivision (a)(4). This Public Reprimand is issued in connection with Respondent's recordkeeping pertaining to five patients, as set forth in First Amended Accusation No. 800-2018-045589.

1. INVESTIGATION/ENFORCEMENT COST RECOVERY: Respondent is hereby relieved from reimbursing the Board its costs of investigation and enforcement under Code section 125.3.

2. FUTURE ADMISSIONS CLAUSE: If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing action agency in the State of California, all of the charges and allegations contained in Accusation No. 800-2018-045589 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict license.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Marvin Firestone, MD, JD. I understand the stipulation and the effect it will have on my Physician's and Surgeon's Certificate. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Medical Board of California.

DATED: 3/30/2022

ERIC COLBURN DISBROW, M.D.
Respondent

I have read and fully discussed with Respondent Eric Colburn Disbrow, M.D. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 3/31/2022

MARVIN FIRESTONE, MD, JD
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Medical Board of California.

DATED: 3/31/2022

Respectfully submitted,

ROB BONTA
Attorney General of California
STEVE DIEHL
Supervising Deputy Attorney General

LYNETTE D. HECKER
Deputy Attorney General
Attorneys for Complainant

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95435511.docx

DR. ERIC COLBURN DISBROW,

Thank you for generating your wallet license using the Medical Board of California's (Board) Wallet License System. The Board implemented this system to expedite the availability of card-sized proof of licensure after license issuance and renewal. Replacement or duplicate wallet licenses can be generated any time, free of charge for licensees with current, valid licenses. In addition to your basic license information, the wallet license features a QR code that modern smart devices can "scan" to access your Department of Consumer Affairs' (DCA) Search License Profile.

For your convenience, you may print this page, cut the card below out along the outer dotted lines, and fold along the center vertical dotted line to carry this card with you.

If you have any questions regarding your wallet license, please contact the Board here or toll-free at (800) 633-2322.

CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

LICENSE: G21038
ORIGINAL ISSUE: 8/9/1971
EXPIRATION: 1/31/2027

PHYSICIAN'S AND SURGEON'S LICENSE
ERIC COLBURN DISBROW
[redacted]

The Medical Board of California
2005 Evergreen Street, Suite 1200 | Sacramento, CA 95815
www.mbc.ca.gov | (800) 633-2322

Scan QR Code to View Complete License Profile

DCA Search Online License Profile

Please be aware that public information regarding your license is available online in your DCA Search License Profile, through the Board's website. The DCA Search License Profile contains various categories of public information, including disciplinary information, where applicable, as described on the Board's License Verification webpage.

The Board encourages you to regularly review your DCA Search License Profile. It can be accessed by scanning the QR code on your wallet license or visiting the Board's License Verification webpage and conducting a search by your license type and name or license number. If any information contained in your profile is inaccurate, please contact the Board immediately.

Has Your Email Changed?

California law requires all licensees to report a change of email address within 30 days. Your email address will be kept confidential and will only be used by the Board to communicate relevant Board information including when it is time to renew your license. You can update the email address associated with your license at any time from the DCA BreEZe system using the Change of Address or Physician Survey options. Additional information regarding changing your email address can be found on the Board's Address of Record / Email Address FAQs webpage.

Has Your Mailing Address Changed?

California law requires all licensees to report a change of mailing address within 30 days. Your address of record is public information, available to any consumer, and is displayed on your DCA Search License Profile. The Board will use the address of record to mail wall certificates, renewal notices, and all other official correspondence. If using a post office box (PO Box) for an address of record, you are required by law to provide the Board with a secondary (non-PO Box) mailing address, which will be kept confidential. You can update the mailing address associated with your license at any time from the DCA BreEZe system using the Change of Address option. Additional information regarding changing your mailing address can be found on the Board's Address of Record / Email Address FAQs webpage.

NSBME - Renewal Approved

noreply@nsbme.nv.us.thentiacloud.net Mon, May 12, 2025 at 11:39 AM
<noreply@nsbme.nv.us.thentiacloud.net>
To: [redacted]

Eric Disbrow,

Your renewal has been approved.

Your license issued date is 2023/09/18

Your license expiration date is 2027/06/30

To obtain your wallet ID card, you must access the licensee portal to download the card. Wallet ID cards are accessible only via the licensee portal.

Thank you,

Nevada State Board of Medical Examiners

Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559
Toll Free (in state): (888) 890-8210

CURRICULUM VITAE

Eric C. Disbrow, M.D.

FAMILY PRACTICE, URGENT CARE, GERIATRICS

[redacted]

EDUCATION

ALBANY MEDICAL COLLEGE OF UNION UNIVERSITY 1966-1970

ALBANY, NEW YORK

1. GRADUATED IN UPPER QUARTER OF CLASS
2. AWARDS
   - SMITHERS FOUNDATION FELLOWSHIP
   - DAGGETT PRIZE IN ANATOMY
   - HEALTH PROFESSIONS SCHOLARSHIP
3. ACTIVITIES
   -RUGBY FOR ALBANY MEDICAL COLLEGE
   -HANDBALL
   -TENNIS
4. EMPLOYMENT
   -X-RAY TECHNICIAN
   -MEDICAL TECHNICIAN
   -NEW YORK STATE PUBLIC HEALTH RESEARCH IN CORONARY HEART DISEASE

COLLEGE-MUHLENBERG 1962 -1966

ALLENTOWN, PA

1. ACTIVITIES
   -VARSITY FOOTBALL 3 LETTERS
   -INTRAMURAL WRESTLING CHAMPION IN 191# FOR 2 YEARS
   -BAND 4 YEARS
   -CHANCEL CHOIR 2 YEARS
   -PRE-MED SOCIETY
   -LAMBDA CHI ALPHA SOCIAL FRATERNITY

SECONDARY EDUCATION AT BINGHAMTON CENTRAL HIGH SCHOOL 1960-1962

BINGHAMTON, NY

1. ACTIVITIES AT SCHOOL
   - -VARSITY FOOTBALL 3 YEARS
   - -TRACK 1 YEAR
   - -SWIMMING 1 YEAR
   - -BAND 4 YEARS
2. OUTSIDE ACTIVITIES
   - -ALPHA ZETA SOCIAL FRATERNITY
   - -EXPLORER SCOUT
     - A. EAGLE SCOUT
     - B. ORDER OF THE ARROW
     - C. COED PLANNING BOARD
   - -HIGH STREET METHODIST CHURCH
     - A. MEMBER OF CHOIR
     - B. PRESIDENT OF YOUTH GROUP
3. PARTICIPATED IN PILOT PROGRAM FOR RECRUITMENT OF STUDENTS FOR THE MEDICAL PROFESSION, SPONSORED BY BROOME COUNTY MEDICAL SOCIETY

INTERNSHIP

ROTATING INTERNSHIP AT SACRAMENTO MEDICAL CENTER IN SACRAMENTO, CA JULY 1970-JULY 1971

RESIDENCY

ONE(1) YEAR SURGICAL RESIDENCY AT SACRAMENTO MEDICAL CENTER, ROTATED THROUGH SURGICAL SUB-SPECIALTIES JULY 1971 - JULY 1972. PRESENTED PAPER TO SACRAMENTO SURGICAL SOCIETY ON PERFORATED GALLBLADDERS 1972

ARMED SERVICES OBLIGATIONS

USAF GENERAL MEDICAL OFFICER, CASTLE AFB, CA AUGUST 1972 - AUGUST 1974

SPECIALTY BOARDS

1. CERTIFIED AMERICAN BOARD OF FAMILY PRACTICE NOVEMBER 1977. RECERTIFIED 1983, 1989, 1995 – 2002, 2002 – 2009, 2009 – 2019, 2019-2029
2. CERTIFIED EMERGENCY MEDICINE - DECEMBER, 1983. RECERTIFIED 1993-2003
3. CERTIFIED IN GERIATRIC MEDICINE - APRIL 1990. RECERTIFIED 2000-2010, 2010-2022
4. CERTIFIED IN SPORTS MEDICINE - APRIL 1995 - 2005

UNIVERSITY APPOINTMENTS

1. ASSISTANT CLINICAL PROFESSOR IN DEPARTMENT OF FAMILY PRACTICE, UNIVERSITY OF CA, DAVIS 1984 TO 1994. MY ROLE WAS TO TEACH PHYSICIAN ASSISTANTS AND TO DEVELOP POST-GRADUATE MEDICAL EDUCATION PROGRAMS FOR EMERGENCY ROOM PHYSICIANS AND FAMILY PRACTITIONERS
2. CLINICAL FACULTY REPRESENTATIVE TO THE PHYSICIAN ADVISORY BOARD FOR CONTINUING MEDICAL EDUCATION, U.C. DAVIS, 1992-1994
3. COMMUNITY PHYSICIAN REPRESENTATIVE TO CONTINUING MEDICAL EDUCATION AD VISORY COMMITTEE AT U.C. DAVIS MEDICAL SCHOOL. 1994 TO 2014. THE COMMITTEE PROVIDES QUALITY ASSURANCE FOR THE POST-GRADUATE MEDICAL EDUCATION PROGRAMS AT U.C. DAVIS TO ENSURE COMPLIANCE WITH THE ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION GUIDELINES.
4. REVIEW ALL POSTGRADUATE C.M.E. PROGRAMS TO DETERMINE ELIGIBILITY FOR AMERICAN ACADEMY OF FAMILY PRACTICE CATEGORY 1 CREDITS -PRESENT
5. APPOINTMENT TO THE CLINICAL FACULTY OF UNIVERSITY NEVADA AT RENO MEDICAL SCHOOL 2022

RESEARCH

- 1993 - CLINICAL RESEARCH FOR PARKE-DAVIS RESEARCHING THE DRUG COGNEX. A DRUG USED IN THE TREATMENT OF ALZHEIMER'S DISEASE
- 2000 - "EVIDENT" STUDY SPONSORED BY ELI LILLY. RESEARCH ON THE EFFECT OF PIOGLITAZONE, A DIABETIES DRUG, ON SERUM LIPIDS
- 2001 - "CARE" STUDY SPONSORED BY JANSEN RESEARCH ON REMINYL, A NEW MEDICATION FOR ALZHEIMER'S DISEASE, RESEARCHING COMPLIANCE ISSUES FOR PATIENTS AND CAREGIVERS.
- 2001 – HUMULOG STUDY SPONSORED BY ELI LILLY. HOMOLOG INSULIN AND ITS EFFECT ON HEMOGLOBIN A_1c
- 2001 – "TREAT" STUDY RESEARCH ON EFFECTIVENESS OF KETEK®, A NEW ANTIBIOTIC FOR THE TREATMENT OF CHRONIC SINUSITIS AND RECURRENT BRONCHITIS
- 2001 – "SUMMIT" STUDY CLINICAL EFFECTIVENESS OF IMMITREX® FOR RECURRENT HEADACHES DIAGNOSED AS SINUS HEADACHES

- 2002 – "GEMINI" STUDY SPONSORED BY PFIZER. RESEARCH ON ATORVASTATIN/AMLODIPINE. A NEW COMBINED MEDICATION FOR DYSLIPIDEMIA AND HYPERTENSION
- 2002 – "GOAL A_1C" STUDY SPONSORED BY AVENTIS PHARMACEUTICAL. RESEARCH ON THE EFFECTS OF LANTUS INSULIN ON HEMOGLOBIN A_1C
- 2003 – "ALERT" STUDY SPONSORED BY WALLACE PHARMACEUTICALS. A PROSPECTIVE OPEN LABEL EVALUATION OF ASTELIN® FOR THE TREATMENT OF SYMPTOMATIC RHINITIS
- 2003 – "GLYCEMIC OPTIMIZATION TREATMENT" SPONSORED BY AVENTIS PHARMACEUTICALS. ASSESSING THE SAFETY OF GLUCOSE CONTROL WITH LANTUS INSULIN USING DOSING ALGORITHMS BY MEASURING THE FREQUENCY AND SEVERITY OF HYPOGLYCEMIC EVENTS

EMPLOYMENT SINCE GRADUATION FROM MEDICAL SCHOOL

1. CARE OF 150 GERIATRIC PATIENTS OF DR. L. FULLER IN NURSING HOMES JULY 1970 TO 1972
2. YOLO COUNTY EMERGENCY ROOM, WOODLAND, CA FOR 2 MONTHS, JULY AND AUGUST, 1972
3. MADERA EMERGENCY ROOM, 8 MONTHS, 1 WEEKEND A MONTH, MARCH 1973-AUGUST 1974
4. EMERGENCY ROOM, SCENIC GENERAL HOSPITAL FOR 1 YEAR, 1 OR 2 NIGHTS A WEEK SEPTEMBER 1972 - DECEMBER 1974, MODESTO, CA
5. MIGRANT WORKER CLINIC, MERCED GENERAL HOSPITAL, ONE NIGHT A WEEK FOR 18 MONTHS. JANUARY 1973 TO AUGUST 1974
6. BLOSS HOSPITAL IN ATWATER, CA EMERGENCY ROOM 1TO 2 NIGHTS A WEEK. JUNE 1973 TO AUGUST 1974
7. DR. W. NEAL CARTER, GENERAL PRACTITIONER, ATWATER, CA FOR 8 TO 12 HOURS ONCE A WEEK. JANUARY 1973 TO AUGUST 1974
8. CHIEF EMERGENCY MEDICAL SERVICES, BLOSS HOSPITAL, ATWATER, CA 1974 TO 1998
9. ATWATER MEDICAL GROUP – PRIVATE FAMILY PRACTICE 1974 TO 2021

MEDICALLY RELATED ACTIVITIES SINCE 1974

1. PRIVATE PRACTICE - FAMILY MEDICINE, AUGUST 1974 TO PRESENT, ATWATER MEDICAL GROUP, 1775 3RD ST., ATWATER, CA 95301
2. EMERGENCY ROOM CONTRACTS:
   - BLOSS MEMORIAL, ATWATER, CA AUGUST 1974 TO 1998
   - CHOWCHILLA DISTRICT HOSPITAL DECEMBER 1979 TO JANUARY 1985
   - MARIPOSA, JOHN C FREMONT HOSPITAL DECEMBER 1981 TO OCTOBER 1986
   - YOLO GENERAL HOSPITAL, WOODLAND,CA JULY 1982 TO OCTOBER 1988
3. CHIEF OF STAFF - BLOSS HOSPITAL 1978, 1989

5. CHAIRPERSON "FINGERS TO TOES", ANNUAL INTENSIVE ORTHOPEDIC REVIEW FOR PRIMARY CARE PHYSICIANS, UNIVERSITY OF CALIFORNIA AT DAVIS POST-GRADUATE COURSE 1990 TO PRESENT. THIS COURSE HAS BEEN PRESENTED FOR 44 YEARS AT THE STANFORD SIERRA LODGE AT FALLEN LEAF LAKE
6. FAMILY PRACTICE CONSULTANT TO "FINGERS TO TOES", AN ORTHOPEDIC APPROACH FOR THE FAMILY PRACTITIONER, SPONSORED BY UCD MEDICAL SCHOOL 1977 TO 1990.
7. CHIEF EMERGENCY MEDICAL SERVICES BLOSS HOSPITAL 1974 TO 1998
8. B.C.L.S. INSTRUCTOR 1977
9. CHAIRPERSON "OPHTHALMOLOGY FOR PRIMARY CARE PHYSICIANS" 1980 U.C. DAVIS POSTGRADUATE COURSE
10. HELI-SKING MEDICAL SYMPOSIUM B.C. CANADA 1979 TO PRESENT
11. MEDICAL DIRECTOR - ANBERRY REHABILITITION HOSPITAL - 1984-85, 99 BED SKILLED NURSING FACILITY AND REHABILITATION CENTER
12. LECTURE "ANIMAL BITES", ANNUAL PRESENTATION AT ORTHOPEDIC CONFERENCE 1980 TO PRESENT
13. EMERGENCY MEDICINE ORAL BOARDS EXAMINER FOR ALPHA-CENTAURI SEMINARS
14. CERTIFIED X-RAY SUPERVISOR 1979 TO PRESENT
15. LECTURE "ALZHEIMER'S DISEASE: THE PHYSICIAN'S ROLE AND RESPONSIBILITIES". PRESENTED TO VARIOUS LAY AND PROFESSIONAL GROUPS
16. LECTURE "THE ZONE DIET"
17. LECTURE "THE GALAPAGOS ISLANDS"
18. MEDICAL DIRECTOR RURAL HEALTH CLINIC, BLOSS HOSPITAL - 1994 TO 1998.
19. MEDICAL DIRECTOR - PETERS CARE HOMES, 1993 – 1994

COMMUNITY INVOLVEMENT – GIVING BACK

- RAN BOSTON MARATHON 1978 AND RAISED $5,000 FOR BLOSS HOSPITAL X-RAY
- RAN LAKE TAHOE ULTRA MARATHON (72 MILES) 1979 RAISED $5,000 FOR BLOSS HOSPITAL
- PHYSICIAN ADVISOR AND PARTICIPANT EMERGENCY MEDICAL SERVICES FAIR, MERCED, CA 1979
- SCOLIOSIS SCREENING:ATWATER, LIVINGSTON, WINTON, DELHI, CA 1977 TO 2010. TEAM PHYSICIAN ATWATER HIGH FOOT BALL TEAM 1974 TO 2000.
- PHYSICIAN ADVISOR AND ELECTED TO BOARD OF ALZHEIMER'S DISEASE AND RELATED DISEASES ASSOCIATION, MERCED CHAPTER 1988
- ANNUAL ATWATER HIGH SCHOOL TEAM PHYSICALS 1975-2015. COLLECTED $10 PER PHYSICAL AND DONATED PROCEEDS TO ATHLETIC DEPARTMENT
- ALPINE MEADOWS DR. PATROLVOLUNTARY SKI PATROL1999- PRESENT FREE EVALUATION AND TRIAGE OF SKI INJURIES
- VOLUNTEER AT THE STUDENT OUTREACH CLINIC TEACHING MEDICAL STUDENTS IN A CLINICAL SETTING 2024 TO PRESENT
- MEDICAL MISSION PROVIDING MEDICAL CARE IN TAKSINDU A REMOTE VILLAGE IN NEPAL 11-24-2024

AWARDS AND HONORS

1. TEACHER RECOGNITION AWARD PRESENTED BY AMERICAN ACADEMY OF FAMILY PRACTICE 1983, 1986, 1987, 1988, 1989
2. AWARDED THE ATWATER SIGNAL "SEAL OF APPROVAL" FOR COMMUNITY SERVICES APRIL 1984
3. DISTINGUISHED SERVICE AWARD PRESENTED TO ATWATER MEDICAL GROUP BY DISABLED AMERICAN VERTERANS 1985
4. "FRIENDS OF LIVINGSTON UNION SCHOOL DISTRICT AWARD" FOR OUTSTANDING COMMITMENT AND SERVICE TO THE STUDENTS 1996
5. ATWATER ELEMENTARY SCHOOL DISTRICT BOARD OF TRUSTEES "CERTIFICATE OF APPRECIATION" FOR 25 YEARS OF SCOLIOSIS SCREENING PRESENTED FEBRUARY 7, 2005
6. CALIFORNIA "LEGISLATIVE ASSEMBLY CERTIFICATE OF RECOGNITION" PRESENTED TO ATWATER MEDICAL GROUP – FOR OUTSTANDING ACHIEVEMENT IN HEALTH CARE 2015
7. "CERTIFICATE OF SPECIAL CONGRESSIONAL RECOGNITION" PRESENTED TO ATWATER MEDICAL GROUP FOR EXCELLENCE IN HEALTH CARE 2015

8. "EXCELLENCE IN BUSINESS" IN RECOGNITION OF DEDICATION AND COMMITMENT TO THE GREATER MERCED COMMUNITY PRESENTED TO ATWATER MEDICAL GROUP BY THE MERCED SUN STAR 2015
9. "STATE OF CALIFORNIA SENATE CERTIFICATE OF RECOGNITION" PRESENTED TO ATWATER MEDICAL GROUP FOR EXCELLENCE IN HEALTH CARE 2015
10. "EXCELLENCE IN BUSINESS AWARD" PRESENTED TO ATWATER MEDICAL GROUP BY MERCED COUNTY 2015
11. "2017" HALL OF FAME AWARD FOR MEDICINE PRESENTED TO ERIC DISBROW, MD BY THE CALIFORNAI LEGISLATURE IN CONJUNCTION WITH THE MERCED SUN STAR AND THE UNIVERSITY OF CALIFORNIA MERCED

MEDICAL LICENSES

1. CALIFORNIA MEDICAL LICENSE G21038 (8-9-1971 TO PRESENT)
2. DEA NUMBER AD 1364152, CURRENTLY GOOD IN CALIFORNIA
3. NEVADA MEDICAL LICENSE 24369 (9-18-2023 TO PRESENT)

11B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Y

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☑ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: Jeffrey Middle: Cameron Last: Backofen

Date of Birth: [redacted] SSN or ITIN [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: 89149

Telephone: [redacted] Email: jeffrey.backofen@uhsinc.com

Degree: D.O. Practitioner License #: SL2464 Specialty: Family Medicine

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Valley Hospital Medical Center

Practice Address: 620 Shadow Lane Suite #:

City: Las Vegas State: NV Zip: 89106

Telephone: (702) 388-8436 Fax: (702) 388-8431 Email: jeffrey.backofen@uhsinc.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

4993 N/P

AV4793042464

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/18/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Backofen
Print Name (First, Last)

6/18/25
Date

Original Signature (electronic, copies or stamps not accepted)

6/18/25
Date

Board Use Only: Date Processed: 7/22/25 Amount: $80 ck0011440 18

Nevada State
Board of Osteopathic Medicine

Attention | **Do not contact licensees directly. Please contact the Board to inquire about a licensee.**

jeffrey backofen

License Number
SL2464

License Status
Active

License Type
Osteopathic Resident (Special License)

Original Date of Licensure
07/17/2025

License Expiration Date
06/30/2026

Place of Practice

None

Post Graduate Training

Hospital Name
David Grant Medical Center/University of California Davis Medical Center

Hospital Address 1
101 Bodin Cir

Hospital Address 2
N/A

City
Fairfield

State
California

Zip Code
94533

Department/Specialty
General Surgery

PGY
1

Postgraduate Type
Internship

From
07/01/2022

To
06/30/2023

Historical Residencies

None

Board Actions

None

Malpractice Claim

None

Superviser To

None

Supervised By

None

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11C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: Jeffrey Middle: _____ Last: Kesten

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: 08759

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 27693 Specialty: Physical Med & Rehabilitation

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Delve Psychiatry

Practice Address: 526 S. Tonopah Drive, Suites 140-160 Suite #: _____

City: Las Vegas State: NV Zip: 89106

Telephone: 702-897-4838 Fax: _____ Email: _____

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Kesten
Print Name (First, Last)

July 30, 2025
Date

[redacted]
O[redacted]tamps not accepted)

July 30, 2025
Date

Board Use Only: Date Processed:	Amount:

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
Letter of Admonition	Colorado	May 22, 2022	2018-5306-B

Criminal Action:	State:	Date:	Case #:	County:	Court:
Felony Conviction	CO	February 24, 2022	1:20-cr-00291-DDD-1	Denver	United States District Court

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Kesten
Print Name (First, Last)

July 20, 2025
Date

[redacted]
opies or stamps not accepted)

July 20, 2025
Date

Board Use Only: Date Processed: _____ Amount: $200 ck 222

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

NEVADA STATE BOARD OF PHARMACY CONTROLLED SUBSTANCE APPLICATION

SECTION 5: PERSONAL AND PROFESSIONAL HISTORY

2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?

On February 22, 2022, I was convicted of conspiracy to violate U.S.C. § 1320(a)-7b(b) regarding illegal kickbacks and bribes. This conviction related to my work as a speaker for Insys Pharmaceuticals, where I entered into an implicit agreement to prescribe Subsys instead of other similar pain medications while being compensated through the speaker program. It is important to clarify that I never illegally distributed pain medication; rather, I allowed my relationship with Insys to influence which brand of medication I prescribed (only to medically appropriate patients, accounting for less than 11% of my total practice). I want to emphasize that, while I do not wish to diminish my situation, my conviction was not connected to providing inappropriate or substandard clinical care.

Please find the attached *Judgment in a Criminal Case* from the United States District Court.

[redacted]
Jeffrey Kesten, M.D.

July 20, 2025
July 20, 2025

 AO 245B (CO Rev. 11/20) Judgment in a Criminal Case

UNITED STATES DISTRICT COURT

District of Colorado

UNITED STATES OF AMERICA

JUDGMENT IN A CRIMINAL CASE

v.

JEFFREY KESTEN Case Number: 1:20-cr-00291-DDD-1

THE DEFENDANT:

☒ pleaded guilty to count(s) 1 of the Indictment

☐ pleaded nolo contendere to count(s)
which was accepted by the court.

☐ was found guilty on count(s)
after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

USM Number: 08159-509

Mary Virginia Butterton Defendant's Attorney

Title & Section Nature of Offense	Offense Ended	Count
18 U.S.C. § 371 Conspiracy to Violate 42 U.S.C. § 1320a-7b(b), Paying/Offering and Soliciting/Receiving Illegal Kickbacks and	Bribes 11/30/2015	1

The defendant is sentenced as provided in pages 2 through 7 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on count(s)

☒ Count(s) 2 through 64 ☐ is ☒ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

February 24, 2022
Date of Imposition of Judgment



Signature of Judge

Daniel D. Domenico, United States District Judge
Name and Title of Judge

February 28, 2022
Date

IMPRISONMENT

The defendant is hereby committed to the custody of the Federal Bureau of Prisons to be imprisoned for a total term of: **twenty-four (24) months.**

☒ The court makes the following recommendations to the Bureau of Prisons:
The Court recommends that the defendant be designated to FCI Otisville or the closest facility commensurate with his security clearance.

☐ The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at ☐ a.m. ☐ p.m. on . ☐ as notified by the United States Marshal.

☒ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons: ☒ before 2 p.m. on within 15 days of designation .

☐ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on to

at , with a certified copy of this judgment.

UNITED STATES MARSHAL

By
DEPUTY UNITED STATES MARSHAL

SUPERVISED RELEASE

Upon release from imprisonment, you will be on supervised release for a term of: **three (3) years.**

MANDATORY CONDITIONS

1. You must not commit another federal, state or local crime.

2. You must not unlawfully possess a controlled substance.
3. You must refrain from any unlawful use of a controlled substance. You must submit to one drug test within 15 days of release from imprisonment and a maximum of 20 tests per year of supervision thereafter.
☒ The above drug testing condition is suspended, based on the court's determination that you pose a low risk of future substance abuse. *(check if applicable)*
4. ☒ You must make restitution in accordance with 18 U.S.C. §§ 3663 and 3663A or any other statute authorizing a sentence of restitution. *(check if applicable)*
5. ☒ You must cooperate in the collection of DNA as directed by the probation officer. *(check if applicable)* 6. ☐ You must comply with the requirements of the Sex Offender Registration and Notification Act (34 U.S.C. § 20901, *et seq.*) as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in the location where you reside, work, are a student, or were convicted of a qualifying offense. *(check if applicable)*
7. ☐ You must participate in an approved program for domestic violence. *(check if applicable)*

You must comply with the standard conditions that have been adopted by this court as well as with any other conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

As part of your supervised release, you must comply with the following standard conditions of supervision. These conditions are imposed because they establish the basic expectations for your behavior while on supervision and identify the minimum tools needed by probation officers to keep informed, report to the court about, and bring about improvements in your conduct and condition.

1. You must report to the probation office in the federal judicial district where you are authorized to reside within 72 hours of your release from imprisonment, unless the probation officer instructs you to report to a different probation office or within a different time frame.
2. After initially reporting to the probation office, you will receive instructions from the court or the probation officer about how and when you must report to the probation officer, and you must report to the probation officer as instructed.
3. You must not knowingly leave the federal judicial district where you are authorized to reside without first getting permission from the court or the probation officer.
4. You must answer truthfully the questions asked by your probation officer.
5. You must live at a place approved by the probation officer. If you plan to change where you live or anything about your living arrangements (such as the people you live with), you must notify the probation officer at least 10 days before the change. If notifying the probation officer in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
6. You must allow the probation officer to visit you at any time at your home or elsewhere, and you must permit the probation officer to take any items prohibited by the conditions of your supervision that he or she observes in plain view.
7. You must work full time (at least 30 hours per week) at a lawful type of employment, unless the probation officer excuses you from doing so. If you do not have full-time employment you must try to find full-time employment, unless the probation officer excuses you from doing so. If you plan to change where you work or anything about your work (such as your position or your job responsibilities), you must notify the probation officer at least 10 days before the change. If notifying the probation officer at least 10 days in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
8. You must not communicate or interact with someone you know is engaged in criminal activity. If you know

someone has been convicted of a felony, you must not knowingly communicate or interact with that person without first getting the permission of the probation officer.
9. If you are arrested or questioned by a law enforcement officer, you must notify the probation officer within 72 hours. 10. You must not own, possess, or have access to a firearm, ammunition, destructive device, or dangerous weapon (i.e., anything that was designed, or was modified for, the specific purpose of causing bodily injury or death to another person such as nunchakus or tasers).
11. You must not act or make any agreement with a law enforcement agency to act as a confidential human source or informant without first getting the permission of the court.
12. If the probation officer determines that you pose a risk to another person (including an organization), the probation officer may, after obtaining Court approval, notify the person about the risk or require you to notify the person about the risk and you must comply with that instruction. The probation officer may contact the person and confirm that you have notified the person about the risk. 13. You must follow the instructions of the probation officer related to the conditions of supervision.

U.S. Probation Office Use Only

A U.S. probation officer has instructed me on the conditions specified by the court and has provided me with a written copy of this judgment containing these conditions. For further information regarding these conditions, see *Overview of Probation and Supervised Release Conditions*, available at: www.uscourts.gov.

Defendant's Signature Date

SPECIAL CONDITIONS OF SUPERVISION

1. You must participate in a program of mental health treatment approved by the probation officer and follow the rules and regulations of such program. The probation officer, in consultation with the treatment provider, will supervise your participation in the program as to modality, duration, and intensity. You must pay for the cost of treatment based on your ability to pay.
2. If the judgment imposes restitution, you must pay the restitution in accordance with the Schedule of Payments sheet of this judgment. You must also notify the court of any changes in economic circumstances that might affect your ability to pay restitution. 3. You must not incur new credit charges or open additional lines of credit without the approval of the probation officer, unless you are in compliance with the periodic payment obligations imposed pursuant to the Court's judgment and sentence. 4. You must provide the probation officer access to any requested financial information and authorize the release of any financial information until all financial obligations imposed by the court are paid in full.
5. You must apply any monies received from income tax refunds, lottery winnings, inheritances, judgments, and any anticipated or unexpected financial gains to the outstanding court-ordered financial obligation in this case.
6. If you have an outstanding financial obligation, the probation office may share any financial or employment documentation relevant to you with the Asset Recovery Division of the United States Attorney's Office to assist in the collection of the obligation. 7. Any business you operate during the term of supervision must be approved by the probation officer. You must operate under a formal, registered entity, and you must provide the probation officer with the name of the business entity and its registered agents. You must maintain business records and provide all business

documentation and records as requested by the probation officer.

AO

245B (CO Rev. 11/20) Judgment in Criminal Case

DEFENDANT: JEFFREY KESTEN
CASE NUMBER: 1:20-cr-00291-DDD-1

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on the following page.

Assessment Restitution Fine AVAA Assessment* JVTA Assessment TOTALS** $ 100.00 $ 344,000.00 $ 0.00 $ 0.00 $ 0.00

☐ The determination of restitution is deferred until . An *Amended Judgment in a Criminal Case (AO 245C)* will be entered after such determination.

☒ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss***	Restitution Ordered	Priority or Percentage
Colorado Medicaid HCPF PICO P.O. Box 5143 Denver, CO 80217	P.O. Box 7520 Baltimore, MD 21207-0520	$29,543.00 (First priority payee)	$29,543.00 (First priority payee)
Centers for Medicare & Medicaid Services Division of Accounting Operations	$314,457.00 (Second priority payee)	$314,457.00 (Second priority payee)	

TOTALS $ 344,000.00 $ 344,000.00 ☐ Restitution amount ordered pursuant to plea agreement **$**

☐ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on the following page may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☒ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☒ the interest requirement is waived for the ☐ fine ☒ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Amy, Vicky, and Andy Child Pornography Victim Assistance Act of 2018, Publ. L. No. 115-299.
** Justice for Victims of Trafficking Act of 2015, Pub. L. No. 114-22.
*** Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows: A

☐ Lump sum payment of $ due immediately, balance due

☐ not later than , or
☐ in accordance with ☐ C, ☐ D, ☐ E, or ☐ F below; or

B ☒ Payment to begin immediately (may be combined with ☐ C, ☐ D, or ☒ F below); or

C ☐ Payment in equal *(e.g., weekly, monthly, quarterly)* installments of $ over a period of *(e.g., months or years)*, to commence *(e.g., 30 or 60 days)* after the date of this judgment; or

D ☐ Payment in equal *(e.g., weekly, monthly, quarterly)* installments of $ over a period of *(e.g., months or years)*, to commence *(e.g., 30 or 60 days)* after release from imprisonment to a term of supervision; or

E ☐ Payment during the term of supervised release will commence within *(e.g., 30 or 60 days)* after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F ☒ Special instructions regarding the payment of criminal monetary penalties:

The special assessment and restitution obligation are due immediately. Any unpaid monetary obligations upon release from incarceration shall be paid in monthly installment payments during the term of supervised release. The monthly installment payment will be calculated as at least 10 percent of the defendant's gross monthly income.

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during the period of imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Case Number
Defendant and Co-Defendant Names
(including defendant number)

Total Amount

Joint and Several Amount

☒ The defendant shall forfeit the defendant's interest in the following property to the United States: Money judgment in the amount of $344,000

Corresponding Payee, if appropriate

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

Payments shall he applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) AVAA assessment, (5) fine principal, (6) fine interest, (7) community restitution, (8) JVTA assessment, (9) penalties, and (10) costs, including cost of prosecution and court costs.

NEVADA STATE BOARD OF PHARMACY CONTROLLED SUBSTANCE APPLICATION

SECTION 5: PERSONAL AND PROFESSIONAL HISTORY

3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?

After completing its investigation on May 22, 2020, concerning my care of a single patient, the Colorado Medical Board determined not to initiate formal proceedings against my professional license. However, the Board did issue a disciplinary action in the form of a Letter of Admonition.

Please find the attached documentation from the Colorado Department of Regulatory Agencies.

Jeffrey Kesten MD
Jeffrey Kesten, M.D.

July 20, 2025
July 20, 2025

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

May 22, 2020

Jeffrey Kesten, M.D.

Re: License Number: DR. 0031919
Case Number: 2018-5306-B

Dear Dr. Kesten:

The Colorado Medical Board has concluded its inquiry into the aforementioned matter. It was the Panel's decision not to commence with formal proceedings against your professional license. However, the Panel did determine disciplinary action in the form of this letter of admonition is warranted.

As you recall, in April 2017, patient C.P., a 32-year old male, presented for evaluation and treatment of whole body allodynia and hyperalgesia, torticollis, anorexia, depression and anxiety disorder. You prescribed frequent ketamine troches and other forms of ketamine to the patient. There was concern for potential drug-seeking behavior, and your medical records reflect your recognition of the potential for "doctor shopping." Also, the patient was previously evaluated at several institutions, and multiple sources questioned the patient's diagnosis of complete regional pain syndrome. In your response to the Board through counsel, you stated that although it is a controlled substance, ketamine is not considered to be physiologically "addictive" as are opioids.

After a review of all the information in this matter, the Panel found that your care and treatment of patient C.P. fell below the generally accepted standards of practice for a physician, constituting unprofessional conduct in violation of section 12-240-121 of the Colorado Revised Statutes. Specifically, you continued to prescribe ketamine despite evidence that the patient's use of ketamine may be excessive in that for at least a 3-week period during your 2.5 years of treatment he was using ketamine on a dose schedule of every 2 hours, while being treated with multiple other controlled substances. While you conclude that ketamine is not addictive, and thus not contraindicated for the patient, the Board is concerned that the patient's presentation and behavior - including the Prescription Drug Monitoring Program data indicating early refills and additional prescriptions for ketamine, escalating doses, lack of sustained improvement, and lack of significant last pain reduction- were indicative of addiction. Additionally, you continued to prescribe ketamine despite continued reports of high levels of pain.

By this letter, the Board takes the formal disciplinary action of admonishing you for the conduct specified above, and warns you that repetition of such practice may lead to imposition of more severe disciplinary action. This letter is an open public record and a reportable action to individuals or entities requesting disciplinary information. The Board strongly encourages you to review and understand the Medical Practice Act requirements and obligations for the practice of medicine in Colorado.

Pursuant to agreement with the Board, you have agreed to waive the right provided by section 12-20-404(4)(b), C.R.S. to contest this Letter of Admonition. You previously exercised your right pursuant to section 12-20-404(4)(b) to contest the Letter of Admonition.

A Letter of Admonition, when accepted, becomes a permanent, public portion of your record. It is not, however, a restriction on your practice as a physician.

If you have further questions or concerns, please visit our website at https://www.colorado.gov/dora/dpo or you can contact our office at dora_medicalboard@state.co.us or by calling (303) 894-7800.

Sincerely,

FOR THE COLORADO MEDICAL BOARD
With Delegated Authority from Inquiry Panel B

Paula E. Martinez
Program Director

cc: Linda Siderius, Esq.

Notice

Your Healthcare Professions Profile will be updated to reflect this Colorado public action. Pursuant to section 12-30-102, C.R.S., your profile must be updated within 30 days of any reportable event. To ensure compliance, you must regularly review and update your profile. To access your profile, go to www.colorado.gov/dora/hppp and click the "Create/Update a Profile" link. For any questions, please contact dora_dpo_hppp@state.co.us.

11D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Y

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

What types of drug(s) will you be prescribing?

☐ Dangerous Drugs ONLY **(Non-Refundable $80 Fee) (PR)**

☒ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V **(Non-Refundable $200 Fee) (CS)**

Select the Controlled Substance Schedules you are applying to prescribe

☒ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Melissa Middle: Rae Last: Case

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip Code: 34639

Telephone: [redacted] Email: [redacted]

APRN License #: 884029 Specialty: Family

(A **current license and active-PRESCRIBING status** with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: NaphCare - Washoe County Detention Facility

Practice Address: 911 East Parr Boulevard Suite #:

City: Reno State: NV Zip: 89512

Telephone: 205-536-8400 Fax: 424-310-0330 Email: mcase8818@gmail.com

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☒ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name:

Collaborating Physician Practice Address: Suite #:

City: State: Zip:

Telephone: Fax: Email:

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	✔	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1,3,4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/19/2008	4/22/2009	OR	Portland	Multnomah

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
09-342	Oregon Board of Nursing

Reason/Charge
Acceptance of Voluntary Surrender of RN license

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Oregon Board of Nursing vs Melissa Rae Waller	

Name of Business/Industry/Entity

Provide explanation below:

Please see attached explanation

Melissa Rae Case

Original Signature (electronic, copies or stamps not accepted)

5/1/2025

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1,3,4 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/19/2008	8/20/2009	FL	Tampa	Hillsborough

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2009-09815	Florida Board of Nursing

Reason/Charge
Suspension of RN license due to acceptance of voluntary surrender by Oregon BON

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Florida Department of Health vs Melissa Rae Waller	

Name of Business/Industry/Entity

Provide explanation below:

Please see attached explanation

Melissa Rae Cox

Original Signature (electronic, copies or stamps not accepted)

5/1/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Melissa Rae Case

Applicant Print Name (First, Last)

Melissa Rae Case

Original Signature (electronic, copies or stamps not accepted)

5/1/2025

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

N/A

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: 5/12/25 Amount: $ 200.00

License explanation

While on a travel nursing assignment in Portland, Oregon from 4/2007-2/2008 (under my maiden name Melissa Rae Waller), I began diverting and using narcotic pain medication as a method to cope with the feelings I was experiencing from the loss of a relationship, the illness of my grandfather, loneliness from being on the other side of the country away from my friends and family who were back home in Florida, and the lack of a local support system to deal with and process these feelings. What I believed to be a harmless way to deal with these feelings, very quickly became an illness I could not control. I was ultimately confronted by hospital management regarding concerns that I was diverting. I admitted to them that this was true, and I was encouraged by management to self-report to the Oregon Board of Nursing (OR BON).

On 2/19/2008, I self-reported to the OR BON and was advised to enter inpatient chemical dependency treatment. I attended a 28-day residential treatment program at Serenity Lane in Eugene, OR, and after completion of the residential portion, I transitioned to their intensive outpatient treatment program. While I had self-reported to the OR BON and attended treatment as advised, I was still in denial of how unmanageable my life had become and did not yet believe that I had a chemical dependency issue.

While trying to figure out how to make ends meet after losing my income and the housing that came along with my travel contract, I accepted a position as a veterinary technician, which is the field I worked in prior to going into nursing. This was not an approved environment to work in during treatment, but I felt I had no other way to make ends meet, as I had no other work experience. I continued using until 11/7/2008, which is the day I admitted to my mother that I was still struggling and couldn't stop. With the assistance of my family, I left Oregon to return home to Florida the following day on 11/8/2008, and 16 years later, this remains my clean date.

I was accepted into a treatment program at the Centre for Women in Tampa, FL, and began their program on 12/12/2008, which was their soonest available opening. The OR BON agreed to monitor me while I attended treatment in Florida, and during one of my counseling sessions, my counselor urged me to become fully honest in order to treat my addiction, and together with my counselor, we called the OR BON on 1/28/2009, to become honest with them about the fact that I had taken the veterinary position even though I had known that this was not an approved environment to work in, and was found to be out of compliance with my monitoring contract. It was at this time that I chose to voluntarily surrender my Oregon RN in lieu of revocation by the OR BON, and my voluntary surrender was accepted on 4/22/2009. Due to the voluntary surrender of my Oregon RN license, my Florida RN license was subsequently suspended on 8/20/2009.

During my time in treatment, I decided that I never wanted to be in the position I was in again and decided that I would not return to the field of nursing. As such, I did not renew my Florida RN license for a period of two renewal cycles, rendering it Null and Void. I successfully

completed the treatment program at the Centre for Women on 6/23/2009 and one year later, in 6/2010, I decided that I missed the career that I once loved so much and contacted the Florida Intervention Project for Nurses (IPN) to see what I would need to do to become active in their nurse monitoring program and return to the field of nursing. They allowed me to enter the IPN monitoring program and I appeared before the Florida Board of Nursing on 2/11/2011 to request reinstatement of my license which was unanimously approved. A new Florida RN license was issued on 2/16/2011 and I went on to successfully complete five years of monitoring with the Florida Intervention Project for Nurses on 3/13/2015.

I have since obtained a bachelor's degree in nursing from the University of South Florida in 5/2014 and a master's degree as a Family Health Nurse Practitioner from the University of South Florida in 5/2018. I maintain Clear/Active Florida multistate compact RN, California RN, and Nevada RN licenses, Clear/Active APRN licenses in Colorado, Florida, Iowa, Nevada, Ohio, Virginia, Washington, Wisconsin, and Wyoming, Clear/Active DEA licenses in Colorado, Florida, Iowa, Washington, and Wyoming, and am Board Certified through the American Nurses Credentialing Center (ANCC).

I have worked extremely hard to repair my professional reputation and am well-respected as an APRN in the hospitals in which I have worked, by the employers I have worked for, by the colleagues with whom I have worked, and by the patients/families for whom I care for. I continue to give back to the University of South Florida by acting as a preceptor for nurse practitioner students and have remained active in my 16 years of recovery by attending 12-step meetings, doing step-work with my sponsor, sponsoring other women, and sharing my story to those who are still struggling with active addiction. While my addiction and license discipline were devastating and life-changing, they have made me extremely protective of my current nursing and DEA licenses, have urged me to ensure that am always practicing within my scope of practice and within the rules and laws of the nursing boards, states agencies, and facilities under which I practice, and have ultimately caused me to become a more empathetic and caring provider to the patients for whom I care for.

I am applying for the ability to prescribe controlled substances in Nevada as I am currently employed as an APRN with a company that is contracted to provide medical care to inmates in correctional facilities across the country, for which we routinely prescribe controlled medications for the purpose of medication-assisted detox from alcohol and other substances. The position I work in provides remote assistance to the onsite providers working in these correctional facilities.

I have attached my completion letters from the Centre for Women and the Intervention Project for Nurses, as well as copies of the administrative complaints and final orders from both the Florida Board of Nursing and the Oregon Board of Nursing. Please let me know if you have any questions or need further clarification on the above and thank you for your consideration of my application.

COPY

BEFORE THE BOARD OF NURSING
OF THE STATE OF OREGON

In the Matter of	)	
	)	STIPULATION FOR
Melissa Rae Waller, RN	)	VOLUNTARY SURRENDER
	)	OF REGISTERED NURSE LICENSE
	)	
License No.: 200740803RN	)	Case No.: 09-342

Melissa Rae Waller, hereinafter referred to as "Licensee" is a licensed Registered Nurse (RN) in the State of Oregon.

Licensee was licensed as a Registered Nurse in Oregon on April 2, 2007.

On February 19, 2008, Licensee self-reported to the Board that she had been diverting narcotic pain medication from Oregon Health Sciences University (OHSU), while working there as a traveler nurse on contract with the hospital.

An audit by OHSU staff of Licensee's narcotics access showed a high amount of fentanyl withdrawals. Further investigation showed Licensee had withdrawn fentanyl for patients who had no orders for the medication.

On February 11, 2008, when confronted with the evidence by her employer, Licensee admitted to having a chemical dependence issue.

On February 25, 2008, Licensee entered in-patient chemical dependency treatment at Serenity Lane, Eugene. She completed in-patient treatment and was moved to a lower level of treatment on March 25, 2008.

On April 14, 2008, during a meeting with Board staff, Licensee admitted that she had diverted fentanyl and dilaudid from OHSU during her duties as an RN. She admitted withdrawing fentanyl under patient's names, even though no order existed for that medication to be administered to that patient. She admitted asking staff to witness her wastage of what she claimed to be fentanyl but, in fact, was not. She stated that she never withheld pain medication from patients.

On May 20, 2008, Licensee signed a contract to enter the Board's Nurse Monitoring Program agreeing to comply with all the requirements of the program.

On January 28, 2009, Licensee was found to be out of compliance with the Nurse Monitoring Program contract.

WHEREAS by the above actions, Melissa Rae Waller is subject to disciplinary action pursuant to violations of **ORS 678.111(1) (e), and (f); and OAR 851-0045-0070(2)(f) and (i);(5)(c), and (7)(e)** which provide as follows:

ORS 678.111 Causes for denial, revocation or suspension of license or probation, reprimand or censure of licensee.

(1) Issuance of a license to practice nursing, whether by examination or by endorsement, of any person may be refused or the license may be revoked or suspended or the licensee may be placed on probation for a period specified by the Oregon State Board of Nursing and subject to such conditions as the board may impose or may be issued a limited license or may be reprimanded or censured by the board, for any of the following causes:

(e) Use of any controlled substance or intoxicating liquor to an extent or in a manner dangerous or injurious to the licensee or others or to an extent that such use impairs the ability to conduct safely the practice for which the licensee is licensed.

(f) Conduct derogatory to the standards of nursing.

OAR 851-045-0070 Conduct Derogatory to the Standards of Nursing Defined

(2) Conduct related to other federal or state statute/rule violations:

(f) Unauthorized removal or attempted removal of narcotics, other drugs, supplies, property, or money from clients, the workplace, or any person.

(i) Possessing, obtaining, attempting to obtain, furnishing, or administering prescription or controlled drugs to any person, including self, except as directed by a person authorized by law to prescribe drugs.

(5) Conduct related to impaired function:

(c) Practicing nursing when physical or mental ability to practice is impaired by use of drugs, alcohol or mind-altering substances.

(7) Conduct related to the licensee's relationship with the Board:

(e) Failing to comply with the terms and conditions of Nurse Monitoring Program agreements.

Licensee acknowledges that the Board would prevail at hearing regarding the above violations and wishes to cooperate with the Board in resolving the present disciplinary problem. She has elected to voluntarily surrender her Registered Nurse license.

THEREFORE, the following will be proposed to the Oregon State Board of Nursing and is agreed to by Licensee:

That the voluntary surrender of the Registered Nurse license of Melissa Rae Waller be accepted. If, after three years, she wishes to reinstate her Registered Nurse license, she shall appear before the Board to request reinstatement of her license as a Registered Nurse. She shall provide evidence that she has received treatment for chemical dependence, complied with all treatment and aftercare requirements, and has two years of documented sobriety. Should the Board reinstate the Registered Nurse license of Ms. Waller, she would be subject to whatever terms and conditions the Board may impose.

Licensee agrees that she will not practice as a Registered Nurse from the date of signature on this Stipulation.

Licensee understands that this Stipulation for Voluntary Surrender is a public record.

Licensee understands that this Stipulation will be submitted to the Board of Nursing for their approval and is subject to the Board's confirmation.

Licensee understands that by signing this Stipulated Agreement she waives the right to an administrative hearing. She acknowledges that no promises, representations, duress or coercion have been used to induce her to sign this Stipulation.

Licensee has read the Stipulation, understands the Stipulation completely, and freely signs the Stipulation.

DATED this 10 day of March, 2009.

Melissa Rae Waller, RN

Melissa Rae Waller, RN

FOR THE BOARD OF NURSING OF THE STATE OF OREGON

Linda Fisher-Lewis
Program Manager
Compliance, Investigation and Practice

David Lilly
Investigator
Compliance and Investigation

BEFORE THE OREGON
STATE BOARD OF NURSING

COPY

In the Matter of Melissa Rae Waller, RN	)	FINAL ORDER
License No.: 200740803RN	)	Case No. 09-342

The Oregon State Board of Nursing (Board) is the state agency responsible for licensing, regulating and disciplining certain health care providers, including Registered Nurses, in the State of Oregon. Melissa Rae Waller (Licensee) is a Registered Nurse in the State of Oregon.

This Matter was considered by the Board on April 22, 2009. Licensee did not appear personally. The issue for the Board was whether to approve the Stipulation signed by Licensee on March 10, 2009, and so dispense with this Matter pursuant to ORS 183.417(3).

Upon review of the Stipulation and the agency file in this Matter, the Board finds that reasonable factual and legal grounds exist to support approval of the Stipulation. It is hereby

ORDERED that the Stipulation signed by Licensee on March 10, 2009, be approved and by this reference incorporated herein, and it is further

ORDERED that the Board accept the Voluntary Surrender of Melissa Rae Waller's Registered Nurse License and that the Stipulation for Voluntary Surrender be adopted.

DATED this 23rd day of April, 2009.

FOR THE BOARD OF NURSING OF THE STATE OF OREGON

James E. McDonald, RN, FNP
Board President

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NUMBER 2009-09815**

MELISSA RAE WALLER, R.N.,

RESPONDENT.

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Nursing against Respondent Melissa Rae Waller, R.N., and in support thereof asserts:

1. Petitioner is the state department charged with regulating the practice of nursing pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 464, Florida Statutes.

2. At all times material to this Complaint, Respondent was a registered nurse (R.N.) within the state of Florida, having been issued license number RN 9226882.

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3. Respondent's address of record is [redacted] 33617.

4. On or about March 10, 2009, Respondent signed and submitted a form that voluntarily surrendered her Oregon nursing license.

5. On or about April 22, 2009, the Oregon State Board of Nursing accepted Respondents voluntary surrender of her Oregon nursing license.

6. The Oregon State Board of Nursing is the licensing authority of the State of Oregon.

7. Section 464.018(1)(b), Florida Statutes (2008), provides that having a license to practice nursing revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of another state constitutes grounds for disciplinary action by the Board of Nursing.

8. The licensing authority for the State of Oregon acted against the license of Respondent by accepting Respondent's voluntary surrender of her Oregon nursing license.

9. Based on the foregoing, Respondent violated Section 464.018(1)(b), Florida Statutes (2008), by having her license to practice nursing revoked, suspended, or otherwise acted against, including the

denial of licensure, by the licensing authority of another state.

WHEREFORE, the Petitioner requests that the Board of Nursing enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and any other relief that the Board deems appropriate.

SIGNED this 20th **day of** August, **2009.**

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angela Barlow
DATE 8/21/09

TREVOR SUTER
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar #0017617
(850) 245-4640
(850) 245-4683 Fax

PCP: August 20, 2009
PCP Members: Hathgood & Kemp

/TS

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

CASE NO.: 2009-09815

v.

MELISSA RAE WALLER, R.N.,

Respondent,

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above named parties hereby offer this Agreement to the Board of Nursing as disposition of the Administrative Complaint, attached hereto as Exhibit "A", in lieu of any other administrative proceedings. The terms herein become effective only if and when a Final Order accepting this Agreement is issued by the Board and filed. In considering this Agreement, the Board may review all investigative materials regarding this case. If this Agreement is rejected, it, and its presentation to the Board, shall not be used against either party.

STIPULATED FACTS

1. Respondent is a **Registered Nurse** in the State of Florida holding license number **9226882.**

2. The Respondent is charged by an Administrative Complaint filed by the Department and properly served upon Respondent with violations of Chapters 456 and/or 464,

Florida Statutes. A true and correct copy of the Administrative Complaint is attached hereto and incorporated by reference as Exhibit A.

3. Respondent neither admits nor denies the factual allegations contained in the Administrative Complaint.

STIPULATED LAW

1. Respondent admits that she is subject to the provisions of Chapters 456 and 464, Florida Statutes, and the jurisdiction of the Department and the Board.

2. Respondent admits that the stipulated facts, if proven true, constitute violations of laws as alleged in the Administrative Complaint.

3. Respondent admits that the Agreement is a fair, appropriate and reasonable resolution to this pending matter.

PROPOSED DISPOSITION

1. The Board of Nursing shall reprimand the license of the Respondent.

2. The Respondent must pay an administrative fine in the amount of **TWO HUNDRED FIFTY-DOLLARS ($250.00)** and investigative costs not to exceed **ONE THOUSAND TWO HUNDRED FOUR DOLLARS AND SIXTY-NINE CENTS ($1,204.69)** within twelve (12) months from the date of entry of the Final Order. However, if the Respondent is in the Intervention Project for Nurses (IPN), the payment is due **prior** to completion of IPN. If the Respondent's license is suspended by the terms of this agreement, the payment is due **prior** to the application for reinstatement of the license. If the Respondent is placed on probation, the payment is due **prior** to the completion of the probationary period. The Respondent has the responsibility to

document financial hardship **prior** to the due date of the payment. Payment must be by money order. Partial payments shall be accepted. Payment shall be made to the Board of Nursing and mailed to, DOH-Client Services, P.O. Box 6320, Tallahassee, Florida 32314-6320, Attention: Nursing Compliance Officer.

3. The license of **MELISSA RAE WALLER, R.N.**, is suspended until she personally appears before the Board and can demonstrate her/his present ability to engage in the safe practice of nursing. That demonstration shall include at least an in-depth psychological evaluation coordinated through the Intervention Project for Nurses, with an MMPI or other appropriate testing from a psychiatrist, psychologist or other licensed mental health counselor. The Respondent shall supply a copy of the Final Order to the evaluator. The evaluation must contain evidence that the evaluator knows of the reason for referral. The evaluator must specifically advise this Board that the Respondent is presently able to engage in the safe practice of nursing or recommend the conditions under which safe practice could be attained. Prior to appearance before the Board, the Respondent must also submit proof of continued treatment and counseling if recommended in the psychological evaluation and a reentry plan. The Board reserves the right to impose reasonable conditions of reinstatement at the time the Respondent appears before the Board to demonstrate the present ability to engage in the safe practice of nursing.

4. Within thirty (30) days, the Respondent shall return her/his license to the Board office, 4053 Bald Cypress Way, Bin C02, Tallahassee, Florida 32399-3252 or shall surrender the license to an Investigator of the Department of Health. The Respondent's

employer shall immediately be informed of the suspension in writing by the Respondent with a copy to the Board office.

5. The Respondent shall not violate Chapter 456 or 464, Florida Statutes, the rules promulgated pursuant thereto, any other state or federal law, rule, or regulation relating to the practice or the ability to practice nursing. Violation of an order from another state/jurisdiction shall constitute grounds for violation of the Board Order adopting this Agreement.

6. It is expressly understood that this Agreement is subject to the approval of the Board and Department and has no force and effect until an Order is entered adopting the Agreement.

7. This Agreement is executed by the Respondent for the purpose of avoiding further administrative action by the Board of Nursing regarding the acts or omissions specifically set forth in the Administrative Complaint attached hereto. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Agreement. Furthermore, should this joint Agreement not be accepted by the Board, it is agreed that presentation to, and consideration of, this Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration or resolution of these proceedings. Respondent shall offer no evidence, testimony or argument that disputes or contravenes any stipulated fact or conclusion of law.

SIGNED this 7th day of April 2010 ~~2009~~.

Melissa Rae Waller RN
MELISSA RAE WALLER, R.N.

Before me personally appeared Melissa Waller whose identity is known to be by FL Drivers License (type of identification), and who under oath, acknowledges that his/her signature appears above.
Sworn to and subscribed by Respondent before me this 7th day of April 2010.

Notary Public
My Commission Expires: July 18, 2011

ARIEL WILLIAMSON
Notary Public, State of Florida
Commission# DD698432
My comm. expires July 18, 2011

APPROVED this 8th day of Apr. 1 2010.

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

Counsel for Petitioner:
Trevor S. Suter
Assistant General Counsel
FBN: 0017617
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, BIN #C-65
Tallahassee, Florida 32399-3265

50124

Final Order No. DOH-10-1640-S -MQA
FILED DATE - 7-8-10
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF NURSING

DEPARTMENT OF HEALTH,

Petitioner,

vs.

Case No.: 2009-09815
License No.: RN 9226882

MELISSA RAE WALLER,

Respondent.
_____/

FINAL ORDER

THIS CAUSE came before the BOARD OF NURSING (Board) pursuant to Sections 120.569 and 120.57(4), Florida Statutes, on June 11, 2010, in Jacksonville, Florida, for the purpose of considering a settlement agreement (attached hereto as Exhibit A) entered into between the parties in this cause. Upon consideration of the settlement agreement, the documents submitted in support thereof, the arguments of the parties, and being otherwise fully advised in the premises, it is hereby

ORDERED AND ADJUDGED that the settlement agreement as submitted be and is hereby approved and adopted in toto and incorporated herein by reference. The costs are $541.99. Accordingly, the parties shall adhere to and abide by all the terms and conditions of the settlement agreement.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 8th day of July, 2010.

BOARD OF NURSING

JOE BAKER, JR.
Executive Director for
Jessie Colin, RN, PhD
Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to MELISSA RAE WALLER, [redacted] 33617; and by interoffice delivery to and by interoffice delivery to Lee Ann Gustafson, Senior Assistant Attorney General, Department of Legal Affairs, PL-01 The Capitol, Tallahassee FL 32399-1050, William Miller, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399-3265 this 8 day of July, 2010.

Deputy Agency Clerk

7010 0780 0002 0796 1802

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PS Form 3800, August 2006 See Reverse for Instructions

305 South Hyde Park Avenue
Tampa, Florida 33606

813-251-8437
Fax: 813-253-2081

www.centreforwomen.org

November 23, 2010

Re: Melissa Waller
[redacted]

To Whom It May Concern:

Since 1980, Project Recovery has proven to be a highly effective, affordable outpatient treatment program. It is designed to meet the special needs of women. Project Recovery is licensed by Florida Department of Children and Families and accredited by Joint Commission to provide outpatient services to women that meet criteria for admission into the program.

Ms. Waller was admitted into Project Recovery on 12-12-08, she successfully completed outpatient treatment on 6-23-09. Ms. Waller attended the intensive outpatient program which provides 21 hours of group and individual counseling per week. She was subsequently admitted into Aftercare on 6-30-09. She attended aftercare once and was discharged on 8-6-09 During the program she made significant progress on her goals and actively participated in the program.

If you have any additional questions, please feel free to contact me at 813-251-8437 ext. 239.

Thank you,

Sonya Bufe

Sonya Bufe LMHC, CAP
Program Manager
Project Recovery

IPN
Intervention Project for Nurses

March 13, 2015

Melissa Waller (Case #64701)
[redacted]

Dear Ms. Waller:

Congratulations! The Intervention Project for Nurses (IPN) is happy to inform you that you have met the criteria for successful completion of the active monitoring phase of this program.

A memo will also be sent to the Board of Nursing office on this date validating your successful completion. We suggest that you contact the Board office (850) 488-0595, and ask for Compliance Section, within the next month to confirm that your record has been revised to reflect your IPN completion status.

We extend to you our sincere best wishes for your continuing success in recovery.

Sincerely,

Miranda Bullington, BS
FBON Case Manager

MB/tnp

PC: Shaw Eberhardt, MSW

SLV6COMP2/2013

12

From:	NukemRx
To:	Brett Kandt; Jessette Phaynarikone; Darlene Nases; David Wuest; Yenh Long; Troy Curnutt
Subject:	Submission of Petition for Advisory Opinion – Advanced Molecular Compounding, LLP
Date:	Friday, June 27, 2025 7:58:10 PM
Attachments:	Petition for Advisory Opinion- NV BOP AMC (2).pdf Cease and Desist_Order - Advanced Molecular Compounding (2).pdf Response to C&D 4-4-2025.pdf BioRx® System Overview_ Compliance, Traceability, and Security Features (Used by Advanced Molecular Compounding, LLP).pdf

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WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Nevada State Board of Pharmacy,

Please find attached a **formal Petition for Advisory Opinion** submitted on behalf of **Advanced Molecular Compounding, LLP**. Also attached are the following supporting documents:

1. A copy of the **Cease-and-Desist letter dated April 1, 2025**
2. AMC's **formal response dated April 4, 2025**

We respectfully request the Board's consideration of this petition in accordance with **NRS 233B.120** and **NAC 639.150**.

Thank you for your time and attention.

Sincerely,
Dr. Justin Curnutt, Pharm.D.
Chief Pharmacist of Operations
Advanced Molecular Compounding, LLP

PETITION FOR ADVISORY OPINION
Pursuant to NRS 233B.120 and NAC 639.150

To:
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

From:
Dr. Justin Curnutt, Pharm.D.
Chief Pharmacist of Operations
Advanced Molecular Compounding, LLP
167 Southside Way, Unit C, Chubbuck, ID 83202
702.960.8640
justin@moleculararcoaches.com or nukemrx@gmail.com

Subject: Formal Petition for Advisory Opinion on Mobile Nuclear Pharmacy Model

Dear Members of the Nevada State Board of Pharmacy,

On behalf of Advanced Molecular Compounding, LLP ("AMC"), we hereby submit this formal written petition requesting an advisory opinion, pursuant to **Nevada Revised Statutes (NRS) 233B.120** and **Nevada Administrative Code (NAC) 639.150**. This petition seeks clarification regarding the applicability of Nevada pharmacy statutes and regulations to a proposed mobile nuclear pharmacy model designed to serve rural and underserved healthcare providers throughout the State of Nevada.

Why This Matters: Ga-68 and Patient Access

Gallium-68 (Ga-68) is a vital diagnostic radiopharmaceutical used in PET imaging to detect serious diseases such as prostate cancer, neuroendocrine tumors, and other life-threatening conditions. Due to its short physical half-life (68 minutes), Ga-68 must be compounded and administered near the point of care. For many patients in rural Nevada, access to this life-saving diagnostic imaging is limited or non-existent due to geographic barriers and the absence of nearby radiopharmacies.

Advanced Molecular Compounding, LLP seeks to bridge this access gap by operating a mobile nuclear pharmacy that safely and compliantly prepares and delivers immediate-use radiopharmaceutical doses in underserved regions.

Background

AMC is an established and experienced nuclear pharmacy operation, with significant expertise in regulatory compliance across USP <825>, USP <797>, 21 U.S.C. § 353a, and all applicable DOT and Nuclear Regulatory Commission (NRC) requirements. We are actively pursuing licensure in multiple states, including Idaho.

On April 1, 2025, AMC received a Cease-and-Desist (C&D) letter from the Nevada State Board of Pharmacy alleging unlicensed activity. In our formal response dated April 4, 2025, we clarified the following facts:

- No nuclear pharmacy operations have occurred in Nevada;
- No prescriptions have been dispensed;
- No sterile or non-sterile compounding has taken place;
- No patient services have been rendered;
- No radiopharmaceutical deliveries have occurred within the State of Nevada.

All cited communications were purely exploratory in nature and were made in good faith as part of our attempt to obtain regulatory guidance *prior* to initiating services. Despite this, we have not received any follow-up or access to a qualified Board representative for discussion.

In Nevada, following the C&D, we have been denied any formal opportunity for discussion, review, or clarification. Accordingly, we are submitting this formal petition for an advisory opinion and requesting it be considered outside of a formal Board hearing, as allowed under NRS 233B.120 and NAC 639.150.

Proposed Model Description

AMC proposes to operate a mobile nuclear pharmacy unit that includes the following features:

- A fully self-contained ISO 5 cleanroom housed within a DOT-compliant trailer;
- Radiation shielding and safety systems compliant with DOT 49 CFR 173, and NRC standards;
- Supervision by a Nevada-licensed nuclear pharmacist;
- Integration with BioRx® pharmacy management software for prescription traceability and electronic recordkeeping.

- Has running hot and cold water.
- Has an onboard bathroom.

The mobile unit is intended to compound Ga-68 doses exclusively for immediate on-site administration, consistent with the “immediate use” provision defined in USP <797> and USP <825>. This model will not engage in anticipatory compounding, batching, retail pharmacy operations, or delivery-based distribution.

Advisory Opinion Questions

We respectfully seek the Board’s legal and regulatory guidance on the following:

1. **Licensure Pathway**
   What specific license(s), if any, are required in Nevada for AMC to legally operate the proposed mobile nuclear pharmacy model?

2. **Immediate Use Applicability**
   Does the Board recognize and adopt the “immediate-use exemption” as defined under **USP <797>** and **USP <825>**? If not, which Nevada statutes or regulations override this exemption?

3. **Scope and Standing of Cease-and-Desist**
   In light of the fact that no activity occurred and all communications were exploratory in nature, what is the legal basis for the April 1, 2025 C&D?
   Will the Board consider rescinding or modifying the C&D to mitigate reputational harm and regulatory confusion?

4. **Mobile and Remote Pharmacy Models**
   Is the Board open to establishing a regulatory framework for mobile nuclear pharmacies similar to existing accommodations for **telepharmacy**, **remote dispensing**, or **limited service outlets**?

5. **Facility Requirements**
   What specific documentation, inspection criteria, or validation protocols would apply to an ISO 5 mobile cleanroom overseen by a Nevada-licensed pharmacist?

Supporting Documents Attached

- AMC's formal April 4, 2025 written response to the Cease-and-Desist
- Copy of the April 1, 2025 Cease-and-Desist letter
- Overview of AMC's mobile cleanroom design, safety systems, and operating protocols
- BioRx® documentation regarding software compliance, traceability, and security features

---

Request for Independent Consideration

Pursuant to **NAC 639.150(2)**, we respectfully request that this petition be reviewed and answered without requiring appearance before the Board, unless the Board deems a hearing necessary for full evaluation. If a public hearing is preferred, we ask that this matter be included on the next available meeting agenda, with sufficient time allocated for discussion..

Conclusion

Advanced Molecular Compounding, LLP remains committed to working in full partnership with the Nevada State Board of Pharmacy. We are seeking only clarity, fairness, and a pathway to safely serve Nevada's rural populations through an innovative but compliant model. This petition has been prepared and submitted in accordance with the procedures outlined in **NRS 233B.120** and **NAC 639.150**, and is intended to assist the Board in offering guidance to licensees and applicants who aim to advance pharmacy practice responsibly.

Thank you for your time, your service to the people of Nevada, and your consideration of this petition.

Sincerely,
Dr. Justin Curnutt, Pharm.D.
Chief Pharmacist of Operations
Advanced Molecular Compounding, LLP
1007 Ridgegate St, Henderson, NV 89002
702.960.8640
justin@moleculargcompounding.com

JOE LOMBARDO
Governor

STATE OF NEVADA

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

J. DAVID WUEST
Executive Secretary

DEPARTMENT OF BUSINESS AND INDUSTRY
OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS
STATE OF NEVADA BOARD OF PHARMACY

April 1, 2025

VIA CERTIFIED U.S. MAIL AND EMAIL TO: nukemrx@gmail.com

Justin Curnutt, PharmD, Chief Pharmacist of Operations
Troy Curnutt, President & CEO
Advanced Molecular Compounding LLC
167 Southside Way Suite E
Chubbuck, ID 83202

Re: CEASE-AND-DESIST ORDER

9489 0178 9820 3037 0189 51

Dear Messrs. Curnutt:

The Nevada State Board of Pharmacy (Board) has determined that Advanced Molecular Compounding LLC, is engaged or intends to engage in dispensing prescriptions to patients in Nevada without a valid license/permit issued by the Board. Specifically, you have stated an intent to operate as a mobile nuclear pharmacy in Nevada, compounding and administering sterile radiopharmaceutical compounded drug products to Nevada patients, without obtaining the required licenses/permits. This constitutes a violation of State and federal law, including, without limitation, NRS 639.100(1), NRS 639.230, NRS 639.2321, NAC 639.5802-.584, *inclusive*, NAC 639.6701-.6702, *inclusive*, NAC 639.6705-.67079, *inclusive*, 21 U.S.C. § 353a and USP-797 standards, U.S.C. § 331(a), (b) and (c), NRS 585.520(1) and (2) and/or NRS 454.351(1).

Advanced Molecular Compounding LLC is hereby ordered pursuant to NRS 639.2895(1) to CEASE and DESIST from dispensing prescriptions to patients in Nevada and/or otherwise operating as a nuclear pharmacy in Nevada without a valid license/permit issued by the Board.

Failure to comply with this cease-and-desist order may result in the issuance of a CITATION for unlicensed activity and assessment of an administrative fine against Advanced Molecular Compounding LLC pursuant to NRS 639.2895(2) and (3). Failure to comply may also result in the filing of administrative charges against Justin Curnutt, PharmD, Certificate of Registration No. 18338, and criminal prosecution of all responsible parties.

If you have any questions please contact me at bkandt@pharmacy.nv.gov.

Regards,

Brett Kandt
General Counsel

Dear Mr. Kandt,

We are writing in response to your letter dated April 1, 2025, regarding the cease-and-desist order issued to Advanced Molecular Compounding LLC (“AMC”) for alleged unlicensed pharmaceutical activity in the State of Nevada.

Commitment to Compliance

First and foremost, AMC respects and fully supports the Nevada State Board of Pharmacy’s regulatory authority and remains committed to full compliance with all federal and state laws governing pharmacy operations, nuclear pharmacy, and sterile compounding.

Clarification of Current Operations

We respectfully clarify that AMC has not engaged in the dispensing of prescriptions, compounding of sterile radiopharmaceuticals, or provision of nuclear pharmacy services within the State of Nevada. No patients have been served, and no physical operations have commenced in Nevada as of the date of this letter.

The communications referenced in your letter reflect internal planning discussions related to a future business model that we hoped could align with existing legal frameworks, such as USP <825> and federal "immediate use" provisions. These exploratory conversations were not intended to imply that any operations had begun without proper licensure. In fact, AMC has been carefully and patiently navigating regulatory planning for more than eight months, during which time we have repeatedly reached out to the Board in an effort to understand the appropriate licensure pathways for our model. Unfortunately, we have not received any formal guidance or actionable direction to date.

Our Intent and Readiness to Engage

AMC is currently licensed and in good standing in other jurisdictions, including Idaho. We remain eager to ensure that any future operations in Nevada are fully compliant with NRS 639, USP <825>, 21 U.S.C. § 353a, and other applicable regulatory standards. Our core mission is to expand access to life-saving radiopharmaceuticals in underserved areas through safe, compliant, and modernized infrastructure.

In light of the Board’s recent communication, we are encouraged that the regulatory conversation has begun in earnest and we would welcome the opportunity to engage in a productive dialogue moving forward.

Request for Guidance

To that end, we respectfully request written clarification or a scheduled meeting to help us understand:

- The applicable licensure pathway for a mobile nuclear pharmacy model that includes a self-contained ISO 5 cleanroom, operating under the direction of a licensed nuclear pharmacist.

- Why our intended model would not qualify under the federal “immediate use” exemption as outlined in USP <797> and <825>, and what provisions of Nevada law override or restrict that applicability.
- Any potential framework the Board would consider (e.g., remote dispensing models, mobile pharmacy permitting, telepharmacy parallels) that could support safe and compliant operation within the state.
- Facility expectations, including inspection procedures, cleanroom validation, and specific pharmacist licensing or storage requirements unique to Nevada.

Request to Modify or Remove the Cease-and-Desist

Given that no dispensing, compounding, or patient-facing activity has occurred in Nevada, we respectfully ask that the Board consider not only clarifying the scope of the cease-and-desist order, but also removing it from AMC’s formal record or status. Since no unlicensed activity has taken place, we are concerned that the presence of this order- even if based on misunderstanding- could create undue barriers to future licensure or hinder the progress of this important healthcare initiative.

We fully understand and respect the seriousness of the Board’s position, and we remain in full cooperation to ensure that no future activity occurs without prior approval and appropriate licensure. Our intent is to move forward with full transparency and mutual understanding, and we hope this matter can be resolved in a way that supports both compliance and innovation.

A Path Forward

We are ready and willing to collaborate on a viable licensing framework that protects patient safety, maintains regulatory integrity, and reflects the evolution of pharmacy practice and delivery models. AMC’s mission is to meet unmet medical needs while strictly adhering to state and federal law- and we cannot do so without the Board’s insight and cooperation.

Please let us know how best to proceed or if a time can be scheduled to discuss this further. Thank you for your time, consideration, and for your ongoing commitment to public health and pharmacy safety in Nevada.

Sincerely,

Justin Curnutt, PharmD, ANP
Chief Pharmacist of Operations
Advanced Molecular Compounding LLC

&

Troy Curnutt
President & CEO
Advanced Molecular Compounding LLC

BioRx® System Overview

Provided by BioRx / EC2 Software Solutions
Integrated with Mirion RADTracker and DoseCalibrator™ Systems
Used by Advanced Molecular Compounding, LLP (AMC)

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1. Regulatory Compliance

The BioRx® platform is purpose-built to meet the stringent documentation and operational requirements of nuclear pharmacies, aligning with:

- **USP <797> and USP <825>**: Captures time-stamped data for dose preparation, labeling, and beyond-use dating, ensuring full traceability.
- **21 CFR Part 11**: Includes electronic signatures, audit trails, and system security measures that meet FDA and DEA standards for electronic records.
- **DOT / NRC Compliance**: Interfaces with shipping modules to generate compliant **Bill of Lading (BOL)** and shipping manifests for radiopharmaceutical transportation.
- **IAEA SSR-6 Transport Protocols**: Supports packaging and dose tracking aligned with international radiation transport standards.

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2. End-to-End Traceability

- **Dose Lifecycle Tracking**: Tracks each unit dose from generator elution, synthesis, quality control (QC), pharmacist verification, to end-user administration.
- **Integrated with Mirion Technologies**: Includes compatibility with **Mirion's DoseCalibrator™**, enabling real-time calibration data capture for each patient-specific dose.
- **Automated Reporting**: Logs lot numbers, elution times, specific activity, activity calibration windows, and decay corrections automatically.

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3. System Security and Access Control

- **User Role Management**: Multi-tiered access with unique login credentials per user (pharmacist, technician, QA, driver).
- **Audit Trail & Logs**: Immutable system audit logs capture every transaction and modification.
- **Secure Data Storage**: Encrypted, HIPAA-compliant storage of all patient and dose data; includes both on-site and cloud-based redundancy.
- **Disaster Recovery**: Daily backups and encrypted recovery protocols ensure business continuity in case of hardware or power failures.

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4. Software in a Mobile Environment

- BioRx is actively used in **mobile nuclear pharmacy setups** nationwide.
- Includes **offline capability**, ensuring uninterrupted functionality in low-connectivity rural environments, with automatic sync upon reconnection.
- AMC's mobile unit integrates BioRx with **radiation shielding**, **workflow safeguards**, and **barcode-driven verification**, allowing for safe, compliant dose preparation and documentation on-site.

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5. Reporting & Inspection Readiness

- **Auto-generated QA Reports**: For board inspections, radioactive materials license review, and internal audits.
- **Customizable Logs**: Including Cleanroom logs, temperature, HEPA maintenance, and dose preparation timelines.
- **Export Functions**: PDF and CSV formats available for rapid retrieval by Board of Pharmacy or NRC officials.

From: Justin Curnutt <justin@molecularcoaches.com>
Sent: Tuesday, August 19, 2025 7:08 PM
To: Gregory Zunino <zunino@pharmacy.nv.gov>
Cc: Troy Curnutt <Nukemdude@gmail.com>; Yenh Long <ylong@pharmacy.nv.gov>; David Wuest <dwuest@pharmacy.nv.gov>; Brett Kandt <bkandt@pharmacy.nv.gov>
Subject: Response to Advisory Opinion on Mobile Nuclear Pharmacy Petition – Proposal for Multi-Location Licensure with Daily Relocation and Cross-Agency Licensing Precedent

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Mr. Zunino:

We appreciate the Board's consideration of our petition regarding licensure of a mobile nuclear pharmacy, and we respect the statutory framework set forth in NRS 639 and NAC 639. We write to address points in the August 8, 2025 advisory opinion and to present a compliance-focused operational model that meets the "specific location" requirement while allowing daily relocation of our pharmacy coach — **in a manner consistent with how other Nevada agencies already license mobile healthcare facilities**.

1. Clarification of Statutory Citations and Intent

The advisory opinion correctly notes that nuclear pharmacies must be licensed under NRS 639.230(2) to a specific person and for a specific location.

We also acknowledge NAC 639.401 and NAC 639.408 restrict the practice of pharmacy to the site of a licensed pharmacy and prohibit maintaining inventory or dispensing outside that licensed premises.

However, our operational intent — as clearly stated in our original submission — is that:

- **No compounding, dispensing, or other pharmacy practice will occur while our coach is in transit.**
- **Operations begin only when the coach is parked and stationary at a licensed address** (e.g., hospital or oncology center with which we have a written

agreement).

This distinction is critical, as the advisory opinion appears to assume "compounding en route," which we have never proposed.

2. Cross-Agency Licensing Precedent for Mobile Medical Operations

Nevada law and regulatory practice already recognize that **mobile units** — identified by VIN and outfitted with specialized medical equipment — can be treated as a "specific location" for licensing purposes. Examples include:

- **DPBH Mobile Unit Licenses (NRS 449/NAC 449.970–.97042):**
  Mobile mammography, PET, CT, MRI, and laboratory coaches are licensed as facilities with defined operating addresses and schedules.

- **Radiation Control Program (NRS/NAC 459):**
  Mobile imaging coaches carrying radioactive materials (including mobile rubidium-82 PET cardiology units) are issued radioactive materials licenses and equipment registrations, with oversight and inspections tied to VIN and operating sites.

- **Mobile Veterinary Clinics (NAC 638.064):**
  Regulated under a vehicle-specific model with requirements for stationary operation at client sites.

In these cases, **the "specific location" requirement is satisfied by tying the license to:**

1. The VIN-bound floor plan and facility design.
2. A roster of scheduled operating sites known to the licensing agency.
3. Compliance with location-specific safety, access, and inspection requirements.

We propose the Board interpret "specific location" in NRS 639 consistent with these existing regulatory precedents, allowing mobile nuclear pharmacies to be licensed when their operating sites are pre-identified and operations are stationary.

3. Proposed Model – Multiple Stationary Licenses with Site Reporting

We propose:

- **Multiple Nevada pharmacy licenses** for each physical address where we will operate.
- submitted for Board approval per NAC 639.5822 and

VIN-bound coach design
NAC 639.5824.

- **Weekly site reporting** to the Board (in advance), identifying:
    - Each address where operations will occur that week.
    - Hours of operation at each site.
    - Confirmation that the coach will be stationary during all compounding and dispensing.
- **Displayed license** at each operating site matching the current stationary address.
- **No pharmacy practice** at any location unless that address is covered by an active Nevada Board-issued license for our facility.

This mirrors the mobile rubidium-82 coach model, where the state knows where the coach is operating on any given day, and inspections can occur at those sites.

4. Safety Features Across All Licensed Addresses

- **Controlled Access & Security:** Electronic Entry Controls – Secure, authorized entry only. Monitored Access Logs – Comprehensive tracking of all entries and exits. 24/7 Camera Access – Starlink-enabled live feed with remote monitoring capability. Intrusion Alarm System – Real-time alerts for any unauthorized access attempts. Removable Hitch – On-site safety feature to prevent unauthorized towing or relocation.
- **Radiation Shielding:** NRC-approved lead-lined compartments, shielding walls, dose-drawing hoods.
- **Environmental Controls:** ISO 5 laminar flow hood, HEPA filtration, temperature/humidity monitoring, pressure differentials per USP <825>.
- **Surveillance:** 24/7 interior/exterior camera coverage with remote monitoring.
- **Operational Tracking:** GPS logs verifying stationary status during operations, available to the Board for review.

5. Request for Interpretive Guidance

We respectfully request that the Board consider and, if acceptable, issue written guidance confirming that this model — **multiple licensed addresses for the same VIN-bound coach, with operations only while stationary and addresses reported in advance** — satisfies the "specific location" requirement of NRS 639.230(2) and complies with NAC

639.401 and NAC 639.408.

We believe this interpretation:

- Fits within existing NRS 639 statutory language.
- Aligns with Nevada's cross-agency precedent for mobile healthcare facilities.
- Eliminates the need for new legislation or rulemaking.
- Preserves the Board's ability to inspect, monitor, and control pharmacy practice locations.

We thank you for your attention and look forward to discussing this plan at the September 4 public meeting.

Respectfully submitted,

Justin Curnutt, Pharm.D.
Chief Pharmacist of Operations
Advanced Molecular Compounding, LLP

Troy Curnutt
President/ CEO
Advanced Molecular Compounding, LLP

Compliance Chart – Statute/NAC vs. Safeguards

Statute / NAC	Requirement	Proposed Safeguard / Compliance Measure
NRS 639.230(2)	License to specific person & location	Multiple NV licenses for each physical address; weekly site schedule to Board; operations only when stationary at licensed address
NRS 639.0097 / NRS 639.2321–.2322	Nuclear pharmacies must meet statutory & nuclear safety requirements	VIN-bound floor plan; NRC/DPBH-approved shielding; nuclear pharmacist onsite
NAC 639.401	Pharmacist practice only at licensed site	No practice in transit; only at stationary licensed address
NAC 639.408	No inventory/dispensing off licensed premises	Inventory secured within coach; GPS logs prove stationary status
NAC 639.5822	Board approval of floor plan	VIN-bound floor plan submitted with compounding/storage/security layout

NAC 639.5824	Pharmacy security requirements	Controlled access, electronic monitoring, cameras
USP <825>	Radiopharmaceutical compounding controls	ISO 5 hood, HEPA filtration, environmental monitoring
NRC / DPBH Radiation Standards	Dose limits for workers/public	Lead-lined compartments, shielding, radiation monitoring
DPBH Mobile Unit Precedent (NAC 449.970xx)	VIN-bound licensing of mobile healthcare facilities	Weekly site reporting; location-specific inspection readiness
Radiation Control Precedent (NAC 459)	Licensing of mobile radioactive materials use	Same compliance model as mobile rubidium-82 imaging coaches

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Presentation on 83rd (2025) Session of the Nevada Legislature by Mike Hillerby

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14A

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – September 4, 2025

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.221, NRS 454.371, NRS 639.070, NRS 639.0727

A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. A homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada may only possess, administer, prescribe and dispense dangerous drugs in conformance with homeopathic pharmacology and in the dosages permitted in the Homeopathic Pharmacopoeia of the United States.

2. A homeopathic physician registered pursuant to NRS 453.226(1) who is not licensed as an allopathic or osteopathic physician in Nevada may only possess, administer, prescribe and dispense controlled substances in conformance with homeopathic pharmacology and in the dosages permitted in the Homeopathic Pharmacopoeia of the United States.

3. The Board hereby adopts by reference the Homeopathic Pharmacopoeia of the United States, promulgated by the Homeopathic Pharmacopoeia Convention of the United States and available at https://www.hpus.com.

3. As used in this section:

(a) "Homeopathic physician" has the meaning ascribed to it in NRS 630A.050.

(b) "Allopathic physician" means a person licensed to practice medicine pursuant to NRS 630.160.

(c) "Osteopathic physician" has the meaning ascribed to it in NRS 633.091.

DRAFT

Section 2. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

A pharmacist shall not fill a prescription issued by a homeopathic physician who is not licensed as an allopathic or osteopathic physician, or dispense a dangerous drug or a controlled substance pursuant to a prescription issued by a homeopathic physician who is not licensed as an allopathic or osteopathic physician, except in dosages permitted in the Homeopathic Pharmacopoeia of the United States.

DRAFT

14B

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

September 4, 2025

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted.

Blue italics - new proposed language.

Red italics – new proposed language suggested by stakeholders.

Green italics - language included from R113-24 that did not receive public comment.

AUTHORITY: §§ 1 and 2, NRS 639.070; §§ 3-5, NRS 639.070 and 639.1371.

A REGULATION relating to pharmacy; establish standards for licensees relating to staffing, supervision, duties of a pharmacy, duties of a pharmacist and requirements related to the timing of dispensing prescription drugs and devices.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2, 3, 4, 5, 6, 7 and 8 of this regulation.

Sec. 2.

1. ***Except as otherwise provided in subsections 4 and 5, a pharmacy that dispenses controlled substances or dangerous drugs must be staffed with at least two pharmacists, who are fully dedicated to performing dispensing services, 80% of the time of each day the pharmacy is opened to the public or 65% of the time of each day the pharmacy is opened to the public if the pharmacy is open to the public 24 hours a day; and***
2. ***During all other times when only one pharmacist is staffed, the pharmacy must be staffed with at least one pharmaceutical technician or intern pharmacist fully dedicated to performing dispensing services or at least two pharmaceutical technicians or two intern***

pharmacists or one pharmaceutical technician and one intern pharmacist dedicated to performing dispensing services if the pharmacy also operates a drive through window; and

3. *If the pharmacy is performing nondispensing services, the pharmacy must be staffed with an additional pharmacist designated to provide the non-dispensing services. This pharmacist may assist in providing dispensing services, including the dispensing of controlled substances or dangerous drugs, if, in the professional judgement of the pharmacist, patient care and safety are not compromised.*
4. *The requirements of subsection 1 do not apply on the days the pharmacy fills fewer than 100 prescriptions which is based on the number of prescriptions filled on the same day in the previous annum.*
5. *The requirements of subsection 3 do not apply on the days the pharmacy fills fewer than 75 prescriptions which is based on the number of prescriptions filled on the same day in the previous annum.*
6. *As used in this section:*
    a. *"Dispensing services" means the filling and dispensing of prescriptions.*
    b. *"Nondispensing services" means all activities that a pharmacist performs except for dispensing services.*

Sec. 3.

In addition to the requirements of section 2, a pharmacy that dispenses controlled substances or dangerous drugs, must:

1. *Staff in a manner that meets the demands of the pharmacy and prioritizes patient care and safety.*

2. *Staff sufficiently at all times in order to minimize fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice competently and safely.*
3. *Provide sufficient time for pharmacists to complete professional duties and responsibilities.*
4. *A pharmacy shall develop a process for pharmacy staff to communicate requests for additional staff or reports of staffing concerns. Requests for additional staff or reports of staffing concerns shall be communicated in writing to the managing pharmacist or to the pharmacist who has been designated by the managing pharmacist to assume the managing pharmacist's duties in his or her absence.*
    a. *The managing pharmacist or his or her designee shall resolve any request for additional staff or reports of staffing concerns in a timely manner, or within 72 hours, to ensure a safe working environment for pharmacy staff. If the managing pharmacist or his or her designee does not have authority to resolve the issues listed, they shall report the issue to the person of authority within 24 hours of receiving the request for additional staff or reports of staffing concerns who shall resolve any issues listed in a timely manner, or within 72 hours, to ensure a safe working environment for pharmacy staff. A copy of the written request for additional staff or reports of staffing concerns shall be maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the Board.*
    b. *The managing pharmacist or his or her designee, or the person of authority who is responsible for responding to a request for additional staff or reports of staffing concerns shall document their actions and provide a written response to the*

request or report of concern within 72 hours of submission which must be communicated to the managing pharmacist or his or her designee, and the pharmacy staff who submitted the request or report of concern. A copy of the written response shall be maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the Board.

5. *A pharmacy shall not retaliate or discipline a pharmacist who, in good faith, makes a request for additional staff or reports staffing concerns pursuant to this section. As used in this section, retaliation or discipline includes, but is not limited to, the following:*
    a. *Removing or suspending the employee from employment;*
    b. *Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;*
    c. *Transferring or reassigning the employee;*
    d. *Denying the employee a promotion that otherwise would have been received;*
    e. *Reducing the employee in pay, position, or scheduled work hours.*

Sec. 4.

1. *A pharmacy shall develop and implement a policy, which shall be maintained in the pharmacy for immediate inspection by an agent, inspector, or employee of the Board. that permits a pharmacist to:*
    a. *Limit the provision of nondispensing services if, in the pharmacist's professional judgment, the provision of such services cannot be safely provided or may negatively impact patient access to medications. The pharmacy's policy shall require pharmacy staff to make an appointment for a patient or refer a patient to another pharmacy offering immunizations and other nondispensing services.*

b. *Limit pharmacy access points, if, in the pharmacist's professional judgment, limiting such access points will minimize fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice competently and safely.*

2. *A pharmacy shall not override the control of the pharmacist on duty as follows:*

   a. *A pharmacist's decision not to administer or supervise immunizations or provide other nondispensing services if, in the pharmacist's professional judgment, the provision of such services cannot be provided safely or may negatively impact patient access to medications. The pharmacy staff shall offer to make an appointment for the patient or refer the patient to another pharmacy offering immunizations and other nondispensing services.*

   b. *A pharmacist's decision to limit pharmacy access points if, in the pharmacist's professional judgment, limiting such access points will minimize fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice competently and safely. Such limitations shall not interfere with a patient's ability to drop off or receive dispensed prescriptions during the pharmacy's posted hours of operation.*

3. *Subsection 1 does not apply to pharmacies that are not open to the public.*

4. *A pharmacy shall not retaliate or discipline a pharmacist who, in good faith, acts in accordance with this section. As used in this section, retaliation or discipline includes, but is not limited to, the following:*

   a. *Removing or suspending the employee from employment;*

   b. *Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;*

c. *Transferring or reassigning the employee;*

d. *Denying the employee a promotion that otherwise would have been received;*

e. *Reducing the employee in pay, position, or scheduled work hours.*

Sec. 5.

1. *The pharmacy and managing pharmacist of the pharmacy that dispenses controlled substances or dangerous drugs shall ensure that the pharmacy complies with sections 2 and 3 of this regulation, to the extent applicable.*
2. *A pharmacist who is on the staff of the pharmacy that dispenses controlled substances or dangerous drugs, including, without limitation, the managing pharmacist of such a pharmacy, shall report to the Board when the pharmacy fails to meet the requirements of section 2 or 3 of this regulation if in their professional judgement such failure may have compromised patient care and safety.*

Sec. 6.

1. *Except as otherwise provided in subsections a through k of this section, a prescription for a dangerous drug or medical device shall be filled within three business days upon the receipt of the prescription by a pharmacy or medical products provider, or if the prescription is a refill, upon the request of the patient, except when:*
    a. *A prior authorization or contact for clarification with the prescribing practitioner of the prescribed dangerous drug or medical device is required;*
    b. *The patient's insurance denies coverage of the medication and cash payment for the medication is not an option for the patient;*
    c. *The prescribing practitioner cancels the prescription;*

d. Upon reviewing the patient's record pursuant to NAC 639.707(4) before dispensing the dangerous drug or medical device prescription it is determined that the prescription is therapeutically inappropriate for the patient or may negatively impact the patient;

e. The prescription is determined to be unlawful, fraudulent, or not issued for a legitimate medical purpose:

f. The pharmacy or medical products provider cannot fill the prescription as prescribed as the dangerous drug or medical device prescribed is not available because there is a documented drug shortage, the medication is on back-order, or the drug is not available from the pharmacy's drug distributor;

g. The pharmacy or medical products provider cannot process the prescription due to a temporary technologic or electronic failure in the computer system necessary to process the prescription or is experiencing a power outage;

h. The pharmacy or medical products provider cannot process the prescription due to a natural disaster, a human made disaster, an outbreak of a pandemic or the declaration of a state or federal emergency, or an incident that significantly impacts the ability of the pharmacy or medical products provider to timely process the prescription;

i. The prescription is for a compounded product;

j. If applicable, based on when the patient last filled a prescription for the same drug and dosage, the patient is not yet due for a refill; or

k. The Board determines there is a reasonable reason why the pharmacy or medical products provider could not timely process a prescription.

2. The pharmacy or medical products provider shall document in the records of the prescription the reason the prescription cannot be filled within three business days pursuant to this section.

Sec. 7. NAC 639.250 is hereby amended to read as follows:

Except as otherwise provided in NAC 639.258:

1. Except as otherwise provided in subsection 5, in ~~[a hospital,]~~ ***an institutional pharmacy or a pharmacy in a correctional institution,*** a pharmacist who is dispensing prescriptions may not supervise more than a total of three pharmaceutical technicians at one time. A pharmacist who is supervising distributive functions may not supervise more than a total of two pharmaceutical technicians and one pharmaceutical technician in training while the trainee is performing technician functions in on-the-job training.

2. ~~[Except as otherwise provided in subsection 5, in]~~ ***In*** any pharmacy, other than ~~[a hospital]~~ ***an institutional*** pharmacy, ***pharmacy in a correctional institution,*** telepharmacy, remote site, satellite consultation site or nondispensing pharmacy, a pharmacist may not supervise more than a total of ~~[three]~~ ***four*** pharmaceutical technicians or ~~[one]~~ ***two*** pharmaceutical ~~[technician]~~ ***technicians*** and two pharmaceutical technicians in training at one time.

3. In any telepharmacy, remote site or satellite consultation site, a pharmacist may not supervise more than a total of three pharmaceutical technicians at one time.

4. In any nondispensing pharmacy, a pharmacist may not supervise more than a total of eight pharmaceutical technicians or six pharmaceutical technicians and two pharmaceutical technicians in training at one time.

5. A pharmacist ***in an institutional pharmacy or a pharmacy in a correctional institution*** may supervise more pharmaceutical technicians and pharmaceutical technicians in training at one time than are otherwise allowed pursuant to ~~[subsections]~~ ***subsection*** 1 ~~[and 2]~~ if:

(a) Not more than three of the pharmaceutical technicians or pharmaceutical technicians in training are performing the duties of a pharmaceutical technician as set forth in NAC 639.245; and

(b) The record kept by the pharmacy pursuant to NAC 639.245 identifies the pharmaceutical technicians and pharmaceutical technicians in training who are performing the duties of a pharmaceutical technician as set forth in NAC 639.245.

6. A pharmacist who is on the staff of a pharmacy, including, without limitation, the managing pharmacist of such a pharmacy, shall report to the Board when the pharmacy fails to meet the requirements of this section.

~~[6.]~~ ***7.*** As used in this section, "nondispensing pharmacy" means a pharmacy that is licensed pursuant to this chapter and chapter 639 of NRS that does not dispense, including, without limitation, drugs, controlled substances, poisons, medicines or chemicals.

Sec. 8.

Sections 1 to 7 become effective 90 days after the Regulation is signed by the Secretary of State.

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Executive Secretary Report

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Legislative Update

September 2025 - Temporary License since last Board Meeting

Pharmacist Name	Pharmacist License #
Jason Fine	24687
Aviance Lewis	24643
Terry Walsh	24691
Sinard Chao	24655
Mario Riccardi	24648
Anthony Ashbrook	24711
Cody Stocks	24690
Joel Elmborg	24712
Michelle Douglas	24686
Kathleen Martin	24715
Vy Tran	24726

Business Name	License Type	City, State
Hill-Rom, Inc	Wholesaler	Batesville, IN
Hill-Rom Manufacturing, Inc	Wholesaler	St. Paul, MN
Hill-Rom Company, Inc	Wholesaler	Las Vegas, NV
Hill-Rom Company, Inc	Wholesaler	Sparks, NV
Silver State Medical Supply, LLC	Wholesaler	Las Vegas, NV
API Expeditors LLC	Wholesaler	Miami, FL
AirLife	Wholesaler	Litchfield Park, AZ

September 2025 – NV Business Address Change Only

Application Received	Business Name	License Number	New Location	City, State and Zip
7/21/2025	ASPN Pharmacies 4, LLC	PH04604	1250 S Buffalo Dr #100	Las Vegas, NV 89117
7/22/2025	Always Your Pharmacy	PH04462	821 N Lamb Blvd #5	Las Vegas, NV 89110

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.520: Security of Pharmacies	09/07/23 Dave to meet with industry							
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise.	5/29/24	6/3/24	R113-24	6/25/24 – To Yenh/Dave for review 7/15/24 –sent revised version to Dave/Yenh	12/10/24	1/16/25 – This public hearing was withdrawn from the agenda and will be heard at a future BM. 4/17/25 – To be heard at a future BM. 9/4/25		
Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto.	10/17/24	10/21/24	R197-24	7/21/25 – Sent to Dave/Yenh for review.				

Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for intermediate care or facilities for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303 and provide other matters properly relating thereto.	12/5/24	12/9/24	R203-24					
Amendment to the Nevada Administrative Code ("NAC") 639.742. The proposed amendments relate to removing the requirement that Dispensing Practitioners must personally dispense at a facility and provide other matters properly relating thereto. The change would allow Dispensing Practitioners to mail prescriptions to individual patients in their care as allowed by the Center for Medicare and Medicaid Services.	12/5/24 – Waiting for the federal reg to pass. The Board would like to see at a future meeting.							
A REGULATION relating to controlled substances adding ethylphenidate and 2-methyl AP-237 to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/5/24	12/9/24	R204-24	7/23/25				

Amendment to Nevada Administrative Code NAC 454. The proposed amendment revises the ability of an advanced emergency medical technicians to possess and administer dangerous drugs upon the order of a practitioner in a license hospital when practicing under their scope of practice as determined by the State of Nevada Health Department.	4/17/25	4/28/25	R004-25	7/22/25 – Sent to Dave/Yenh for review				
Amendment to Nevada Administrative Code (NAC) 639. The proposed amendment specifies the requirements for pharmacies and practitioners to be authorized to engage in the sterile or nonsterile compounding of drug products.	7/17/25							
A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto.	9/4/25							

Amendment to Nevada Administrative Code (NAC). The proposed amendments establish standards for licensees relating to staffing, supervision, duties of a pharmacy, duties of a pharmacist and requirements related to the timing of dispensing prescription drugs and devices	9/4/25							

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 1**
  - **Other: 1**
- **Citation & Fine –**
  - **Unlicensed Practice: 8**
  - **Misfill: 2**
  - **Other: 5**

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